

**The development and evaluation of an online Behavioural
Activation programme for the treatment of low mood and
depression in adolescents**

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Abstract

Background: Depression is a major health concern, with an estimated prevalence of 2% in UK adolescents. Behavioural Activation (BA), a psychological therapy that is simple and can be delivered by a wide variety of clinicians has demonstrated effectiveness in the treatment of adults. However less research has examined its application with young people. Receiving timely and effective treatments is essential for recovery and prevention of recurrence but can be impeded by both individual and service-related barriers. Evidence from systematic reviews and meta-analyses suggests that delivering interventions in an online format may circumvent these barriers. This research aimed to develop and evaluate an online BA programme for adolescents with low mood and/or depression.

Methods: Aligning to important phases of co-design in intervention development, this work encompasses stages of assessment, development, and evaluation. The findings from a systematic review and meta-analysis and qualitative work with young people and healthcare professionals informed the development of a new online BA intervention (BALM). The intervention's acceptability was examined in a non-randomised feasibility study.

Results: Through consolidating and synthesising the findings from the assessment stages of this thesis whilst considering the biopsychosocial development of adolescents, a ten-session online BA programme (BALM) was developed. An initial evaluation of BALM with 12 adolescents experiencing low mood and/or depression demonstrated it is feasible to recruit to a treatment of this type. However, whilst several therapy components were deemed acceptable, low adherence and high dropout highlighted the modifications required both to BALM and the delivery of future, similar research.

Conclusions: This thesis has provided additional support to considering BA as an alternative treatment option for adolescents experiencing low mood and/or depression notwithstanding the need to carefully consider measures to support engagement and adherence. Online delivery may help to address the multifaceted barriers faced by adolescents when accessing timely support.

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Author declaration

I declare that this thesis is a presentation of original work, and I am the sole author. This work has not previously been presented for an award at this, or any other, university. All sources are acknowledged as references. Publications accepted in peer-reviewed journals arising from completion of this thesis include:

Tindall, L., Toner, P., Mikocka-Walus, A. & Wright, B. (2021). Perceptions of and Opinions on a Computerized Behavioral Activation Program for the Treatment of Depression in Young People: Thematic Analysis. *Journal of Medical Internet Research*, 23(4), e19743.

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Thesis introduction

This thesis presents the development and initial evaluation of a new online Behavioural Activation (BA) programme for adolescents (aged 11-16 years) experiencing mild to moderate low mood and/or depression. This work was conducted on a part-time basis over six years (2014 to 2021) and completed at a time when Child and Adolescent Mental Health Services (CAMHS) experienced significant pressures with evident gaps between treatment provision and need (Crenna-Jennings & Hutchinson, 2020). During this work, mental health service provision has been further negatively affected by the COVID-19 pandemic (e.g. Pierce et al., 2020) which arose in the final year of its completion. For those able to access services, receiving appropriate treatments is frequently impacted by a variety of barriers, most notably long waiting lists (Sadler, 2018). This provided the rationale for considering the development of a new online intervention, which aimed to alleviate some of these treatment pressures.

Adopting a 'participatory' or 'empathy-based' approach and basing the progression of the thesis on important phases of co-design (Eyles et al., 2016) this research follows the logical progression through stages of assessment, development and evaluation. Expanding upon the rationale for developing a new online intervention, a systematic review and meta-analysis and qualitative work with adolescents and healthcare professionals were conducted to identify the important components for consideration in the development of the new intervention. A synthesis of the findings from this work, whilst also considering the important developmental changes occurring during the adolescent period, informed the development of a new online BA programme for adolescents. The final sections of this thesis present the findings from a non-randomised feasibility study which sought to examine the initial acceptability of the new programme. The implications of these findings, as well as those presented in earlier chapters, for future research and development of the area are discussed.

The thesis is presented in six chapters:

Chapter One: Depression in children and adolescents, Behavioural Activation and online therapy delivery

Chapter One provides the initial rationale for this thesis. Specific focus is placed upon low mood and/or depression in young people including its prevalence, impact and treatment guidelines as well as highlighting the multifaceted barriers to this group accessing support in a timely manner. Considering BA as an alternative to current

recommended approaches is explored as well as examining whether adopting an online therapy delivery may ameliorate barriers to service access. The chapter closes with an introduction to the important phases of co-design as described by Eyles et al. (2016), each of which are followed throughout the thesis.

Chapter Two: Is Behavioural Activation effective in the treatment of depression in young people? A systematic review and meta-analysis

Chapter Two describes the findings of a systematic review and meta-analysis conducted as part of this thesis to examine current research in the area and inform the development of a new online BA programme. The review provides an overview of available research examining behavioural therapies for young people with low mood and/or depression.

Chapter Three: Perceptions and opinions on a computerised Behavioural Activation programme for the treatment of depression in adolescents: A qualitative approach

Chapter Three presents the findings from qualitative work which explored the views and preferences of adolescents and healthcare professionals regarding the development of a new online BA therapy for adolescents with low mood and/or depression. This research adopted an exploratory qualitative design employing a critical realist approach and provided information to inform the development of the new programme.

Chapter Four: Adapting Behavioural Activation for adolescent use: A synthesis of evidence

Chapter Four reports how the findings from Chapters One to Three were consolidated and operationalised into the development of a new online BA programme (BALM) for adolescents with low mood and/or depression. Areas of adolescent development important for consideration in the programme design are explored and discussed throughout the chapter as appropriate. The rationale as to how this information influenced the final programme is provided, specifically regarding programme content, structure and presentation/delivery.

Chapter Five: Online Behavioural Activation programme for the treatment of low mood and/or depression in adolescents: Findings from a non-randomised feasibility study

Chapter Five presents the findings from a non-randomised feasibility study used to examine the acceptability of the newly developed BALM programme. Overall, 12 adolescents were recruited to the study and asked to work through the programme as well as complete evaluative outcomes. Important feasibility outcomes are presented as well as information regarding the programme's perceived acceptability.

Chapter Six: Conclusions, implications, and future directions

Chapter Six integrates the key findings from the thesis. As part of this, the implications for future research, policy and practice are discussed. Both the strengths and limitations of the methodologies employed throughout the thesis are explored with suggestions made for modifications, both to the BALM programme and research methods, to inform a future pilot RCT.

This thesis, through the employment of varied methodological approaches, has made original contributions to knowledge in three respects: assessment, development and evaluation. Information regarding the delivery of BA in an online format for adolescents has been provided. Whilst the conclusions drawn are preliminary and more research in this area required, this work has provided a basis on which further developments of online BA therapies for adolescents can be made.

Chapter One: Depression in children and adolescents, Behavioural Activation and online therapy delivery

This chapter examines depression in young people (those aged ≤ 18 years) with particular focus upon its prevalence, impact and current treatment guidelines. Within the National Institute for Health and Care Excellence (NICE, 2019) guidelines, recommendations have been made for research examining the use Behavioural Activation (BA) with young people. BA, an alternative psychological intervention, has demonstrated its effectiveness in the treatment of adults (e.g. Ekers et al., 2014; Chartier & Provencher, 2013). BA is presented with an examination of its application with adults experiencing depression before suggestions are made for its use as a treatment option for young people also. The development of BA and its theoretical underpinnings are reviewed as part of this. The barriers often associated with treatment provision for young people are then discussed with recommendations made for adopting online treatment deliveries. The rationale for examining this area in relation to adolescents is provided and the framework for the rest of the thesis presented.

1.1 Depression in young people

1.1.1 Defining adolescence

When discussing individuals aged ≤ 18 years, NICE adopts the terms 'children' to refer to those aged five to 11 years and 'young people' for those aged 12 to 18 (Lawton & Moghraby, 2016). However, others adopt the term 'adolescence'. Although 'adolescence' is not synonymous to the NICE use of the term 'young people' it often encompasses those in this age range. Whilst commonly defined as the life stage between childhood and adulthood (Kaplan, 2004), the exact age range that adolescence includes varies considerably owing to cultural, temporal and individual differences (Curtis, 2015; Degner, 2006). Curtis (2015) examined the varied chronologic definitions of adolescence suggesting that the period could be as broad as the ages of nine to 26 years but is more commonly seen as between ten and 18 and comprising several sub-stages. Although there is no clear classification of the ages and sub-stages of adolescence, Curtis (2015) identified three distinct periods: early adolescence (11 to 13 years), adolescence (14 to 17 years) and young adulthood (18 to 25 years). For the purpose of this thesis, the term 'adolescence' will be used to describe individuals aged between 11 and 17 years, 'children' for those aged zero to ten years and 'young people' when the groups have been combined. When reporting

findings where a different definition has been applied, this will be made clear with the corresponding age ranges provided.

1.1.2 Depression classification and prevalence

Depression, also referred to as clinical depression and major depressive disorder (MDD) relates to a group of symptoms manifesting in, and creating impairments within, mood, thinking, and activity levels (Roberts, 2013; Thapar et al., 2012). The International classification of diseases-10 [ICD-10; WHO, 1992] and the American diagnostic and statistical manual of mental disorders, 5th edition [DSM 5; American Psychiatric Association, 2013] the two main systems used to classify mental health disorders, outline a broad range of symptoms characteristic of depression (Table 1). Although both systems outline similar features as indicative of depression in both adults and young people (Thapar et al., 2010; Lewinsohn et al., 2003), DSM 5 identifies irritability as a core diagnostic symptom in place of depressed mood when diagnosing depression in young people, which is not the case with the ICD-10. Besides this notable difference, when examining the criteria just in relation to young people, DSM 5 identifies loss of energy and fatigue as an additional symptom of depression, unlike the ICD-10 which regards it as core. In addition, loss of confidence or self-esteem are included in the ICD-10 but not DSM 5.

Regardless of the classification system used and, unlike adults, information from multiple sources including the individuals themselves, parents, teachers and healthcare professionals is often used in the diagnosis of depression in young people (Emslie, Mayes & Ruberu, 2005).

Table 1: DSM 5 and ICD-10 depression symptom criteria

	DSM 5	ICD-10
Core symptoms	At least one symptom of depressed mood, irritable mood or loss of interest or pleasure in life activities and at least 5 of the following symptoms that cause clinically significant impairment in social, work or other important areas of functioning every day:	In typical depressive episodes of all three varieties (mild, moderate, and severe), the individual usually suffers from depressed mood for most of the day on most days, loss of interest and enjoyment, and reduced energy leading to increased fatigability and diminished activity.
Additional symptoms	Diminished ability to think or concentrate or indecisiveness Insomnia or hypersomnia Psychomotor agitation or retardation Feelings of worthlessness or excessive guilt Recurrent thoughts of death or suicidal ideation Significant unintentional weight loss or weight gain Fatigue or loss of energy	Reduced concentration and attention Sleep disturbance Change in psychomotor activity, agitation, or retardation Ideas of guilt and unworthiness (even in a mild type of episode) Recurrent thoughts of death, suicide, or any suicidal behaviour Change in appetite with corresponding change in weight Loss of confidence or self-esteem
Duration	Symptoms present for at least 2 weeks	Symptoms present for at least 2 weeks

The presentation of depressive symptoms may vary across individuals and can be characterised as mild, moderate or severe. Whilst the ICD-10 adopts a symptom count approach to classify depression severity (i.e. mild: four symptoms, moderate: five to six symptoms, severe: seven or more symptoms), this is less clearly defined with DSM 5 where clinicians instead make judgements about severity relative to functional impairment ratings and the severity and number of symptoms. Individual differences in the experiences of depression also exist regarding some demographic characteristics including age and gender. Not only does depression risk increase between childhood and adolescence, differences are also apparent in its presentation; children display more physical complaints (e.g. headaches and abdominal pain) whilst adolescents are more likely to report anhedonia, hopelessness and suicidal attempts (Grover & Avasthi, 2019). This transitional period also sees a change in depression presentation amongst

the sexes with a ratio of 1:1 between males and females in pre-pubertal children shifting to 1:2 (males: females) following puberty (Thapar et al., 2012).

In 2008 it was predicted that depression would be the most burdensome disease worldwide by the year 2030 (WHO, 2008). Accurate estimates of depression prevalence (number of existing cases) and incidence (number of new cases) are often hard to establish especially regarding young people where fewer epidemiological studies have been conducted (Birmaher & Brent, 2007). Indeed, many young people experiencing mental health conditions like depression may be both under-recognised and undertreated (Grover & Avasthi, 2019) with prevalence estimates being much higher than what is reported in studies (Stengård, & Appelqvist-Schmidlechner, 2010).

Internationally, several large-scale studies have examined depression prevalence in young people. Polanczyk et al. (2015) conducted a meta-analysis of community studies to calculate the worldwide prevalence of mental disorders in individuals aged ≤ 18 years. For inclusion, studies had to have reported the use of a standardised assessment procedure aligning to DSM or ICD criteria. Overall, 48 studies published between 1985 and 2012 in 27 countries were included. The results reported that 13.4% of young people had a mental health disorder with a prevalence of 2.6% for any depressive disorder.

Several studies have also been conducted specifically with USA populations. Costello, Erkanli and Angold (2006) completed a meta-analysis on studies of individuals born between 1965 and 1996 that assessed depression using structured diagnostic interviews. Twenty-six studies, reporting approximately 60,000 observations of young people (≤ 18 years) were included with depression prevalence estimated to be 2.8% for those aged < 13 years and 5.6% when aged 13 to 18 years. Increases in these numbers have been reported more recently. In a large-scale population-based study, MDD prevalence estimates were examined using data from a national survey with 10,123 adolescents aged 13 to 18 years (Avenevoli et al., 2015). A 12-month prevalence of 7.5% for MDD and a lifetime prevalence of 11% were reported. When considering severity, a 12-month prevalence of 2.3% and a lifetime prevalence of 3% were reported for severe MDD with 8% and 5.2% reported for mild to moderate MDD, respectively. The authors noted that increases in MDD prevalence were strongly associated with increases in age. At a similar time Mojtabai, Olfson and Han (2016) examined trends in MDD episodes over 12-months with 176, 245 adolescents (aged 12 to 17 years). Using data from National surveys conducted in 2005 and 2014, a 12-

month prevalence of 8.7% was reported which remained stable between 2005 and 2011 and then increased to 11.3% by 2014.

Research has also focused upon depression prevalence within UK populations. In 2004 a large-scale survey was conducted to examine the mental health of 12,294 young people (aged 5 to 16 years) living in Great Britain (Green et al., 2005). Overall, one in ten were identified as having a clinically diagnosed mental health disorder with 4% of these having anxiety or depression. Depression alone accounted for 0.9% of this. When these results were combined with the findings from a similar survey conducted in 1999 (Meltzer et al., 2003), 86% of those experiencing depression were aged between 11 and 16 years.

Aligning to international research, more recent UK studies have reported increases in depression amongst young people also. A 2017 survey examining the mental health trends of 9,117 individuals aged two to 19 years in England (Sadler et al., 2018) reported that 14.4% of 11- to 16-year-olds met the ICD-10 diagnostic criteria for a mental health disorder measured using the Development and Well-Being Assessment (DAWBA: Goodman et al., 2000). Of these, emotional disorders were the most common and experienced by 8% of five- to 19-year-olds and 9% of 11- to 16-year-olds, with 2% classified as a depressive disorder.

Recently several studies have examined adolescent mental health in UK school settings. Deighton et al. (2019) conducted a large-scale survey including a sample of 28,160 11- to 14-year-olds from six geographical regions in England. Assessing mental health using the Strengths and Difficulties Questionnaire (SDQ: Goodman, 1997), 18.4% of the sample attained scores above the threshold for emotional problems. Similarly employing the SDQ, Wright et al. (2020) conducted a cross-sectional survey with 6328 11- to 16-year-olds recruited from 21 UK secondary schools. Here, 14% of the sample scored 'very high' on the SDQ with a greater proportion of those aged 15 to 16 years (18%) attaining this score compared to younger individuals aged 12 to 13 years (12%).

Increases in depression have also been reported over time. In a recent ten-year longitudinal study of health-related behaviours, Patalay and Gage (2019) examined the mental health of two cohorts of adolescents aged 14 years in England, one group born between 1991/2 and the second between 2000/2. Reporting on nearly 17,000 individuals the authors found a 6% increase in those above the threshold for depression from 2005 (9%) to 2015 (14.9%).

Whether considering the findings of internationally or UK-based studies, increases in depression prevalence in young people have been reported both alongside increases in age and over time with more recent studies reporting higher rates. However, accurate estimates of prevalence are hard to establish owing to the significant heterogeneity present in the data available, particularly the variability across methodologies employed (Ferrari et al., 2013) which can limit their comparability (Polanczyk, et al., 2015).

In the studies presented above, there is heterogeneity in data collection methods and the diagnostic criteria used. Caution is therefore needed in the interpretation of the findings. Whilst some studies adopted self-reported measures (e.g. Deighton et al., 2019; Sadler et al., 2018), others relied on interviews administered by trained staff (e.g. Avenevoli et al., 2015). Whilst both of these approaches assess similar symptoms, self-reported screening questionnaires for depression do not examine functional impairment or consider other non-psychiatric conditions that can produce similar symptoms (Thombs et al., 2018). Therefore, according to Thombs et al., (2018) self-report screening questionnaires can overestimate prevalence in comparison to diagnostic interviews. Where interviews were used, varied structured and semi-structured approaches were taken. According to Levis et al. (2018) the use of structured interviews, which allow for less clinical judgement, can result in the reporting of higher prevalence estimates compared to a semi-structured approach. Differences were also apparent in the study samples employed with some including both children and adolescents (e.g. Polanczyk et al., 2015; Green et al., 2005) and reporting prevalence rates based on the pooling of these groups. As depression prevalence has been suggested to vary with age (e.g. Costello et al., 2006) these estimates may not provide an accurate reflection of age group differences. Where studies have focused specifically on the prevalence of depression in adolescents, the varied definitions of this life stage (see 1.1.1) have resulted in differences amongst the ages of those recruited. Furthermore, some studies adopted DSM diagnostic criteria (e.g. Mojtabai et al., 2016) whilst others referenced ICD (e.g. Sadler et al., 2018). The differences between these classification systems (see 1.1.2) may have contributed to differences in reported prevalence rates (Anselmi et al., 2010) as could the varied data collection methods used, and participant samples included.

Whilst all of the studies reported here provide useful information about depression prevalence both internationally and in the UK, the estimates vary. The study by Sadler et al. (2018) is considered to provide the most accurate estimates for the purposes of

this thesis. This study is contemporary, employed a large and nationally representative UK sample, collected data using validated and multi-informant diagnostic measures and used clinically trained raters to review data (Ford et al., 2020). Based on this it can be expected that approximately 14% of young people will have a mental health disorder of which 2% will be classified as having depression.

1.1.3 The impact of depression and young people

The impact of depression on those who experience it can be extensive, negatively affecting social, emotional and physical health (NICE, 2015). Much research has examined the impact of depression on young people, demonstrating its negative impact not only at the time of a depressive episode but also for future health outcomes. Associations have been identified between depression and increased risk of engagement in various negative behaviours including smoking, alcohol use (Haarasilta et al. 2004) substance use (Birmaher & Brent, 2007), offending behaviours, self-harm and suicide (Cash & Bridge, 2009). Depression in young people has also been associated with poor social functioning (Birmaher & Brent, 2007) and academic impairments including educational underachievement, school drop-out (Fletcher, 2008) and high rates of absenteeism (Green et al., 2005).

In the long-term, it has been suggested that adolescent depression may predict future mental health disorders (Thapar et al. 2012) with NICE (2015) stating that up to 30% of those who have experienced depression during adolescence will continue to have difficulties in adulthood. In 2002, Fergusson and Woodward conducted a longitudinal study which followed 1265 individuals from birth to 21 years. Depression was assessed between the ages of 14 to 16, with future follow-ups examining various psychosocial outcomes. Complete data were obtained for 964 of the sample. The findings demonstrated that those who had experienced depression during adolescence had a significantly increased risk of future depression, anxiety and suicidality as well as increased likelihood of smoking and being alcohol dependent. These individuals were also more likely to have experienced school failure and less likely to enter further education. Following logistical regression analyses, Fergusson and Woodward (2002) concluded that a direct link between adolescent depression and future depression was evident but that other outcomes (e.g. smoking, alcohol use, educational underachievement, future unemployment, suicidality) were likely to be associated with additional confounding factors.

A later longitudinal study (Naicker et al., 2013) examined the impact of adolescent depression on future social and health outcomes. Overall, 1027 individuals aged 16 and 17 years were recruited and asked to complete several outcome measures every two years over a ten-year period. At baseline 7% of the sample were considered to be depressed and exhibited higher rates of smoking, migraines and lower self-reported health than those not depressed. During the first follow-up (ages 18/19 years) depression was found to be significantly associated with most outcomes with those depressed at baseline more likely to smoke, abuse alcohol, exhibit psychological distress, experience migraines and have lower self-reported health. After ten-years several outcomes, including higher psychological distress, migraines and lower self-reported health were still evident in those depressed at baseline. Unlike Fergusson and Woodward (2002), Naicker et al., (2013) found no significant associations between adolescent depression and education or employment outcomes.

The high rate of depression in young people has an important societal impact. According to the WHO (2019), 16% of the global burden of disease and injury in those aged between ten and 19 years can be accounted for by mental health conditions with depression one of the main causes of disability in this age range. In 2005 it was estimated that depression in young people was associated with a UK national cost of £2,879 million per year (NICE, 2015), whilst in 2011, the Department of Health (DoH) reported that mental illness in young people equated to UK costs of £11,030 to £59,130 annually per person (DoH, 2011).

Whilst extensive research has suggested associations between adolescent depression and negative outcomes, establishing the causal links between these is complex. Kraemer et al. (1997) outlined several inaccuracies that can arise during research observing risk-outcome relationships. Particularly, the authors highlighted the limitations of relying on retrospective data, owing to recall bias and re-interpretation. These approaches have been identified in several studies conducted within this context (e.g. Green et al., 2005; Haarasilta et al. 2004). Furthermore, Kraemer et al. (1997) highlighted how if temporal precedence cannot be determined, then, whilst a factor may correlate with an outcome, it cannot be considered a risk factor. This highlights the importance of adopting longitudinal designs which allow temporal precedence to be established. However, when examining the impact of depression on future outcomes with young people, the risk-outcome relationship has demonstrated complexity even when longitudinal designs have been employed. In their longitudinal study (Fergusson and Woodward, 2002) explained that while a direct link between adolescent depression and an outcome may exist, establishing whether depression is the cause or

consequence of an outcome may be particularly difficult. This was demonstrated in a systematic review and meta-analysis by Cairns et al. (2014) who found an association between adolescent depression and both tobacco and alcohol use. However, despite only including prospective studies within the review to enable temporal precedence of the risk factor, firm conclusions could not be drawn regarding whether increased alcohol or tobacco use were risk factors for depression, a consequence of depression or whether relationships were bidirectional. The authors highlighted that this was because they were unable to control for baseline depression symptoms owing to variations in the variables controlled for across studies as well as the inconsistent reporting of effect sizes. Similar findings have been reported in relation to educational attainment (Verboom et al., 2014; Naicker et al., 2013) also. However, once again although both studies were longitudinal their conclusions were tentative with both outlining attrition, often associated with longitudinal research, as a limitation.

Fergusson and Woodward (2002) also suggested that confounding factors associated with early depression may contribute to future outcomes. In support of this, Keenan-Miller, Hammen and Brennan (2007) highlighted how several factors including life stressors that may make individuals more vulnerable to depression may also be responsible for pre-disposing them to engagement in negative health behaviours. A final link suggested by Fergusson and Woodward (2002) related to when the relationship between depression and outcomes may be explained by other variables. This may be particularly important when considering the impact of adolescent depression as several of the negative behaviours considered as potential outcomes of depression (e.g. smoking, alcohol use) have been identified as behaviours that usually begin within the adolescent period (Sawyer et al., 2012).

Although caution is required when interpreting research findings examining the links between depression and outcomes in young people, extensive research suggests that associations exist between depression in young people and both short and long-term negative outcomes. Whilst treatment costs are high, it has been suggested that the presence of a mental illness during childhood/adolescence could increase the costs during adulthood by up to ten times (Suhrcke, Pillas, & Selai, 2007). As Kessler et al. (2005) reported that as many as half of lifetime mental health problems have presented in individuals by the age of 14, with 75% having developed by the age of 24 years, the benefits of delivering interventions to young people could be much greater than if delivered at any other time in the lifespan (Idsoe et al., 2019; DoH, 2011). Owing to this, prioritising the treatment of depressive disorders in adolescence could be

essential in reducing both individual and societal burden and improving health both in the short-term and later in life (Sawyer et al., 2012).

1.1.4 Depression and young people: Recommended treatment approaches

Several psychological interventions are recommended for the treatment of young people according to NICE guidelines. These include Cognitive Behavioural Therapy (CBT), Interpersonal Therapy (IPT), family therapy and psychodynamic psychotherapy (NICE, 2019). Of these, CBT has been the most studied treatment of adolescent depression (Hussain, Dubicka & Wilkinson, 2018; Weisz, McCarty & Valeri, 2006).

Earlier studies of CBT for depression in young people have reported moderate to large effect sizes. For example, in a meta-analysis comparing the effectiveness of CBT approaches to control groups including wait-list, relaxation, self-control and supportive therapies, effect sizes of -1.02 post-treatment and -0.61 at follow-up were reported (Reinecke, Ryan & Dubois, 1998). According to Delaney (2009) this meta-analysis, amongst others, contributed to CBT becoming a NICE recommended treatment. However, more recent studies within this context have been more robust with more modest effect sizes reported (Hussain et al., 2018).

In 2007, Klein, Jacobs and Reineke employed meta-analytic procedures to examine whether decreases in the effect sizes reported in more recent studies examining CBT for depression in adolescents were related to methodological characteristics. After searching studies conducted between 1980 and 2006, 11 Randomised Controlled Trials (RCT) were included. Each study compared CBT with varied comparators (e.g. wait-list, active treatments targeting depression, medication placebos) in treating adolescents (aged 12 to 18 years) meeting depression diagnostic criteria. A statistically significant post-treatment effect size of 0.53 was reported which, despite methodological limitations of some included studies, provided support for CBT as an efficacious and effective treatment of depression in adolescents. However, the authors reported both decreases in effect sizes and narrowing of confidence intervals since earlier trials and attributed these to several methodological characteristics. Specifically, associations were observed between smaller effect sizes and the incorporation of active comparator conditions, the delivery of treatments in clinical settings and the inclusion of intention to treat (ITT) analyses. Methodological rigor was also identified as a contributor, with studies fulfilling fewer Consolidated Standards of Reporting Trials (CONSORT: Schulz, Altman & Moher, 2010) criteria reporting larger effects (Klein et al., 2007).

More recently, Oud et al. (2019) examined the effectiveness of CBT for young people with depression in a systematic review and meta-regression analysis. For inclusion, studies needed to be RCTs reporting on CBT delivered as either a treatment or prevention intervention and compared with at least one inactive intervention (e.g. wait-list, placebo, attentional control). Overall, 69 articles, reporting on 31 trials (n=4335) and published between 1990 and 2017 were included. The findings suggested that CBT was an effective treatment for reducing depression symptoms at both post-treatment ($SMD=-0.41$) and follow-up (17 and 39 weeks) ($SMD=-0.20$). Although based on less robust evidence, the authors also reported that those who received CBT were 45% more likely to have symptom decreases and 36% had more chance of recovery. Furthermore, where subclinical depressive symptoms were reported and CBT was delivered as a preventative intervention, individuals were 63% less likely to have a depressive disorder at follow-up.

Although reported effect sizes in research examining CBT for young people have decreased alongside increases in methodological rigor, much research has supported its use in this context. However, the availability and accessibility of CBT remains scarce (Thapar et al., 2012). In a UK survey with 540 specialist CAMHS clinicians, Stallard et al. (2007) reported that whilst CBT was the NICE recommended treatment for several common mental health disorders in young people, including depression, only 21.4% of responders reported CBT as their dominant treatment approach. Furthermore, as few as 21% had received specialist, post-qualification training and only 28.6% described their expertise as fairly good or good, thus suggesting that clinician capacity and training were insufficient to meet demand. This is particularly concerning since the effectiveness of CBT has been associated with the skills of the therapist delivering it (Richards et al., 2016). Similar findings have been reported in the delivery of psychological therapies within school settings. In a large cross-sectional survey of UK primary (n=599) and secondary (n=137) schools, Vostanis et al. (2013) found that only a third were delivering evidence-based practices with many instead focusing upon delivering interventions developed locally. Furthermore, although less than 3% of the sample stated that they used mental health professionals external to their school, few of those responsible for supporting young people had received any specialist training to do so.

Recently, the trends in effect sizes across studies examining psychotherapy treatments more generally in the treatment of both internalising disorders (such as anxiety and depression) and externalising disorders (ADHD, conduct problems) in young people

have been explored (e.g. Weisz et al 2017; Weisz et al, 2019). In a multi-level meta-analysis including RCTs conducted between 1960 and 2013 Weisz et al. (2017) found that the weakest effects reported were those for the treatment of depression.

Furthermore, when considering teacher-reported outcomes, some young people (aged 4 to 18 years) in receipt of a psychotherapy demonstrated worse outcomes than those randomised to a control condition. Similar findings were reported in a later review (Weisz et al, 2019) where the authors found a significant decline in the treatment effects for depression over time.

Considering these findings, as well as the limitations of currently recommended treatments such as CBT, it is timely to consider alternative approaches with increased accessibility and availability for young people, that can be widely disseminated. Examining alternative approaches is also timely given the expansion of therapy provision into non-NHS services. In their 2017 Green Paper the Department of Health and Social Care (DHSC) and the Department for Education (DfE) published plans for increased mental health provision within schools. This includes increasing the delivery of school-led interventions for young people with mild to moderate mental health difficulties as well as funding mental health support teams, managed jointly by schools and the NHS, to support this. One such alternative intervention is Behavioural Activation (BA), a treatment based on operant conditioning principles, which has demonstrated both its clinical and cost-effectiveness with adults and its capability of being delivered by both trained and non-specialist therapists (Richards et al., 2016; Ekers et al., 2014; 2011). BA has therefore been identified as a treatment type warranting further research into its application with young people (NICE, 2019).

1.2 Behavioural Activation

1.2.1 The development of Behavioural Activation

Dimidjian et al. define BA as '(a) structured, brief psychotherapeutic approach that aims to (a) increase engagement in adaptive activities (which often are those associated with the experience of mastery or pleasure), (b) decrease engagement in activities that maintain depression or increase risk for depression, and (c) solve problems that limit access to reward or that maintain or increase aversive control (2011, p. 4).'

In the early 1970s when much clinical practice was derived from a psychoanalytical framework (Dimidjian et al., 2011) alternative depression models, based upon behavioural theory, emerged. One of these by Ferster (1973) was developed from

learning theory and emphasised the importance of conducting a functional analysis to identify what factors in an individual's environment impacted upon their behaviour. According to Ferster (1973), individuals with depression would engage less frequently in pleasant and satisfying behaviours that would provide positive reinforcement and more so on activities that would provide negative reinforcement (Abreu & Santos, 2008). Within this context, negative reinforcement would include engaging in avoidant behaviours as a means to escape aversive thoughts, feelings or situations (Veale, 2008) which in turn would further reduce positively reinforcing behaviours (Ferster, 1973). According to Ferster's (1973) theory, decreases in positive reinforcement and increases in negative reinforcement could be associated with characteristics including irritability and self-criticism that are frequently displayed by depressed individuals (Abreu & Santos, 2008).

At a similar time, Lewinsohn and colleagues were working towards a behavioural model of depression that was consistent with much of Ferster's work (Martell, Dimidjian & Hermann-Dunn, 2013). This model was based upon the assumption that depression could be associated with low 'response-contingent positive reinforcement' (Lewinsohn, 1974), thus reinforcement being dependent upon the action of an individual (Martell et al., 2013). Lewinsohn, Biglan and Zeiss (1976) contended that there were three main reasons an individual who is depressed might experience low response-contingent positive reinforcement: (1) previously positive reinforcing events were no longer effective as such, (2) changes in an individual's environment meant that a positive reinforcer was no longer available, (3) an individual is no longer able to access a positive reinforcer (Abreu & Santos, 2008). From this model, Lewinsohn and colleagues developed the first behavioural treatment for depression which placed emphasis on the importance of engagement in pleasant events to increase positive reinforcement (Lewinsohn et al., 1976). Owing to this, the treatment focused upon increasing both the frequency and quality of engagement in pleasant activities and social interactions in an individual's environment (Abreu & Santos, 2008). This approach however was not, at this stage, referred to as BA which was being used in neuroscience literature; instead, it was presented under the more general term of 'behavioural treatment'. According to Dimidjian et al. (2011) it was not until the 1990s that the term BA started to be used in psychotherapy when Hollon and Garber (1990) applied it when defining the procedures used in cognitive therapy for depression.

In the mid-90s, Jacobson et al. (1996) conducted a study to identify and assess the components of cognitive therapy as developed by Beck et al. (1979). Here the term BA as used by Hollon and Garber (1990) was applied to describe the behavioural

components of cognitive therapy including activity scheduling and activity monitoring. Overall, 150 adults with depression were randomised to one of three groups: BA only, BA plus cognitive challenges to automatic thoughts and full cognitive therapy (i.e. BA plus cognitive challenges to automatic thoughts and schema work). The aim was to assess whether simply encouraging people with depression to increase contact with potentially positive reinforcing experiences through activation could account for the benefits of cognitive therapy (Jacobson et al., 1996). No statistically significant differences were found between treatment conditions, suggesting that BA alone performed as well as full cognitive therapy. This was true also for relapse prevention over a two-year follow-up (Gortner et al., 1998). According to Dimidjian et al. (2011) these findings led to BA being applied as an independent treatment for depression and linked to the initial behavioural models developed by Ferster (1973) and Lewinsohn et al. (1976).

1.2.2 The components of Behavioural Activation

As BA has developed, a wide variety of behavioural strategies are now employed in its delivery with much variation in both the combination of the strategies used and how they are applied. In a narrative review Kanter et al. (2010) sought to provide an overview of the fundamental components of BA. Three meta-analyses (Mazzucchelli et al., 2009; Ekers et al., 2008; Cuijpers, van Straten & Wamerdam 2007) collectively reporting on 44 trials of BA, were included. Following exclusions, 32 studies were reviewed by Kanter et al. (2010) for information about the types of BA interventions used by each. As part of this any associated treatment manuals were obtained where possible. Across the 32 included studies six treatment manuals were cited as the basis for the BA delivered; however, some did not include all therapy components as outlined in their corresponding manual. From their review, Kanter et al. (2010) identified eight overarching categories of BA interventions:

Activity monitoring

Activity monitoring was a consistent component identified in most included trials and included in all cited treatment manuals. This was used as a mechanism to support behaviour change and, according to Kanter et al. (2010), typically serves two functions; informing activation through identifying baseline activity levels and associated moods and demonstrating to individuals the meaningful relationships that exist between their activity and mood.

Assessment of goals and values

Most BA treatments in Kanter et al.'s (2010) review, and aligning with other psychotherapeutic approaches, involved discussions about an individual's treatment goals. This was often conducted early in treatment and used to guide activation. Alongside this several studies also assessed values with Kanter et al. (2010) referencing the BA model Behavioural Activation for Depression (BATD) by Lejuez, Hopko and Hopko (2001) (see 1.2.3) as an example of this. In BATD, a structured values assessment is used where the valued life domains of an individual (e.g., family relationships, social relationships, etc.) are identified and used to inform the activation plans formulated.

Activity scheduling

Like activity monitoring, activity scheduling was a component of BA consistently identified in the trials reviewed and evident in all cited treatment manuals (Kanter et al., 2010). Early forms of BA generally based activity scheduling on organising pleasant events whilst later versions adopted different criteria such as identifying alternatives to avoidant behaviours or scheduling events resulting in mastery. Within BA, activity scheduling is generally completed between sessions as 'homework' with individuals encouraged to engage in specific behaviours. Although the function of activity scheduling (i.e. to increase contact with sources of positive reinforcement) remained the same across trials, nuances in activity scheduling were identified in Kanter et al.'s (2010) review. For example, the use of graded task assignments was reported, with strategies to achieve this including the use of activity hierarchies where activities are scheduled and completed in order of difficulty (e.g. Lejuez, et al., 2001).

Skills training

Kanter et al. (2010) described how some BA models applied techniques referred to as 'skills training' in instances when individuals are unsure of how to engage in effective behaviour. They contended that without the necessary skills, some individuals would fail at activity scheduling and highlighted that, for most, the skills individuals experiencing depression lacked were often social. For interventions involving social skills training several techniques were identified and included modelling, role-playing and clinicians providing therapeutic feedback. In interventions where focus was placed upon non-social skills, problem-solving tasks were generally employed.

Contingency management

According to Kanter et al. (2010) contingency management in BA relates to individuals addressing situations where their moving towards improved behaviours is not being reinforced by their environment and therefore appropriate changes are required. Contingency management was incorporated in many of the included trials where individuals were encouraged to reward themselves for achieving a goal. Variations of contingency management were also evident with some encouraging individuals to make formal contracts with family or friends to reinforce desired behaviours (Kanter et al., 2010).

Procedures targeting verbal behaviour

Within Kanter et al's (2010) review several included BA deliveries used techniques to target covert verbal behaviour. Again, there was much variation in the techniques employed. According to Kanter et al. (2010) these methods, including thought monitoring, direct suppression and rehearsal of positive thoughts about oneself, are employed to reduce the number of occurrences of negative covert verbal behaviours and increase positive ones. The approaches do not try to restructure any cognitive content. An example of this is presented in the delivery of BA by Martell, Addis and Jacobson (2001; see 1.2.3). Here focus is placed upon rumination which the authors contended represents an avoidant behaviour maintained by negative reinforcement which results in an individual's reduced contact with their environment. To 'target verbal behaviour' in this context Martell et al. (2001) proposed that clinicians should assess rumination via functional analysis to identify its triggers and the factors that maintain it. This allows an individual to refocus on their environment and be able to identify the contributors and consequences of their behaviour and thus activate alternative, healthy behaviours (Kanter et al., 2012).

Procedures targeting avoidance

The final BA intervention type identified by Kanter et al. (2010) related to procedures targeting avoidance. Whilst only BA specific to Martell et al. (2001; see 1.2.3) used this, Kanter et al. (2010) included it as one of the overarching BA components due to the empirical support the approach has received. Martell et al. (2001) emphasise the importance of targeting avoidance with specific focus upon replacing avoidance patterns with alternative coping strategies. The purpose of this is two-fold: to target

avoidance through effective activation and to encourage activation towards alternative coping strategies (Kanter et al., 2010).

Relaxation training

A small number of trials in the review by Kanter et al. (2010) used relaxation training within their BA deliveries. This was predominantly an optional component and was reported by some as used to target difficulties with sleeping.

'Ancillary' components

Besides the eight BA components presented by Kanter et al. (2010), several additional strategies used in the BA models within the review were identified. These were referred to as 'ancillary' and included establishing a therapeutic relationship, agenda setting, maximising the effectiveness of homework, relapse prevention and providing treatment rationales. Although described as common to other psychotherapies, none of these strategies was discussed in detail within the review as they were deemed to be secondary to 'BA's mechanism of action' by the authors.

From their review, Kanter et al. (2010) concluded that, although the inclusion of activity scheduling and monitoring was consistent across the studies and included in all cited treatment manuals, there was much variance in the components used in BA. There did not appear to be specifications as to what clinicians could choose to implement and what components, or combination of components, were necessary for maximum effectiveness of BA.

1.2.3 Contemporary Behavioural Activation approaches

Only two studies included within Kanter et al.'s (2010) review were based on manuals produced post-2000 (the most recent before these being that by Gallagher et al., 1981). These contemporary approaches are Brief Behavioral Treatment for Depression (BATD) by Lejuez et al. (2001) and Behavioral Activation (*BA*¹) by Martell et al. (2001). According to Hopko et al. (2003), both approaches are consistent with traditional behavioural models yet contain advancements in both case conceptualisation and the treatment components employed.

¹ For the purposes of this thesis, and for clarity, all mention of the BA therapy as developed by Martell et al. (2001) are italicised.

Brief Behavioral Treatment for Depression (BATD/BATD-R) (Lejuez, et al. 2011; 2001)

BATD was initially developed by Lejuez et al. in 2001 and is based upon the premise that depression is maintained through little availability of reinforcement for non-depressed behaviour or high reinforcement for depressed behaviour. The aim of BATD is to decrease depressed behaviour through encouraging individuals to increase exposure to reinforcement for healthy behaviours and reduce exposure to reinforcers for depressed behaviour (Hopko et al., 2003).

BATD is generally delivered in 10 to 12 sessions and uses a range of treatment strategies. The initial sessions present the treatment rationale and use psychoeducation to provide information about depression. Individuals are also encouraged to assess their depression severity, monitor their activity engagement and make their environment more conducive in supporting healthy behaviours (e.g. talking to family/friends). After this, individuals identify and schedule activities that they want to achieve based upon important areas of their lives (relationships, education, employment, etc.). The frequency and duration of activities are established and presented within a hierarchy where they are ranked in order of difficulty. Further sessions monitor progress via behavioural checklists and activity logs with any adjustments made accordingly.

In 2011, ten years after its development, the BATD manual was modified and a revised version (BATD-R) produced (Lejuez, Hopko, Acierno et al., 2011). The aim was to simplify the approach and add clarification where needed. Whilst the theoretical underpinnings of the approach remained unchanged, the treatment was consolidated into five treatment sessions with five additional sessions for concept review and to discuss the end of treatment or post-treatment planning. The number of sessions is however not prescriptive and can be amended based upon individual needs. Additional changes to BATD-R included more information about the treatment rationale and therapeutic relationship, more clarity for values and activities, the use of fewer and simplified treatment forms, an increase in procedural details (i.e. how to address treatment challenges) and adaptations to make the treatment suitable for those with low literacy (Lejuez et al., 2011).

Behavioral Activation (BA) (Martell et al., 2001)

Following the work of Jacobson et al. (1996) which suggested that BA alone performed as well as full cognitive therapy, BA (Martell et al., 2001) was developed. This

approach focuses on both the events experienced by an individual and their subsequent responses and contends that depressed behaviour is a means of coping with environmental circumstances providing little positive reinforcement or high aversive control (Jacobson, Martell & Dimidjian, 2001).

Like BATD/BATD-R (Lejuez, et al., 2011; 2001), the initial sessions of *BA* (Martell et al., 2001) use psychoeducation to provide information about depression, introduce individuals to the treatment model and encourage them to formulate treatment goals through activity scheduling. Unlike BATD, *BA* involves a functional analysis in which focus is placed upon contextual triggers to depression and how individuals respond to these with the findings used to guide the remaining therapy. Using the functional analysis as a basis, individuals are encouraged to identify and engage in activities that they deem to be positively reinforcing and thus helpful to them. Activity logs and pleasure ratings are used to monitor activities engaged in, whilst contextual factors that may have affected mood are discussed. As with BATD/BATD-R, activities are graded and moved through in order of difficulty. In addition, during *BA*, individuals are encouraged to follow regular routines and identify situations where they most frequently ruminate replacing avoidance patterns with alternative coping. The intervention's final sessions focus upon relapse prevention planning.

Of the eight overarching *BA* interventions (Kanter et al., 2010) *BA* (Martell, et al., 2001) uses seven – omitting only relaxation training. BATD/BATD-R (Lejuez, et al., 2011; 2001) in comparison only includes four; activity monitoring, goals and values assessment, activity scheduling and contingency management whilst omitting both skills and relaxation training and procedures targeting both verbal and avoidant behaviour.

1.2.4 Effectiveness of Behavioural Activation in the treatment of adults

Since Jacobson et al.'s (1996) study and the development of *BA* as a standalone treatment, multiple studies have examined its effectiveness in treating adult depression. In a systematic review, Chartier and Provencher (2013) found *BA* to be as effective for symptoms of depression as other psychotherapies including CBT, whilst in a meta-analysis of 17 studies Ekers et al. (2008) found *BA* was significantly superior to controls, brief psychotherapy and supportive therapy and equal to CBT in its effectiveness for ameliorating depression symptoms. Other meta-analyses have further supported its effectiveness in treating adult depression with Cuijpers et al. (2007) finding *BA* to be as effective as cognitive therapy across 16 studies and

Mazzuccheli et al. (2009) reporting a large effect size (0.78) in favour of BA over controls in 34 studies. A later review examining depression symptom levels, (Ekers et al., 2014) found BA to be superior to control groups (including wait-lists, placebos, usual care) and anti-depressant medication.

More recently, Richards et al. (2016) conducted a non-inferiority RCT (COBRA) examining the costs and outcomes of BA compared to CBT for depression in adults. Overall, 440 adults meeting MDD diagnostic criteria were randomised to CBT or BA. Both therapies comprised up to 20 face-to-face, hour-long sessions delivered over 16-weeks. No evidence of BA inferiority was found, supporting the contention that BA could be as equally effective as CBT in reducing depression symptoms. Furthermore, the study demonstrated that BA can be delivered by individuals not formally trained as psychological therapists, suggesting that it could be more cost-effective than CBT (Richards et al., 2016) which requires therapists to have a particular level of training for its delivery. Similarly, McCauley et al. (2016) contended that BA can be delivered by professionals with different levels of expertise and across varied settings. This was attributed to BA's reliance on a few basic treatment strategies making it both easy to learn and administer (McCauley et al., 2016). It has also been suggested that BA may be easier to deliver (Ekers et al., 2011) and simpler to understand for individuals who are depressed (Mazzuchelli et al., 2009).

Although there is more clinical evidence available for CBT in this context (Richards et al., 2016), given the support BA has received as an efficacious treatment it has been included within NICE (2009) guidelines as an evidence-based treatment for depression in adults.

1.2.5 Behavioural Activation in the treatment of young people

Although not currently a NICE recommended treatment option for young people with depression, the emergence of research examining BA within this context has provided preliminary support for its use. In case series and case reviews, treatment satisfaction and clinical benefits including symptom reductions have been reported with BA in the treatment of young people with depression and/or anxiety (e.g. Jacob et al., 2013; Wallis et al., 2012; Chu et al., 2009). More recently, larger studies including an RCT of an adolescent BA programme (McCauley et al., 2015) have been conducted. Here, the Adolescent Behavioural Activation Program (A-BAP) adapted from BA (Martell et al., 2001) demonstrated similar effectiveness to evidence-based treatments (CBT or IPT), for adolescent depression.

Extensive work has also been conducted by researchers at the University of Reading (UK), who have developed 'Brief BA' (Pass & Reynolds, 2014); an adolescent-specific intervention adapted from BATD/BATD-R (Lejuez et al., 2011; 2001). The authors contended that BA could be a promising treatment for adolescents given its simplicity and the ease of embedding it into their lives. Furthermore, BA does not require a cognitive component which the authors suggested could be challenging for adolescents who are depressed especially during the period of their lives involving ongoing cognitive development (Pass, Brisco & Reynolds, 2015). Across case studies (Pass, Hodgson et al., 2018; Pass et al., 2016; Pass, et al., 2015) and pilot and feasibility work (Pass, Sancho et al., 2018; Pass, Lejuez & Reynolds et al., 2017), the acceptability and clinical effectiveness of Brief BA have been demonstrated within both CAMH and school-based settings.

In 2020, Kitchen et al. conducted the first known European feasibility RCT of BA for adolescents with depression. The trial, conducted within three UK CAMH centres, randomised 22 adolescents (aged 12 to 17 years) to BA or usual care. The BA delivered was manualised and comprised eight, weekly, hour-long, face-to-face sessions. Descriptive data suggested that those in receipt of BA had better outcomes than the comparator group. For example, at three months 57% of those who received BA no longer met criteria for MDD compared to 13% in the comparator group. Furthermore, functioning scores (measured by the Children's Global Assessment Scale (CGAS); Shaffer et al., 1983) improved for those in the BA group but reduced for the comparator group. At six months follow-up, although scores on the Mood and Feelings Questionnaire (MFQ; Angold et al., 1987) reduced in both groups, this was greater in the BA group with self-esteem scores also being more improved for the BA group than the comparator at this time point. Results from an embedded survey demonstrated positive feedback about BA from most participants and their parent/guardians. These findings, alongside high attendance rates, add support to BA as an acceptable treatment for adolescents experiencing depression.

Given the emerging literature supporting the effectiveness of BA within this context, further examination of BA for use with young people is both required and timely (Chartier & Provencher, 2013). This contention has been further supported by NICE which in 2019 made recommendations for research to investigate the effectiveness of BA for young people (NICE, 2019). This was in response to the committee acknowledging the treatment's specific focus on common symptoms of depression in young people including withdrawal, inactivity and avoidance. Furthermore, it was

suggested that BA may provide an alternative treatment to those who may find the concepts of CBT difficult to engage with (NICE, 2019).

1.3 Barriers to treatment and clinical implications

If left untreated, those who experience recurrent depressive episodes or whose depression develops into a chronic disorder which continues into adulthood are likely to experience considerable disability and impairment as a result (NICE, 2015). It has been estimated that whilst 10% of young people with depression will spontaneously recover within three months, approximately 50% will still be depressed at twelve months (NICE, 2015) and approximately 70% will experience a relapse within five years (Cox et al., 2012). Furthermore, as part of a longitudinal cohort study examining contact with mental health services by young people with a mental health disorder, it was reported that those who had not had access with mental health services in the preceding year were up to seven times more likely to report clinical depression ten years later than those who were similarly depressed but did access services (Neufeld et al., 2017). It is therefore important that young people experiencing depressive episodes are identified early and receive effective treatments to deal with the impact of their depression and reduce the likelihood or impact of future episodes (Birmaher & Brent, 2007). However, only approximately 35% of young people seek help (Gladstone et al., 2015) with the barriers to accessing support being multifaceted.

On an individual-level, a variety of factors may impact upon whether a young person chooses to seek support. Such factors may include concerns about stigma, worries about treatment expenses, having transportation issues or feeling embarrassed about asking for help (Gulliver, Griffiths & Christensen, 2010; Rickwood et al., 2005). Many young people may also be reluctant to engage one-to-one with a therapist (Rickwood et al., 2005) with some suggesting that young people favour self-reliance over receiving external help (Gulliver et al., 2010; Rickwood et al., 2010). A lack of awareness of signs and symptoms (Gulliver et al., 2010) as well as limited understanding about the services available and how to access them (Anderson et al., 2017) may serve as additional barriers to service provision.

Where young people are able to overcome these individual difficulties and seek support, additional service-specific barriers are often present. Referral pathways can be complicated (Anderson et al., 2017), and even when successfully navigated through do not guarantee treatment. In 2018 The Care Quality Commission (CQC) conducted an independent review of mental health services for young people across ten areas

within England (CQC, 2018). The review provided an insight into the problems many young people faced when trying to access support for mental health difficulties, specifically being accepted into services. Resulting from funding reductions, increased service demands and limited capacity, eligibility thresholds for service entry had become more restrictive and therefore, many young people in need of support were not accepted. A further independent review by the Education Policy Institute, reported that as many as one quarter of those referred to CAMHS were not accepted for treatment between 2018 and 2019, equating to approximately 133,000 young people (Crenna-Jennings & Hutchinson, 2020). Worryingly, the CQC (2018) report outlined how, when rejected from services, many young people were re-referred following deterioration in their conditions.

When young people have been able to access services, receiving appropriate treatment has been further affected by limited numbers of trained clinicians, limited resources (Roberts, 2013; Saxena et al., 2007; Crenna-Jennings & Hutchinson, 2020) and long waiting lists, with over 50% of those entering CAMHS waiting longer than four months for treatment (Young Minds, 2018) and 20% reporting waiting times of over six months for first contact with a mental health provider (Sadler et al., 2018). In 2003 it was reported that over an 18-month period only 22% of young people with significant mental health disorders had received therapies from specialist CAMHS in the UK (Ford, Goodman, & Meltzer, 2003). Of these, individuals experiencing an emotional disorder were the least likely to receive help. In addition, the drop-out rate across all types of psychological therapy with young people is substantial (de Haan et al., 2013).

1.3.1 Online therapy delivery

Delivering therapies in an online format might circumvent some of the barriers associated with young people accessing treatment, providing benefits to both individuals and services.

On an individual level, many benefits of adopting an online therapy delivery are evident. Compared to traditional face-to-face approaches, online therapies have increased availability and accessibility (Stallard, Velleman & Richardson, 2010) allowing individuals who may be unable (e.g. owing to travel restrictions) or reluctant to engage one-to-one with a therapist to access care (Fleming et al., 2014). Furthermore, they can offer increased anonymity (Pretorius et al., 2019), reduced stigmatisation (McCashin, Coyle & O'Reilly, 2019) and, through their flexibility, enable access at any time (Proudfoot et al., 2011) whilst having the potential to be disseminated broadly

(Christensen & Griffiths, 2002). Therapies adopting an online approach can also be delivered in a format attractive to many young people who have been described as 'digital natives' (Prensky, 2001) or 'digitally literate' (National Health Service (NHS), 2015).

In 2014, the mental health charity Young Minds conducted a survey about the provision of mental health information and services with 1136 individuals aged 14 to 25 years. Speed, ease of use and anonymity were identified as popular components of digital services. Elsewhere, it has been suggested that the perceived anonymity associated with online interventions can create a 'disinhibition effect' where self-disclosure is increased (Suler, 2004).

Service providers may also benefit from an online treatment approach. At a time when CAMH services have high demand but limited resources, online treatments may help bridge the gap between demand and supply (Scholten & Granic, 2019); reducing therapist time and waiting lists alongside providing increased treatment fidelity and consistency (Andersson & Titov, 2014; Cuijpers, Van Straten & Andersson, 2008). Furthermore, online approaches may offer a cost-effective alternative to therapy delivery and increase access to low-intensity evidence-based treatments (McCashin et al., 2019).

Given their evident benefits, online treatments are increasingly being used to treat a range of psychological disorders with computerised CBT (CCBT) identified as a potential treatment approach for adults with mild to moderate depression and anxiety (NICE, 2006). Unsurprisingly, much research with young people has focused upon the delivery of CCBT (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009), with support for its effectiveness demonstrated within systematic reviews and meta-analyses (e.g. Hollis et al., 2017; Pennant et al., 2015; Richardson, Stallard & Velleman, 2010). Consequently, CCBT is now identified as a recommended first line treatment for young people experiencing mild depression (NICE, 2019).

As research has demonstrated both the effectiveness (performance within real-world settings) and efficacy (performance within controlled environments) of BA in treating adults with depression, research has started to emerge into online deliveries of BA also. Calbring et al. (2013) conducted an RCT of an online BA programme which incorporated several non-BA components including acceptance and commitment therapy (ACT) and mindfulness with 80 adults experiencing mild to moderate depression. The intervention lasted eight weeks and was compared to a wait-list

control. The results demonstrated a post-treatment between groups effect size of $d=0.98$ with 25% of those in the intervention group no longer meeting the criteria for depression at post-treatment (measured by the Beck Inventory-II) compared to 5% of the control group. These results, although tentative, suggested that the online BA programme was as effective as a CCBT programme previously examined by the authors (Andersson et al., 2005) with the effect size aligning to those found in previous systematic reviews and meta-analyses of face-to-face delivered BA (Mazuchelli et al., 2009; Ekers et al., 2008; Cuijpers et al., 2007). Although this study did not examine BA as a standalone treatment, it provided initial evidence that BA could be delivered online.

Spates et al. (2013) conducted an evaluation of an internet-delivered BA programme comprising ten treatment sessions with 15 adults experiencing depression. The findings provided preliminary evidence for the efficacy of the BA programme with statistically significant reductions in depression symptoms reported during the treatment phases that were maintained at a six-month follow-up. In addition, significant improvements in quality of life (QoL) were also reported at the six-month follow-up and high participant satisfaction with the programme found. More recently, Spates et al. (2016) reviewed the web-based BA interventions available or under development in 2015 and reported on five programmes that had shown initial promise. Besides the interventions previously described (Calbring et al., 2013; Spates et al., 2013), the authors found an additional three BA programmes developed for use with adults with depression, two of which were developed for mobile phone delivery (Ly et al., 2012; Burns et al., 2011) and the third, an internet-based BA programme developed specifically for post-partum depression (O'Mahen et al., 2014). In an RCT examining the latter of these interventions, statistically significant reductions in depression were found in mothers using the BA programme compared to standard care. Similarly, depression and anxiety symptoms were significantly reduced following use of the programme developed by Ly et al. (2012). Whilst no significant changes in depression and anxiety symptoms were reported by Burns et al. (2011), positive changes in valued actions and psychological flexibility were reported following use of the BA intervention delivered. Thus, early indications are promising for the adaptation of BA in an online format in adults.

There is less evidence about the use of online BA in young people. In the development of an online treatment package for adolescents and their families affected by disasters in the USA, BA strategies were embedded into a module specifically focussing upon depressed mood (Ruggiero et al., 2015; Davidson et al., 2014). This was described as

a brief intervention approach and designed for use with adolescents experiencing both subthreshold and case-level depression. As part of a larger feasibility study, Davidson et al. (2014) conducted an evaluation of the programme's depression module with 24 adolescents. The results found that most participants were satisfied with the depression module including the embedded BA tool. The authors concluded that web-based approaches such as this may address several of the barriers faced by adolescents experiencing depression but highlighted the requirement of further research to examine the efficacy of BA when delivered online (Davidson et al, 2014).

Owing to BA's initial promise in the treatment of young people and the emerging literature suggesting its effectiveness when delivered in an online format, an online version of BA for young people may be beneficial. Specifically, this may provide an alternative treatment option in a format that ameliorates several barriers faced by young people when accessing support. However, as outlined by Davidson et al. (2014) more research in this context is required.

1.3.2 Delivery approaches and online therapies

Different approaches to online therapy delivery can be adopted including 'guided' (therapy completed alongside therapist support), 'unguided' (therapy completed independently) or 'blended' (therapy initially completed independently followed by additional face-to-face support) (Rasing, Stikkelbroek & Bodden, 2020). The 2019 NICE guidelines stated that it was unclear whether guided or unguided deliveries of online therapies were more effective, thus outlining the requirement for further research in this area. In a recent systematic review and individual patient data network meta-analysis Karyotaki et al. (2021) examined the efficacy of internet-based CBT for adults with depression when adopting an unguided or guided approach. Overall, 36 RCTs reporting on 8107 adults were included. The findings demonstrated that at post-treatment and follow-up (six and 12-months post-randomisation) there were greater reductions in depressive symptoms following both unguided and guided CBT deliveries compared to both usual care and wait-list control groups. Although a guided delivery was found to be more effective post-treatment than unguided, these differences were not maintained long-term (Karyotaki et al., 2021). Although reporting comparability in outcomes of guided and unguided deliveries, the authors highlighted that an unguided approach may have the potential to provide a cost-effective treatment option, that can be extensively disseminated whilst allowing clinician time to be reserved for more severe and complex depressive presentations. In addition, they proposed that by

seeking an internet-based intervention, some individuals may be implicitly suggesting a preference for an unguided approach (Karyotaki et al., 2021).

Several RCTs have also been conducted to compare guided and unguided treatment approaches. In an RCT comparing two CBT treatments (disorder-specific vs transdiagnostic) for adults with MDD, Titov et al. (2015) examined outcomes relative to whether a clinician-guided or self-guided approach was employed. The results demonstrated similar symptom improvements following treatment in both groups which were maintained at 24-months as well as comparable rates of session completion and programme satisfaction. Similar improvements in symptoms, completion rates and acceptability have also been reported across groups when examining guided and self-guided deliveries of CBT with older adults with depression and anxiety (Titov et al., 2016). In a later RCT, Dear et al. (2018) compared guided and unguided deliveries of a transdiagnostic CCBT programme for adults with anxiety and depression. Here comparable positive outcomes were reported across both groups including reduced anxiety and depression symptoms post-treatment alongside improved scores on measures of disability, distress and satisfaction with life, findings which were maintained at three and 12-months follow-up (Dear et al., 2018).

In 2020 Rasing et al. conducted a literature review including 33 studies to examine the barriers and facilitators of delivering online interventions to individuals with depression (aged 12 to 23 years) relative to whether a guided, unguided or blended delivery was adopted. The authors found both adherence and intervention withdrawals to be comparable across studies; adherence was reported to be 62-94% for unguided deliveries, 61-70% for guided and 90% for a blended approach whilst withdrawals were 0-21% for unguided, 17% for guided and 0-13% for blended. Acceptability, participant satisfaction and decreases in depressive symptoms were also seen across all treatment approaches (Rasing et al., 2020). However additional benefits including increased privacy and increased perceived control were reported specifically regarding an unguided approach (Logsdon et al., 2018; Bradley, Robinson & Brannen, 2012).

These findings suggest that in online therapy deliveries adopting an unguided approach may be comparable to a guided one relative to clinical outcomes (Karyotaki et al., 2021) and both adherence and withdrawals (Rasing et al., 2020). Furthermore, several additional barriers to treatment provision including limited clinician availability and treatment accessibility alongside high treatment costs may be addressed using an unguided approach. Therefore, this thesis reports on the development of a new, unguided online BA programme for adolescents experiencing low mood and/or

depression. This aims to provide not only important information about the delivery of BA for young people in an online format but also whether it can be successfully delivered when adopting an unguided approach.

Despite the benefits of online deliveries in circumventing barriers to treatment provision (see section 1.3.1) concerns about risk have been associated with online delivery approaches. In particular, whether online interventions are suitable for those with severe presentations of depression and can adequately monitor risk including instances of self-harm and suicidal ideation (Rasing et al., 2020). Whilst such concerns have been expressed regardless of whether a guided, blended or unguided approach is adopted (Rasing et al., 2020), unguided approaches, where users work through an intervention independently, particularly require consideration of risk monitoring. Therefore, this thesis reports of the development of an unguided online BA programme only for those experiencing mild to moderate low mood and/or depression.

1.4 Thesis population and development framework

1.4.1 Rationale for the thesis population

Whilst depression in both children and adolescents has been examined within this chapter, the main focus of the thesis is on adolescents only. Although depression occurs in children, its prevalence significantly increases with age (see 1.1.2) making adolescents particularly vulnerable. Whilst the term 'adolescence' can apply to a broad age range (see 1.1.1), a narrower sample of those aged 11 to 16 years, ages corresponding to those in UK secondary education, were selected for the focus of this thesis. Whilst chronologically this age range could be considered broad, with many apparent differences between those aged 11 and those aged 16, selecting a sample from a similar educational cohort provided a more homogenous sample than if extended to include those in primary or further education. However, whilst the focus of this thesis was only upon those aged 11 to 16 years, owing to individual differences, some of the changes and challenges associated with the adolescent period may extend to both younger and older individuals.

Except infancy, the period of adolescence encompasses more biological, psychological and social changes than any other time of life (Lerner, et al., 2018; Viner et al., 2012). Biologically, most notably is the onset of puberty which normally occurs around the age of 11 years for females and 12 years for males (NHS, 2016). During this time, individuals progress towards physical and sexual maturation with three particular

endocrine events taking place - adrenarche, gonadarche and the activation of the growth axis (Blakemore, Burnett & Dahl, 2010). Whilst adrenarche and gonadarche relate to sexual maturation, activation of the growth axis is associated with the body's physical growth with changes to both its size and composition. Metabolic changes, the activation of new drives and motivations and alterations in sleep and circadian regulation are also associated with puberty (Crone & Dahl, 2012). Although it is hard to determine what changes occur as a direct result of puberty and not other factors (e.g. age), several studies have demonstrated that the hormonal changes associated with puberty can influence both the structural and functional development of the brain (e.g. Blakemore et al., 2010; Forbes & Dahl, 2010; Schulz, Molenda-Figueira, & Sisk, 2009) which in turn may influence cognition, mood and behaviour (Walker, 2002). Specific brain changes associated with adolescence include changes in synaptic density and myelination (Blakemore & Choudhury, 2006).

The adolescent period has also been associated with significant advancements in cognitive functioning (Crone, 2009). Much research links these advances to functional maturation in the brain (e.g. Satterthwaite et al., 2013; Rubia, 2013) specifically within the frontal cortex (Blakemore & Choudhury, 2006). Executive functioning, the ability to control both thoughts and actions to reach future goals (Diamond, 2013), increases during adolescence (Tyler, 2020^a). Encompassing abilities associated with cognitive flexibility, inhibition and working memory, executive functioning has been linked to several important development areas including academic performance and psychological wellbeing (Poon, 2018). With the development of executive function skills, adolescents have also been shown to use more emotion regulation strategies and exercise increased control over their emotional expressions (Thompson & Goodman, 2010). Additional improvements have also been reported during this period. These have included improved information processing, including both processing speed and attention (Connolly, Abramson & Alloy, 2016) as well as improved metacognition which relates to an individual's ability to use knowledge about their own cognitions to achieve goals (Garber, Flavel & Herrington, 2016).

Besides the many biological and psychological changes occurring during the adolescent period, social changes are also evident. Adolescence sees the emergence of focus upon self-identity with individuals considering who they are relative to aspects of their lives including their appearance, relationships and interests (Tyler, 2020^b). Despite parents playing a dominant role during childhood, adolescence sees an increase in independence from the family (Stamato, Johnson & Cheng, 2018) and an increased emphasis on peer involvement (Bradford-Brown & Klute, 2003; Neinstein,

2002). These relationship changes can have a profound effect on adolescents with escalations in emotional conflict between parents and their offspring reported (e.g. De Goede, Branje, & Meeus, 2009) and family conflict being associated with the development and maintenance of both depression and suicide risk in adolescents (Ewing, Diamond & Levy, 2015). Furthermore, peer relationships, which may also include conflict (Meeus, 2016) have been seen to influence treatment, being both beneficial (e.g. promoting treatment methods) and detrimental (promoting non-compliance, providing insufficient support) to treatment efficacy (Flessner & Piacentini, 2017). Alongside these relationship changes is the increased need of young people to exercise autonomy with many wanting increased responsibility for aspects of their own lives including their health (Christie & Viner, 2005). Although striving for autonomy, the desire of adolescents to exercise it can lead to several issues including resistance, detachment and disengagement from treatment (Rubenstein, 2003; Stallard, 2002^a).

Indeed, the period of adolescence is unique and characterised by a series of specific changes and challenges as individuals transition from childhood to adulthood. Many of these changes can contribute to the development of depression (e.g. Thapar et al., 2012; Paus, Keshavan & Giedd, 2008) with some playing a role in the maintenance of symptoms (e.g. Ewing, Diamond & Levy, 2015). It is perhaps unsurprising that adolescents are a particularly vulnerable group with regard to depression prevalence. Therefore, as many do not receive appropriate help, they are a particularly important focus for the development of accessible new treatments.

1.4.2 The importance of co-design in intervention development

Scholten and Granic (2019) referred to the concept of 'empathy-based design' as an approach to intervention development that focuses upon *who* an intervention is being designed for as opposed to simply basing development on factors such as appearance and content. As this thesis sought to develop a new intervention for adolescents, consideration for the specific challenges faced by this age group was required to avoid adopting a 'one-size-fits-all' approach. Therefore, an empathy-based approach was adopted with the developmental characteristics of the adolescent period considered and used to inform the intervention development. According to Scholten and Granic (2019), implementing this approach can address a number of weaknesses in digital interventions including low adherence and high attrition by increasing user engagement and motivation. This is revisited later in the thesis.

Aligning to Scholten and Granic's (2019) concept of empathy-based design, others have recognised the importance of adopting a participatory approach and incorporating target end users, alongside stakeholders, in intervention development (Boyd et al. 2012). Often referred to as co-design, like empathy-based design this aims to ensure that what is developed meets the needs and preferences of the end user (Jones et al., 2020). Through the collaboration seen in co-design, developed interventions are more likely to be regarded by users as engaging, satisfying and useful (Thabrew, et al. 2018).

In 2016, Eyles et al. conducted a systematic review to identify the methods and processes frequently used during the co-design of mobile health delivered interventions. From their review, including nine studies, the authors identified six common phases within the participatory frameworks reported (Table 2).

Table 2:The phases of co-design (Eyles et al., 2016) relative to the thesis structure

The key phases of Co-design (Eyles et al., 2016)	Thesis chapter structure
Phase 1: Assessment of background knowledge and evidence	Chapter One: Depression in children and adolescents, Behavioural Activation and online therapy delivery
	Chapter Two: Is Behavioural Activation effective in the treatment of depression in young people? A systematic review and meta-analysis
Phase 2: Assessment of user needs to inform intervention focus	Chapter Three: Perceptions and opinions on an online Behavioural Activation programme for the treatment of depression in adolescents: A qualitative approach
Phase 3: Assessment of user needs to inform technology type	
Phase 4: Development of the intervention including content and framing	Chapter Four: Adapting Behavioural Activation for adolescent use: A synthesis of evidence
Phase 5: Pre-testing of intervention prototypes following changes based upon feedback	Chapter Five: Online Behavioural Activation programme for the treatment of low mood/ depression in adolescents: Findings from a non-randomised feasibility study
	Chapter Six: Conclusions, implications, and future directions
Phase 6: Intervention pilot testing in the 'real world'	<i>[Informed by the above and investigated in future research]</i>

This thesis reports the development of one of the first known UK online BA programmes for adolescents with low mood and/or depression. Adopting a co-design approach to intervention development, this thesis closely follows the first five phases of co-design as described by Eyles et al. (2016). The thesis concludes with a discussion about the considerations for the sixth phase: pilot testing in a real-world setting. As part of this the changes required to the intervention and the key considerations for conducting a pilot RCT as informed from the findings of a feasibility study are presented. The structure of the PhD relative to the phases identified by Eyles et al. (2016) is presented in Table 2.

1.5 Chapter summary and thesis aims

This chapter has provided the context for this thesis, describing current treatment provision for young people with low mood and/or depression and introducing the potential value of exploring BA delivered in an online format. Through adopting a co-design process, the thesis presents the development and evaluation of a new online BA programme for adolescents with low mood and/or depression. Over subsequent chapters the thesis aims to:

- Explore the current use of BA with young people experiencing low mood and/or depression via a systematic review and meta-analysis
- Examine the views and preferences of adolescents and healthcare professionals regarding the development of a new online BA therapy through adopting an exploratory qualitative design.
- Consolidate the findings from the above phases of research alongside considering the biopsychosocial development associated with the adolescent period to develop an online BA programme for adolescents with low mood and/or depression
- Examine the acceptability of the newly developed BA programme and assess the feasibility of undertaking a pilot RCT of the intervention.
- Examine whether the newly developed BA programme can be successfully delivered using an unguided treatment approach

The next chapter presents the findings of a systematic review and meta-analysis of BA use with young people experiencing low mood and/or depression.

Chapter Two: Is Behavioural Activation effective in the treatment of depression in young people? A systematic review and meta-analysis

This chapter presents the findings from a systematic review and meta-analysis of BA use with young people. Aligning to phase one of co-design (Eyles et al., 2016), this work provides important information as part of the assessment of background knowledge and evidence required during the preliminary stages of developing new interventions.

2.1 Introduction

2.1.1. Background and rationale

As discussed in Chapter One, psychological morbidity is high amongst young people with approximately 14% having a mental health disorder of which 2% will be classified as having depression (Sadler et al., 2018). Despite the condition's short and long-term impact, few young people seek help (O'Dea, Calear & Perry, 2015; Rickwood et al., 2005). A variety of barriers associated with both young people and services, have been considered to influence this reduced help-seeking behaviour. Chapter One presented BA as a treatment approach that has demonstrated effectiveness in adults across multiple studies (e.g. Chartier & Provencher, 2013; Mazzucchelli et al., 2009; Ekers et al., 2008; Cuijpers et al., 2007) and has been included within the NICE (2009) guidelines as an evidence-based treatment for adult depression. Research examining BA use with young people experiencing low mood and/or depression has started to emerge in recent years with preliminary findings suggesting its effectiveness in this context also (E.g. Wallis et al., 2012; Jacob et al., 2013; Chu et al., 2009). However, more research in this area is both required and timely (Chartier & Provencher, 2013).

To ameliorate several barriers to accessing services, delivering therapies in an online format has been suggested, with the benefits of this approach demonstrated in extensive research (e.g. McCashin et al., 2019; Pretorius et al., 2019; Stallard et al., 2010) in particular regarding CCBT (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009). Although adult research has also often focused upon CCBT for depression, research into online BA has started to emerge (e.g. Spates et al., 2016). Owing to its demonstrated effectiveness with adults and simple delivery, BA may have

the potential to be adapted for young people and delivered in an online format to address the barriers often associated with accessing therapies.

When planning new research, consideration for existing knowledge is essential (Clarke & Hopewell, 2013). However, with continued increases in public health outputs (Torgerson et al., 2020; Lasserson, Thomas & Higgins, 2019) and empirical evidence outlining the common biases inherent to individual studies (Wilson & Pettigrew, 2008) keeping up-to-date with research advances and formulating accurate conclusions can be difficult. Systematic reviews, developed to ensure that decision making is based upon a comprehensive understanding of up-to-date research evidence (Lasserson et al., 2019) have been increasingly recommended to ameliorate these problems (e.g. Page et al., 2016; Wilson & Pettigrew, 2008). Through the completion of a systematic review, vast information about a particular question can be synthesised allowing more reliable conclusions to be drawn than when considering single studies alone (Page et al., 2016). Furthermore, important information about gaps in knowledge can be identified (Page et al., 2016; Centre for Reviews and Dissemination (CRD), 2009).

Many systematic reviews also include the completion of a meta-analysis (Liberati et al., 2009). These allow the results of two or more studies to be statistically combined to examine the effectiveness of an intervention compared to a comparator (Deeks, Higgins & Altman, 2019). According to Deeks et al. (2019) the benefits of conducting meta-analyses include allowing improved precision in results, enabling questions to be addressed that have not been covered by individual studies and enabling further assessments of any conflicting findings across studies.

To examine the assertion that BA may have the potential to be adapted for young people and delivered in an online format, an examination of current research within this context was required. This was particularly important in establishing whether BA in an online format had been used with young people experiencing depression and, if so, whether it was demonstrated to be an effective treatment. Owing to their identified methodological strengths, the completion of a systematic review and meta-analysis were deemed suitable for this purpose.

2.1.2 Aims of the review

This review sought to investigate:

- Whether BA is effective in the treatment of depression in young people

- Whether BA delivered in an online format is effective in the treatment of depression in young people

2.2 Methodology

This review was completed with reference to the guidelines reported in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Liberati et al., 2009). The review protocol (Appendix A) was registered on the International Prospective Register of Systematic Reviews (PROSPERO), an online database for systematic review protocols (reference: CRD42015020453).

2.2.1 Information sources

2.2.1.1 Data sources

The following electronic databases were searched between July and August 2015: Cochrane Library, EMBASE, MEDLINE, CINAHL Plus (EBSCO), PsychINFO, Scopus, and the ISRCTN registry. The selected databases were identified as sources providing large collections of research with relevance to health sciences. To cover peer review and grey literature sources the Health Management Information Consortium (HMIC), NHS evidence, Open Grey, the Networked Digital Library of Theses and Dissertations, Web of Science Conference Proceedings and ZETOC were searched with the search simplified accordingly. The reference lists of all included studies were examined and forward citation searching carried out in Google Scholar. All relevant studies, published and unpublished, were included in the review with no restrictions placed on language or year of production.

Experts in the field were contacted to identify additional references whilst a selection of authors were contacted for further information when required. This also provided an opportunity to enquire about any further research that had been undertaken/was ongoing since the reviewed papers were produced.

2.2.1.2 Search terms

The search strategy used was based on terms from the three main constructs under review: *behavioural interventions* (including behavioural activation, behavioural therapy, behavioural interventions, self-monitoring, activity scheduling), *depression*

(including depressive disorder, depressive, depression, depressed) and *young people* (including adolescents, children, teen, youth, juvenile, pre-pubescent, student). The constructs were connected using the Boolean principle AND whilst variations in definitions used within each construct were connected using OR. The final search strategy for Medline (Appendix A) was checked and approved by an information specialist based within the CRD at the University of York.

2.2.2 Study eligibility criteria

2.2.2.1 Population and rationale

As depression treatment recommendations for adults and young people differ (see 1.1.2) only papers examining the treatment of children and adolescents were included. The population of interest was young people aged ≤ 18 years. Studies including a population that crossed the age of 18 were included if a minimum of 90% of the sample was under 18. Whilst the main focus of this thesis was on adolescents, including children in the population sample under review ensured that studies of relevance would not be missed. For inclusion, study participants had to be experiencing depression or depressive symptoms as established by a validated screening measure or a diagnosis based on a structured clinical interview conducted to internationally recognised standards (e.g. ICD, DSM).

2.2.2.2 Interventions

Included interventions were behavioural treatments for depression. For inclusion treatments had to be based upon either operant conditioning/learning theory principles or comprise techniques fundamental to behavioural treatments of depression (i.e. activity scheduling, self-monitoring). Interventions based on third-wave CBT principles (e.g. ACT) were excluded. No restrictions were placed on intervention duration, delivery setting (community, healthcare, educational, etc.) or delivery mode (online, face-to-face).

2.2.2.3 Comparators

To avoid excluding any relevant studies reporting on BA, no restrictions were placed upon the comparators or control groups employed. These could include wait-list, treatment as usual (TAU) (e.g. counselling, CBT, etc.) and any other treatments (i.e.

pharmacological, psycho-therapeutic, etc.). Studies not employing a control group were also included.

2.2.2.4 Outcome measures

Primary outcome measure

The primary outcome measure was levels of depression/depressive symptoms as measured by validated assessments. Assessments could include self-report measures and clinician or researcher administrated ratings.

Secondary outcome measures

The secondary outcome measures examined were:

- Levels of anxiety symptoms as measured by validated assessments (e.g. measurement scales, clinician ratings, etc.)
- Cost-effectiveness
- Quality of life (QoL)
- School attendance

No restrictions were placed on the timings of the outcome measures.

2.2.2.5 Study designs

Initially only studies employing an RCT methodology were to be included. However, following a preliminary search, few studies were found. Consequently, this criterion was expanded to include any studies incorporating a pre/post study design and presenting outcomes in numerical values. No exclusions were placed upon sample sizes nor sampling methodologies.

2.2.3 Study selection

Titles and abstracts were screened by the lead researcher alongside a second reviewer (SG). Both screened full papers deemed suitable from the initial search and checked papers against a pre-designed relevance checking proforma (Appendix A). If any disagreements occurred between the two researchers, these were discussed. In the event that a decision could not be reached, a third researcher would be consulted

and asked to screen the disagreed paper and make an overall decision about selection.

2.2.4 Data extraction

Information relevant to the inclusion criteria was extracted. The authors of primary studies were contacted and asked to provide any additional or missing data. Data required to make decisions about screening were stored within Endnote to assist with the management of the review and allow the identification of any duplicate citations.

A pre-piloted extraction form (Appendix A) was used to extract the following information from each included study:

- Study characteristics (study name, author(s), year of publication/production (if unpublished), study location, setting)
- Study design
- Study populations (basic participant demographics, depression diagnosis methods)
- Intervention details and comparators (intervention type, comparator (if applicable), intervention duration, session number)
- Relevant outcome data for effect size calculations (depression severity, unit of measurement)

2.2.5 Quality assessment

The methodological quality of included studies employing an RCT design was formally assessed using the Cochrane risk of bias tool (Higgins, Altman et al., 2011) and the quality rating scale by Moncrieff et al. (2001). Both tools were applied to examine whether any potential risks were evident in included studies which may have biased their results. In the Cochrane risk of bias tool, risks are categorised as high or low with the option of 'unclear' to highlight where studies have not supplied sufficient information for risk to be assessed. Risk areas assessed include sequence generation, allocation of participant concealment, selective reporting, blinding and the reporting of outcome measures.

The Moncrieff scale was specifically designed to assess the quality of controlled studies examining interventions for depressive and non-psychotic symptoms. Scores between zero and two are awarded to studies based on their success at addressing 23

items. A total score of 46 can be attained with higher scores representing higher quality. Given the nature of the subject area the inclusion of this scale allowed the quality of included papers to be assessed within the context of the condition under review. Furthermore, through employing the Moncrieff scale the quality of RCTs as identified by this measure could be compared to those from the Cochrane risk of bias tool, a more generic quality assessment tool.

The Moncrieff scale was also used to assess the methodological quality of included within-participant design studies. Although several items on the Moncrieff scale were not applicable to these studies, the scale allowed an adequate assessment of methodological quality.

The quality of included case studies/series was formally assessed using the single case experimental design scale (SCED; Tate et al., 2008). Whilst this 11-item scale was specifically designed to assess the quality of studies of single participant cases, given the commonality of such studies to include more than one participant in their design its use extends to case series/studies with larger samples also. Scores of zero or one are assigned based on whether studies meet 11 criteria with a score of one suggesting a criterion has been met and zero suggesting not. The higher the score, the lower the level of bias likely to be present. Any papers omitting to report information about a particular criterion automatically attain a score of zero for that domain.

The methodological quality of included studies was assessed using the appropriate scale/scales (Appendix A) by two reviewers (LT and SG).

2.2.6 Data synthesis

2.2.6.1 Overview of analysis strategy

A narrative synthesis of included studies was conducted to provide a summary of the outcome measures for each alongside quality appraisal scores.

2.2.6.2 Details of meta-analysis

A summary of the outcome measures of included studies is presented alongside a forest plot providing a graphical display of the study outcomes of the RCTs. Given the limited number of RCTs only one meta-analysis was conducted for the Children's

Depression Rating Scale-Revised (CDRS-R; Poznanski & Mokros, 1996). Owing to the nature of the data presented, studies were pooled using the generic inverse variance method with a random effects model. All analyses were undertaken in STATA version 13 (StataCorp, 2013).

No dichotomous outcomes relevant to this review were reported within the studies included in the meta-analysis. However, had any been reported, odds ratios (measures of association between exposures and outcomes) would have been calculated alongside the associated 95% confidence interval.

2.2.6.3 Assessing heterogeneity

Statistical heterogeneity was assessed using the I^2 statistic. Here, a value of 25% is regarded as low, 50% as moderate and 75% as high (Higgins et al., 2003). If moderate to high statistical heterogeneity was present ($I^2 \geq 50\%$) the analysis was re-run with any outliers excluded. Any outliers would be identified through examination of their associated confidence intervals.

2.2.6.4 Analysis of publication bias

According to the Cochrane handbook for systematic reviews of interventions (version 5.1.0; Higgins, Thomas et al., 2011) the assessment of publication bias can only be conducted where there are ten or more included studies. As only three RCTs were included in this review (see 2.3.3.1) publication bias could not be examined for the studies in the meta-analysis using funnel plots.

2.3. Results

2.3.1 Results of the search

Electronic databases were searched during July and August 2015 for studies reporting on behavioural interventions for treating depression in young people aged ≤ 18 years. The original search, including grey literature searching, identified 5931 potentially relevant records of which 5495 remained after duplicates ($n=436$) were removed. No additional studies were found from reverse citation searches. The screening of titles and abstracts was undertaken by the primary (LT) and secondary (SG) reviewers who identified 42 full-text articles for assessment. After relevance checking was independently conducted ten papers were deemed to be eligible for inclusion. No

disagreements about inclusion occurred between reviewers. Figure 1 presents a PRISMA diagram of the results.

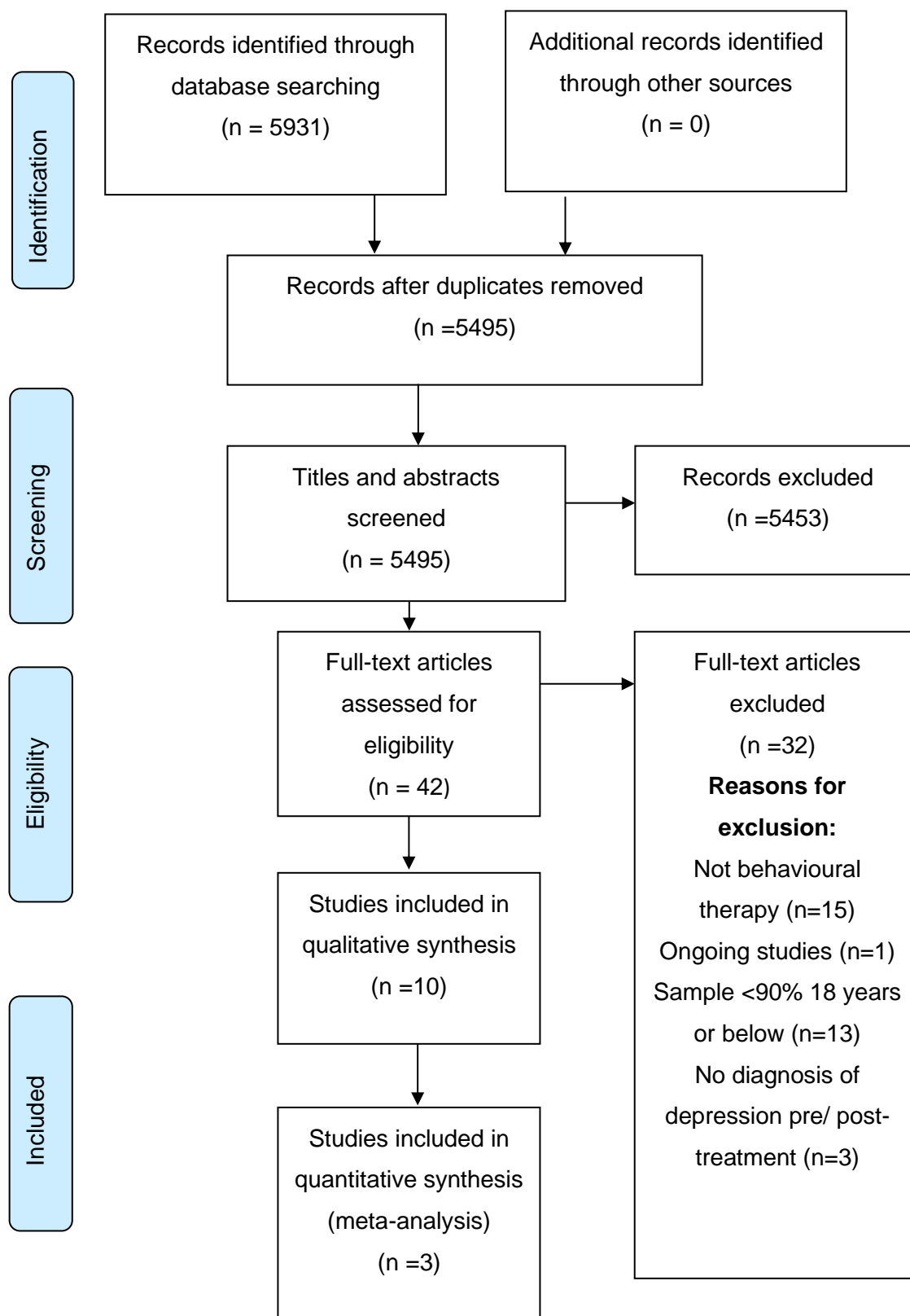


Figure 1: PRISMA flow diagram

2.3.2 Excluded studies

Out of the 42 full-text articles assessed for inclusion in the review, 32 were excluded (Appendix A). Reasons for exclusion included: having <90% of the sample aged 18

years or below (n=13), not reporting on a behavioural therapy (n=15), being an ongoing study and thus having currently unreported results (n=1) or examining a sample who had not received a diagnosis of depression at baseline or follow-up (n=3).

2.3.3 Included studies

2.3.3.1 Study design

Ten studies met the review's inclusion criteria: three RCTs (Chu et al., 2016; McCauley et al., 2015; Stark, 1985), two within-participant designs (Riley & Gaynor, 2014; Douleh, 2013) and five case studies/series (Jacob et al., 2013; Wallis et al, 2012; Ritschel et al., 2011; Chu et al, 2009; Weersing et al., 2008). The characteristics of included studies are presented in Table 3 whilst a full data extraction table for each can be found in Appendix A.

Table 3: Characteristics of included studies

Study	Setting and sample	Study design	Intervention	Comparator	Outcome Measures
Chu et al. (2016)	<p>Setting: One public middle school, USA</p> <p>Participants n=35</p> <p>Age: 12-14 (<i>M</i>:12.03, <i>SD</i>:.45)</p> <p>Gender: 10 males, 25 females</p> <p>Diagnosis: Current clinical principal diagnosis of either a unipolar depression disorder or an anxiety disorder based on CDRS-R or ADIS-IV (no cut-offs specified)</p>	RCT	<p>Group behavioural activation therapy (GBAT)</p> <p>Duration: 10 1-hour sessions over 10 weeks</p> <p>Delivery: Face-to-face (1 clinical psychologist, 4 graduate students, 2 school counsellors)</p> <p>n=21 (ITT – 2 lost to follow-up)</p> <p>Manual: Yes</p>	Wait-list n =14 (ITT – 1 lost to follow-up)	<p>Depression measures: CDRS-R CES-D</p> <p>Anxiety measures: ADIS-IV SCARED</p> <p>QoL measures: N/A</p> <p>Timings: Pre-treatment Post-treatment 4 months follow-up</p>
McCauley et al. (2015)	<p>Setting: One hospital-based mental health clinic, USA</p> <p>Participants: n=60</p> <p>Age: 12 to 18 (<i>M</i>: 14.9, <i>SD</i>:1.53)</p> <p>Gender: 38 females, 22 males</p> <p>Diagnosis: Depressive disorder based on DSM IV criteria, or raw score of ≥ 45 (T score ≥ 65) on CDRS-R, and score of ≥ 11 on SMFQ</p>	RCT	<p>Adolescent behavioural activation program (A-BAP)</p> <p>Duration: 14 sessions</p> <p>Delivery: Face-to-face (2 doctoral students, 1 social worker)</p> <p>n=35 (ITT – 8 lost to follow-up)</p> <p>Manual: Yes</p>	Evidence-based practice for depression Duration: ≤ 14 sessions Delivery: Face-to-Face n =25 (ITT – 9 lost to follow-up)	<p>Depression measures: K-SADS diagnostic interview CDRS-R SMFQ</p> <p>Anxiety measures: MASC</p> <p>QoL measures: N/A</p> <p>Timings: Pre-treatment Post-treatment 6 months follow-up 12 months follow-up</p>
Stark (1985)	<p>Setting: One elementary school, USA</p> <p>Participants: n=29</p> <p>Age: 9-12 years (<i>M</i>: 11.2)</p> <p>Gender: 16 males, 13 females</p>	RCT	<p>Behaviour therapy</p> <p>Duration: 12 45-minute sessions over 5 weeks</p> <p>Delivery: Face-to-face (1 study therapist, 1 clinical psychologist)</p> <p>n=10, 9 included in analysis</p>	Self-control therapy or wait-list Self-control therapy: Duration: 12 45-minute sessions over 5 weeks Delivery: Face-to-Face	<p>Depression measures: CDI CDS CDRS-R</p> <p>Anxiety measures: RCMAS</p>

	Diagnosis: Depressive disorder based on CDI (≥ 16)		Manual: Yes	n = self-control therapy: 9 (all included in analysis, wait-list: 9 (all included in analysis))	QoL measures: N/A Timings: Pre-treatment Post-treatment 8 weeks follow-up
Riley & Gaynor (2014)	Setting: 3 elementary schools, 1 middle school, USA Participants: n=11 Age: 8-12 years (<i>M:</i> 9.8, <i>SD:</i> 1.26) Gender: 9 males, 2 females Diagnosis: Depressive disorder based on CDRS-R (≥ 12) and CDI (≥ 40)	Within-participant design	Non-directive therapy (NDT) only: Duration: 3 sessions over 3 weeks Delivery: Face-to-face (Doctoral students) n=11 n=7, all included in the analysis NDT and behaviour therapy (BT) As above plus 9 sessions Manual: Yes	N/A	Depression measures: CDRS-R CDI Anxiety measures: N/A QoL measures: FQOLS Timings: Pre-treatment Post-treatment (both groups) 2 months follow-up
Douleh (2013)	Setting: 2 High schools, USA Participants: n=14 Age: 14 – 18 (<i>M:</i> 15.71) Gender: 8 (57%) males, 6 (43%) females Diagnosis: Depressive disorder based on CDRS-R (≥ 45)	Within-participant design	Motivational Interviewing (MI) Duration: 1 to 4 sessions over 4 weeks Delivery: Face-to-face (study therapist) n= 14 (2 lost to follow-up) MI and Fun activities (FA) Duration: 1 to 4 sessions over 4 weeks Delivery: Face-to-face (study therapist) n= 7 (3 lost to follow-up) MI and FA and values based behavioural activation (VBBA) Duration: 1 to 4 sessions over 6 weeks Delivery: Face-to-face	N/A	Depression measures: CDRS-R BDI-II MINI-KID Anxiety measures: N/A QoL measures: HRQOL (measure not specified) Timings: A1: Pre-treatment A2: Post MI (4 weeks post pre-treatment) A3: Post FA (10 weeks post pre-treatment) A4: Post VBBA (16 weeks post pre-treatment)

			n= 1 (1 included in analysis) Manual: Yes		A5: 20 weeks post pre-treatment
Ritschel et al. (2011)	Setting: Outpatient adolescent mood clinic, USA Participants: n=6 Ages: 14-17 Gender: 3 males, 3 females Diagnosis: Depressive disorder based on K-SADS or CDRS-R (≥ 45)	Case study/series	Behavioural Activation Duration: 22 sessions over 18 weeks Delivery: Face-to-face (2 doctoral level staff, 1 graduate student) n=6 (all included in analysis) Manual: Yes	N/A	Depression measures: KSADS CDRS-R BDI-II Anxiety measures: N/A QoL measures: N/A Timings: Pre-treatment Post-treatment
Chu et al. (2009)	Setting: One public middle school, USA Participants: n=5 Ages: 12-14 Gender: 2 males, 3 females Diagnosis: Current clinical principal diagnosis of either a unipolar depression disorder or an anxiety disorder based on CES-D (≥ 15) or ADIS-IV (no cut-offs specified)	Case study/series	Group behavioural activation therapy (GBAT) Duration: 13 sessions over 13 weeks Delivery: Face-to-face (mental health specialists) n= 5 (all included in analysis) Manual: Yes	N/A	Depression measures: CES-D Anxiety measures: ADIS-IV MASC QoL measures: N/A Timings: Pre-treatment Post-treatment (13 weeks)
Wallis et al. (2012)	Setting: Local mental health service, Australia Participants: n=5 Ages: 14-15 Gender: All female Diagnosis: Depressive disorder based on CES-D (no cut-offs specified)	Case study/series	Behavioural Activation Duration: 10 sessions over 10 weeks Delivery: Face-to-face (2 social workers) and workbooks n=5 (all included in analysis) Manual: Yes	N/A	Depression measures: CES-D BDI-II Anxiety measures: N/A QoL measures: N/A Timings: Pre-treatment 2 weeks 3 weeks 6 weeks

					Completion (10 weeks)
Weersing et al. (2008)	Setting: Primary care practice, USA Participants: n=2 Ages: 13 and 17 Gender: 1 male and 1 female Diagnosis: Depressive disorder based on CDI (≥ 13), or anxiety disorder SCARED (≥ 25)	Case study/series	Integrated brief behavioural therapy for anxiety and depression Duration: 8 30-minute sessions over 12 weeks Delivery: Face-to-face (mental health specialists) n=2 (all included in analysis) Manual: Yes	N/A	Depression measures: CDI K-SADS Anxiety measures: SCARED QoL measures: N/A Timings: Pre-treatment Post-treatment (12 weeks) 24-week follow-up
Jacob et al. (2013)	Setting: Community mental health clinics, USA Participants: n=3 Ages: 14-17 Gender: 2 males, 1 female Diagnosis: Depressive disorder based on K-SADS, CDRS-R (≥ 45) and BDI-II (≥ 14)	Case study/series	Behavioural Activation (adapted for low-income, African-American Adolescents) Duration: 14-17 sessions over 6 months (length of sessions not specified) Delivery: Face-to-face (3 study therapists) n=3 (all included in analysis) Manual: Yes		Depression measures: KSADS CDRS-R BDI-II Anxiety measures: N/A QoL measures: N/A Timings: Pre-treatment At each session (BDI-II) Week 9 (CDRS-R) Post-treatment (6 months)

Notes. *Depression Measures:* CDRS-R: Children's depression rating scale – revised (Poznanski & Mokros, 1996); SMFQ: Short Mood and Feelings Questionnaire (Angold et al., 1995); CES-D: Center for epidemiologic studies depression scale (Radloff, 1977); CDI: Children's depression Inventory (Kovacs, 2011); CDS: Children's Depression Scale (Reynolds, 1980); BDI-II: Beck Depression Inventory (Beck, Steer & Brown, 1996); K-SADS: Kiddie Schedule for affective disorders (Kaufman et al., 1997); MINI-KID: Mini International Neuropsychiatric Interview for Children and Adolescents (Sheehan et al., 2010). *Anxiety Measures:* MASC: Multi-dimensional anxiety scale for children (March et al., 1997); SCARED: Screen for anxiety related emotional disorders (Birmaher et al., 1999); RCMA: Revised children's manifest anxiety scale (Reynolds & Richmond, 1978); ADIS-IV: Anxiety disorders interview schedule for DSM-IV child interview (Silverman & Albano, 1996). *QoL Measures:* FQOLS: The Family Quality of Life Scale–Family Interactions Subscale (Hoffman et al., 2006).

2.3.3.2 Sample size

The sample sizes of included studies ranged from two (Weersing et al., 2008) to 60 (McCauley et al., 2015) with an overall sample of 170. Of these 26 were lost to follow-up. When examining the sample sizes relative to study design these ranged from 28 to 60 in the RCTs (21 lost to follow-up), 11 to 14 in the within-participant designs (five lost to follow-up) and from two to 6 in the case studies/case series (zero lost to follow-up)

2.3.3.3 Setting

Nine of the included studies were conducted in the USA (Chu et al., 2016; 2009; McCauley et al., 2015; Riley & Gaynor, 2014; Douleh, 2013; Jacob et al., 2013; Ritschel et al., 2011; Weersing et al., 2008; Stark, 1985) with the remaining one, a case study/series, conducted in Australia (Wallis et al., 2012). Five studies were set in academic centres (Chu et al., 2016; Riley & Gaynor, 2014; Douleh, 2013; Chu et al., 2009; Stark, 1985;), three in secondary care settings (McCauley et al., 2015; Wallis et al., 2012; Ritschel et al., 2011) and two in primary care settings (Jacob et al., 2013; Weersing et al., 2008).

2.3.3.4 Participants

Participants ranged in age from 8 to 18 years, with the ratio of males to females varying across study designs. Most participants were female in the included RCTs (Chu et al., 2016; McCauley et al., 2015; Stark, 1985), whilst the inverse was seen for studies employing a within-participant design (Riley & Gaynor, 2014; Douleh, 2013). Similar numbers of male and female participants were recruited in four of the case studies/series (Jacob et al., 2013; Ritschel et al., 2011; Chu et al., 2009; Weersing et al., 2008) whilst one (Wallis et al., 2012) recruited only females.

2.3.3.5 Interventions and comparators

Behavioural interventions were all delivered face-to-face with the number of sessions ranging from one (Douleh, 2013) to 22 (Ritschel et al., 2011). Two studies (Chu et al., 2016; 2009) delivered the intervention in a group format whilst the remaining eight adopted a one-to-one approach. Varied professionals delivered the interventions including clinical psychologists (Chu et al., 2016; Stark, 1985), students (graduate, doctoral and post-doctoral; Chu et al., 2016; McCauley et al., 2015; Riley & Gaynor,

2014; Ritschel et al., 2011), mental health clinic staff (Chu et al., 2009; Weersing et al., 2008), social workers (McCauley et al., 2015; Wallis et al., 2012), school counsellors (Chu et al., 2016) and study therapists (Douleh, 2013, Jacob et al., 2013; Stark, 1985). All studies delivered a behavioural intervention following a treatment manual with the addition of a workbook in one study (Wallis et al., 2012) used to support delivery.

2.3.3.5.1 RCTs

In the three RCTs (Chu et al., 2016; McCauley et al., 2015; Stark, 1985) between ten and 14 sessions of behavioural therapy were delivered across a period of five to 14 weeks. Sessions lasted between forty-five minutes (Stark, 1985) and one hour (Chu et al., 2016; McCauley et al., 2015). Although the behavioural interventions employed had common elements, some differences were apparent. Chu et al. (2016) delivered Group Behavioural Activation Therapy (GBAT) (Chu et al., 2009), a transdiagnostic therapy aimed to treat young people with anxiety, depression or both. This was adapted from a number of BA programmes developed for adults (Lejuez et al., 2011; Martell et al., 2013; Addis & Martell, 2004). The programme included in-session exposures, assessments of valued life domains and an emphasis on graded challenge hierarchies (Chu et al., 2016). McCauley et al. (2015) delivered a behavioural intervention to participants entitled the Adolescent Behavioural Activation Program (A-BAP) which comprised activities designed to promote competence, psychoeducation regarding depression and the self-monitoring of moods and behaviours. Finally, the behaviour therapy employed by Stark (1985) sought to increase participant's understanding of their own behaviour and its impact on mood through in-session presentations and homework tasks. Non-directive therapists were used here to discuss problems in a traditional psychotherapy format (Stark, 1985) and increase activity levels.

Comparators varied across the RCTs with Chu et al. (2016) employing a wait-list control and McCauley et al. (2015) providing up to 14 appointments of evidence-based TAU. In the study by Stark (1985) two comparator groups were employed: self-control therapy or wait-list. The self-control therapy comprised 12 hour-long sessions teaching participants skills relating to self-monitoring, self-evaluating performance, attributing the cause of good and bad outcomes and self-consequating.

2.3.3.5.2 Within-participant designs

In the two studies adopting a within-participant design (Riley & Gaynor, 2014; Douleh, 2013) participants received between one and nine sessions of a behavioural intervention delivered after other treatment approaches had been applied yet depression severity had not improved. In the study by Riley and Gaynor (2014) all participants received three sessions of non-directive therapy (NDT) delivered over three weeks. NDT, comprising aspects not specific to a single therapy, involved the therapist providing support to participants whilst refraining from providing interpretations or advice (Vostanis et al., 1999). Nine sessions of behaviour therapy, based upon components of Primary and Secondary Control Enhancement Training (Weisz, Moore, & Southam-Gerow, 1999) and Caregiver-Child Relationship Enhancement Training (Eckshtain & Gaynor, 2003; 2012) were then offered to those not demonstrating an improvement in depression severity following this. These sessions focused upon increasing non-depressive behaviour, positive interactions and participation in meaningful activities and improving problem-solving.

In the study by Douleh (2013) all participants initially received three weekly sessions of Motivational Interviewing (MI). Those not demonstrating a decrease in CDRS-R-rated depressive symptoms following this were offered up to four sessions of fun activities (FA). This involved psychoeducation for depression, discussions about fun activities and the subsequent completion of such activities alongside the completion of mood diaries. Those still not demonstrating improvements in depressive symptoms then received a Values-based Behavioural Activation (VBBA) intervention comprising four treatment sessions. VBBA, based upon the Gaynor and Harris (2008) manual used psychoeducation with a focus upon activities deemed important to participants with emphasis placed upon participants' own personal values.

2.3.3.5.3 Case studies/series

In the five included case-studies/series (Jacob et al., 2013; Wallis et al., 2012; Ritschel et al., 2011; Chu et al., 2009; Weersing et al., 2008) participants received between eight and 22 sessions of behavioural therapy. Common features of therapy included problem-solving, goal setting and relapse prevention, with techniques including role-play (Chu et al., 2009), practice sessions (Chu et al., 2009; Weersing et al., 2008) and relaxation techniques (Weersing et al., 2008) employed. In one study (Chu et al.,

2009) MI was conducted prior to behavioural therapy to examine participant motivation and to set realistic therapy targets.

2.3.3.6 Outcome measures

Seven of the ten studies examined depression scores using the CDRS-R (Chu et al., 2016; McCauley et al., 2015; Riley & Gaynor, 2014; Douleh, 2013; Jacob et al., 2013; Ritschel et al., 2011; Stark, 1985;). The CDRS-R is the most widely used measure of child and adolescent depression severity in research trials internationally (Kim et al., 2014; Plener et al., 2012) and demonstrates good 2-week test-retest reliability (.80) and good to excellent internal consistency ($\alpha = .74 - .92$) within this context (Mayes et al., 2010).

Five of the included studies collected outcome data relating to anxiety. Three of these (Chu et al., 2016; 2009; Weersing et al., 2008) adopted a transdiagnostic approach and included participants experiencing anxiety, depression or both. The remaining two studies (McCauley et al., 2015; Stark, 1985) examined behavioural therapies with individuals experiencing depression but collected outcome data relating to anxiety alongside. Four separate anxiety measures were employed across studies; the ADIS-IV (Chu et al., 2016; 2009), SCARED (Chu et al., 2016; Weersing et al., 2008), the MASC (McCauley et al., 2015; Chu et al., 2009) and the RCMAS (Stark, 1985).

Only one included study (Riley & Gaynor, 2014) collected QoL data using the FQOLS. Although Douleh (2013) reported values relating to Health-Related QoL (HRQoL) the measure employed was not reported. Neither of the remaining secondary outcome measures of interest proposed *a priori* (BA impact on school attendance, BA cost-effectiveness) were reported in sufficient detail in any of the included studies.

2.3.4 Methodological quality of included studies

As previously described (see 2.2.5) the methodological quality of included studies was formally assessed using the Cochrane risk of bias tool (Higgins, Altman et al., 2011), the quality rating scale proposed by Moncrieff et al. (2001) and the SCED (Tate et al., 2008). The Cochrane risk of bias tool can only be applied with studies adopting an RCT methodology and thus only three studies (Chu et al., 2016; McCauley et al., 2015; Stark, 1985) could be assessed using this tool alongside the Moncrieff scale. The quality of the two within-participant design studies were assessed using the Moncrieff

scale with the five included case studies/series assessed using the SCED. Within this thesis the wording of the Moncrieff scale has been slightly adapted with the term 'subjects' (used on several items of the scale) replaced with 'participants'.

2.3.4.1 The Cochrane risk of bias tool

On the Cochrane risk of bias tool all three RCTs demonstrated low risk for the reporting of other sources of bias, incomplete outcome data and blinding outcome assessors. Level of bias was unclear where no or insufficient information regarding a particular domain (allocation concealment (Chu et al., 2016; Stark, 1985), random sequence generation (Stark, 1985)) was provided. With no pre-published protocols, it was hard to determine whether all pre-specified outcomes had been reported in each RCT and therefore the level of bias due to selective reporting was unclear. As the RCTs involved the delivery of BA neither participants nor personnel could be blinded to allocation. However, a lack of blinding meant that all three RCTs demonstrated a high risk of bias on this domain. See Table 4 for the results of the Cochrane risk of bias tool.

Table 4: Results of the Cochrane risk of bias tool: RCTs

Domain	McCauley et al. (2015)	Chu et al. (2016)	Stark (1985)
Random sequence generation	+	+	?
Allocation concealment	+	?	?
Selective reporting	?	?	?
Other sources of bias	+	+	+
Blinding participants and personnel	-	-	-
Blinding (outcome assessment)	+	+	+
Incomplete outcome data	+	+	+

Notes. '-' low risk of bias; '+' high risk of bias; '?' unknown risk of bias.

2.3.4.2 The Moncrieff scale (RCTs)

On the Moncrieff domains all three included RCTs attained the maximum quality score of two for: method of allocation, providing clear descriptions of treatment, using clear diagnostic criteria, the recording of exclusion criteria, clearly describing outcome measures, including all participants in analyses (ITT), presenting results with the

inclusion of data for the re-analysis of main outcomes and providing clear justifications for any conclusions made.

Of the three RCTs, McCauley et al. (2015) and Chu et al. (2016) attained the highest score (36) on the Moncrieff scale suggesting a lower risk of bias than Stark (1985) which attained a score of 30. However, for all three studies a score of one was attained on several domains suggesting that, whilst bias had been minimised it was still present. This was the case for all RCTs regarding their assessment of treatment compliance and the appropriateness of the statistical analyses employed both of which were regarded as adequate across studies. In the study by McCauley et al. (2015), although the study's main objectives were outlined these were not specified *a priori* which added potential bias to the results reported. Only basic demographic information was reported and no information about participant sampling was supplied questioning representativeness. Although the assessor of the outcome measures was blinded to treatment allocation, no information was supplied as to what this method was. Furthermore, compliance to treatment was only partially reported. In the study by Chu et al. (2016) a score of one was attained for withdrawals where, although the number was reported, reasons given were not supplied. Only adequate information was reported for providing information on comparability and adjustment for differences in analysis, again increasing the risk of bias for this domain. However, Chu et al. (2016) attained a maximum score for reporting side-effects, with neither of the other two RCTs discussing this. Like McCauley et al. (2015), in the study by Stark (1985) although the assessor was blinded to treatment allocation no test of this was reported, again meaning the study could only receive a score of one on this domain. In addition, a score of one was awarded for the length of intervention which was regarded as 'reasonable'.

High risk of bias was reported where studies provided no or insufficient information about power calculations, concealment of allocation (Chu et al., 2016; Stark, 1985), sample sizes, declarations of interest (Stark, 1985) and side-effects (McCauley et al., 2015; Stark, 1985). As previously outlined, blinding was not possible in any of the included studies and therefore all studies received zero on this domain. See Table 5 for the Moncrieff scale results for the RCTs.

Table 5: Results of the Moncrieff scale: RCTs

Domain	McCauley et al. (2015)	Chu et al. (2016)	Stark (1985)
Objectives and specifications, main outcomes a priori	1 (<i>objectives clear but main outcomes not specified a priori</i>)	2 (<i>objectives clear with a priori specifications of main method for outcomes</i>)	2 (<i>objectives clear with a priori specifications of main method for outcomes</i>)
Adequate sample size	2 (<i>large or specified by power calculations</i>)	2 (<i>large or specified by power calculations</i>)	0 (<i>inadequate</i>)
Appropriate duration of the trial and follow-up	2 (<i>long enough for assessment of long-term outcomes</i>)	2 (<i>long enough for assessment of long-term outcomes</i>)	1 (<i>reasonable length</i>)
Power calculations	2 (<i>details of calculations provided</i>)	0 (<i>not reported</i>)	0 (<i>not reported</i>)
Method of allocation	2 (<i>randomised allocation</i>)	2 (<i>randomised allocation</i>)	2 (<i>randomised allocation</i>)
Concealment of allocation	2 (<i>concealment of allocation code detailed</i>)	0 (<i>not done or not reported</i>)	0 (<i>not done or not reported</i>)
Clear description of treatments	2 (<i>full details of main and adjunctive treatments</i>)	2 (<i>full details of main and adjunctive treatments</i>)	2 (<i>full details of main and adjunctive treatments</i>)
Blinding of participants	N/A	N/A	N/A
Sources of participants/ representative sample	1 (<i>source of participants given but no information of sampling/unrepresentative sample</i>)	2 (<i>sources of participants described plus representative sample</i>)	2 (<i>sources of participants described plus representative sample</i>)
Use of diagnostic criteria	2 (<i>diagnostic criteria plus specification of severity</i>)	2 (<i>diagnostic criteria plus specification of severity</i>)	2 (<i>diagnostic criteria plus specification of severity</i>)
Record of exclusion criteria	2 (<i>criteria and number of exclusions and refusals reported</i>)	2 (<i>criteria and number of exclusions and refusals reported</i>)	2 (<i>criteria and number of exclusions and refusals reported</i>)
Description of sample demographics	1 (<i>basic details</i>)	2 (<i>full description</i>)	2 (<i>full description</i>)
Blinding of assessor	1 (<i>done but no test of blind</i>)	2 (<i>done and integrity of blind test</i>)	1 (<i>done but no test of blind</i>)
Assessment of compliance with treatments	1 (<i>assessed for some experimental treatments</i>)	1 (<i>assessed for some experimental treatments</i>)	1 (<i>assessed for some experimental treatments</i>)
Details on side-effects	0 (<i>inadequate details</i>)	2 (<i>Full side effect profiles by group</i>)	0 (<i>inadequate details</i>)
Record of number and reasons for withdrawal	2 (<i>withdrawals and reason by group</i>)	1 (<i>withdrawals by group reported without reason</i>)	2 (<i>withdrawals and reason by group</i>)

Outcome measures described clearly	2 (main outcomes clearly described or valid and reliable instrument used)	2 (main outcomes clearly described or valid and reliable instrument used)	2 (main outcomes clearly described or valid and reliable instrument used)
Information on comparability and adjustment for difference in analysis	2 (Sufficient information on comparability with appropriate adjustment)	1 (some information on comparability with appropriate adjustment)	2 (Sufficient information on comparability with appropriate adjustment)
Inclusion of all participants in analyses (ITT)	2 (95% or more included)	2 (95% or more included)	2 (95% or more included)
Presentation of results with inclusion of data for re-analysis of main outcomes	2 (Comprehensive)	2 (Comprehensive)	2 (Comprehensive)
Appropriate statistical analysis	1 (adequate)	1 (adequate)	1 (adequate)
Conclusions justified	2 (yes)	2 (yes)	2 (yes)
Declarations of interest	2 (yes)	2 (yes)	0 (no)
Total	36	36	30

2.3.4.3 Comparisons between Cochrane and Moncrieff results

By employing both the Cochrane risk of bias tool and the Moncrieff scale, comparisons could be made to determine whether similar levels of bias were found in the RCTs using a general assessment tool and one specifically related to the subject area. Generally, similarities in risk of bias across each of the three studies were found. When employing the Cochrane risk of bias tool, McCauley et al. (2015) demonstrated lower risk, a finding also demonstrated by the Moncrieff scale. Similarly, Stark (1985) demonstrated the highest risk of bias, a finding demonstrated by both instruments. However, the Moncrieff scale suggested a similar level of risk in the studies by McCauley et al. (2015) and Chu et al. (2016) where the two studies attained the same score overall. This was not the case on the Cochrane risk of bias, with the study by McCauley et al. (2015) demonstrating a slightly lower risk attributed to the allocation concealment domain.

2.3.4.4 The Moncrieff Scale (within-participant designs)

Scores on the Moncrieff scale for the two within-participant design studies differed by two points (Riley & Gaynor, 2014: 25, Douleh, 2013: 22) although were substantially

lower than those attained by the RCTs. Through not employing a randomised methodology several items on the Moncrieff scale (i.e. methods of allocation, concealment of allocation) were not applicable. Therefore, these studies could not attain the maximum scores on the scale which likely explains why their overall scores were lower than those for the RCTs.

Similarities were apparent in the scores obtained by the within-participant design studies across several domains. Both received the maximum two points for providing clear objectives *a priori*, details about treatments, participant demographics, diagnostic criteria, exclusion criteria, outcome measures and completing ITT analyses. However, neither study conducted power calculations, reported side-effects nor blinded assessors and both employed inadequate sample sizes – domains they both received zero for.

Neither study obtained the maximum score for length of the intervention or follow-up. Although both conducted interventions with durations that could be considered adequate, the follow-up periods were not. On the Moncrieff scale two points are awarded if a follow-up is conducted at six months or longer and one point if it is between three and six months. Douleh (2013) conducted a follow-up at four months, attaining a score of one whilst the follow-up by Riley and Gaynor (2014) was only two months.

Both studies attained scores of one for participant sampling as although the participant sources were given, information as to the sampling technique was not. Whilst both provided numbers of withdrawals, reasons were not provided. Other domains where both studies attained a score of one were information on comparability and adjustments in analyses, presentation of results with the inclusion of data for re-analysis and appropriate statistical analyses. Although these factors were reported adequately, more information and/or improvements in the particular methods employed would have improved methodological quality. Higher scores were attained in the study by Riley and Gaynor (2014) on the remaining domains: treatment compliance, justified conclusions and declarations of interest. Like with the RCTs, owing to the delivery of treatment across studies, blinding of participants was not possible. See Table 6 for the results of the Moncrieff scale for the within-participant design studies.

Table 6: Results of the Moncrieff scale: Within-participant design studies

Domain	Douleh (2013)	Riley and Gaynor (2014)
Objectives and specifications, main outcomes a priori	2 (<i>objectives clear with a priori specification of main method for assessment of outcomes</i>)	2 (<i>objectives clear with a priori specification of main method for assessment of outcomes</i>)
Adequate sample size	0 (<i>inadequate</i>)	0 (<i>inadequate</i>)
Appropriate duration of the trial and follow-up	1 (<i>reasonable length</i>)	0 (<i>too short</i>)
Power calculations	0 (<i>not reported</i>)	0 (<i>not reported</i>)
Method of allocation	N/A	N/A
Concealment of allocation	N/A	N/A
Clear description of treatments	2 (<i>full details of main and adjunctive treatments</i>)	2 (<i>full details of main and adjunctive treatments</i>)
Blinding of participants	N/A	N/A
Sources of participants/ representative sample	1 (<i>sources of participants given but no information on sampling/ unrepresentative sample</i>)	1 (<i>sources of participants given but no information on sampling/ unrepresentative sample</i>)
Use of diagnostic criteria	2 (<i>diagnostic criteria plus specification of severity</i>)	2 (<i>diagnostic criteria plus specification of severity</i>)
Record of exclusion criteria	2 (<i>criteria and number of exclusions and refusals reported</i>)	2 (<i>criteria and number of exclusions and refusals reported</i>)
Description of sample demographics	2 (<i>full description</i>)	2 (<i>full description</i>)
Blinding of assessor	0 (<i>not done</i>)	0 (<i>not done</i>)
Assessment of compliance with treatments	1 (<i>assessed for some experimental treatments</i>)	2 (<i>assessed for all experimental treatments</i>)
Details on side-effects	0 (<i>inadequate details</i>)	0 (<i>inadequate details</i>)
Record of number and reasons for withdrawal	1 (<i>withdrawals by group reported without reason</i>)	1 (<i>withdrawals by group reported without reason</i>)
Outcome measures described clearly	2 (<i>main outcomes clearly described or valid and reliable measures used</i>)	2 (<i>main outcomes clearly described or valid and reliable measures used</i>)
Information on comparability and adjustment for difference in analysis	1 (<i>some information on comparability with appropriate adjustment</i>)	1 (<i>some information on comparability with appropriate adjustment</i>)
Inclusion of all participants in analyses (ITT)	2 (<i>95% or more included</i>)	2 (<i>95% or more included</i>)
Presentation of results with inclusion of data for re-analysis of main outcomes	1 (<i>adequate</i>)	1 (<i>adequate</i>)
Appropriate statistical analysis	1 (<i>adequate</i>)	1 (<i>adequate</i>)
Conclusions justified	1 (<i>partially</i>)	2 (<i>yes</i>)
Declarations of interest	0 (<i>no</i>)	2 (<i>yes</i>)
Total	22	25

2.3.4.5 *The SCED scale*

The first criterion on the SCED relates to demographic information about the participant(s) who received an intervention and is not scored. Therefore, the maximum score that can be attained on the measure is ten.

Total SCED scores for the five case studies/series ranged from four (Wallis et al., 2012; Chu et al., 2009) to nine (Ritschel et al., 2011). All received a score of one regarding their replicability attributed to the fact that they examined the effectiveness of behavioural therapies with more than one participant. Despite employing a range of baseline measures, all were completed in a single session and not at multiple time points. To attain a score of one, baseline data collection needs to occur over a minimum of three time-points and therefore all studies received zero for this domain.

Wallis et al. (2012) was the only study to receive zero for defining target measures at the study start. Insufficient information was also provided for participant demographics and their clinical histories. Chu et al. (2009) was the only study to receive zero for the number of phases employed within the research design, the reporting of sufficient data during the treatment phase (measures were only completed pre/post-treatment and not during) and the reporting of raw data scores.

Through not employing independent assessors to measure outcomes, zero was awarded to the studies by Jacob et al. (2013), Wallis et al. (2012) and Chu et al. (2009). These, alongside the study by Weersing et al. (2008), also attained zero for statistical analysis as insufficient/no analysis was undertaken.

On the inter-rater reliability domain, studies obtained a score of one if outcomes were measured with sufficient objectivity. This criterion could be met if a standardised instrument with demonstrated inter-rater reliability was used and referenced alongside the relevant coefficient to support this. Although employing standardised measures, Wallis et al. (2012) and Weersing et al. (2008) did not provide information about their inter-reliability and thus received zero on this domain. To receive a score of one on the final domain, 'generalisation' studies needed to have measured at least one other variable, besides the target behaviour, to determine whether other behaviour changes had occurred as a result of the intervention. Only three of the five studies (Ritschel et al., 2011; Chu et al., 2009; Weersing et al., 2008) provided sufficient information to receive a score of one here. Results of the SCED are presented in Table 7.

Table 7: Results of the SCED scale

Domain	Chu et al. (2009)	Ritschel et al. (2011)	Wallis et al. (2012)	Weersing et al. (2008)	Jacob et al. (2013)
Clinical history specified. Must include age, sex, aetiology and severity. <i>(N.B: not included in overall score)</i>	Yes	Yes	No	Yes	Yes
Target behaviours. Precise and repeatable measures that are operationally defined. Specify measure of target behaviour	Yes	Yes	No	Yes	Yes
Design 1: 3 phases. Study must be either A-B-A or multiple baseline	No	Yes	Yes	Yes	Yes
Design 2: Baseline (pre-treatment phase). Sufficient sampling was conducted	No	No	No	No	No
Design 3: Treatment phase. Sufficient sampling was conducted	No	Yes	Yes	Yes	Yes
Design 4: Data record. Raw data points were reported	No	Yes	Yes	Yes	Yes
Observer bias: Inter-rater reliability was established for at least one measure of target behaviour	Yes	Yes	No	No	Yes
Independence of assessors	No	Yes	No	Yes	No
Statistical analysis	No	Yes	No	No	No
Replication: either across participants, therapists or settings	Yes	Yes	Yes	Yes	Yes
Evidence for generalisation	Yes	Yes	No	Yes	No
Total	4	9	4	7	6

2.4 Narrative synthesis and meta-analysis

The effectiveness of BA is reported separately for each of the study designs within the review. Owing to the limited number of RCTs only one meta-analysis could be

conducted. However, a forest plot depicting depression outcomes on all measures employed within the 3 RCTs is provided.

2.4.1 Behavioural Activation effectiveness and depression

2.4.1.1 RCTs

Only three included studies adopted an RCT methodology (Chu et al., 2016; McCauley et al., 2015; Stark, 1985). Whilst there were variations in the treatment arms delivered (see 2.3.3.5.1), improvements in depression were reported for individuals receiving a behavioural therapy in all three studies.

Two of the RCTs measured depression outcomes using two continuous measures (Chu et al., 2016: CDRS-R, CES-D; McCauley et al., 2015: CDRS-R, SMFQ) whilst the third reported on three (Stark, 1985: CDRS-R, CDI, CDS). Given the limited number of studies and minimum outcomes a meta-analysis was not completed. However, a forest plot was produced to provide a graphical display of the study outcomes (Figure 2).

During data extraction it was noted that in the study by Chu et al. (2016) there was a baseline imbalance in depression severity scores (intervention 42.57 ($SE= 5.08$), wait-list 46.00 ($SE 3.95$)) and an obvious error in the reporting of the standard error for the depression severity scores post intervention (wait-list $SE=0$; intervention $SE=5.36$). Rather than exclude this study from the analysis, the reported estimates and standard errors from the adjusted models (including adjustments for baseline scores) were used to ensure inappropriately large differences were not attributed to the intervention.

significance of these results cannot be inferred. Finally, Stark (1985) reported reductions in mean CDRS-R depression scores for those receiving BA to be from 33.50 (*SD*: 10.27) at pre-treatment to 24.02 (*SD*: 6.01) at end of treatment and then to 24.28 (*SD*: 4.68) at follow-up. For those receiving self-control therapy mean CDRS-R scores reduced from 37.22 (*SD*: 8.36) at pre-treatment to 22.90 (*SD*: 4.36) at end of treatment and to 20.69 (*SD*: 3.45) at follow-up. Reductions in the wait-list group reduced from 27.57 (*SD*: 3.51) at pre-treatment to 27.24 (*SD*: 5.74) at end of treatment and to 22.60 (*SD*: 5.03) at follow-up. However, the results of an ANCOVA test demonstrated that the difference between groups on the CDRS-R at end of treatment was not significant ($p < .30$).

As all studies measured the effectiveness of BA on depression using the CDRS-R and were considered to be sufficiently similar, a meta-analysis was conducted. The effect of BA on CDRS-R depression scores was moderate with a pooled mean difference of -4.17 (95% CI: -8.25, -0.09) (Figure 3). This demonstrates a statistically significant difference in CDRS-R scores in favour of BA. The I^2 statistic was 0% ($p=0.926$) suggesting no statistical heterogeneity was present (Higgins et al., 2003).

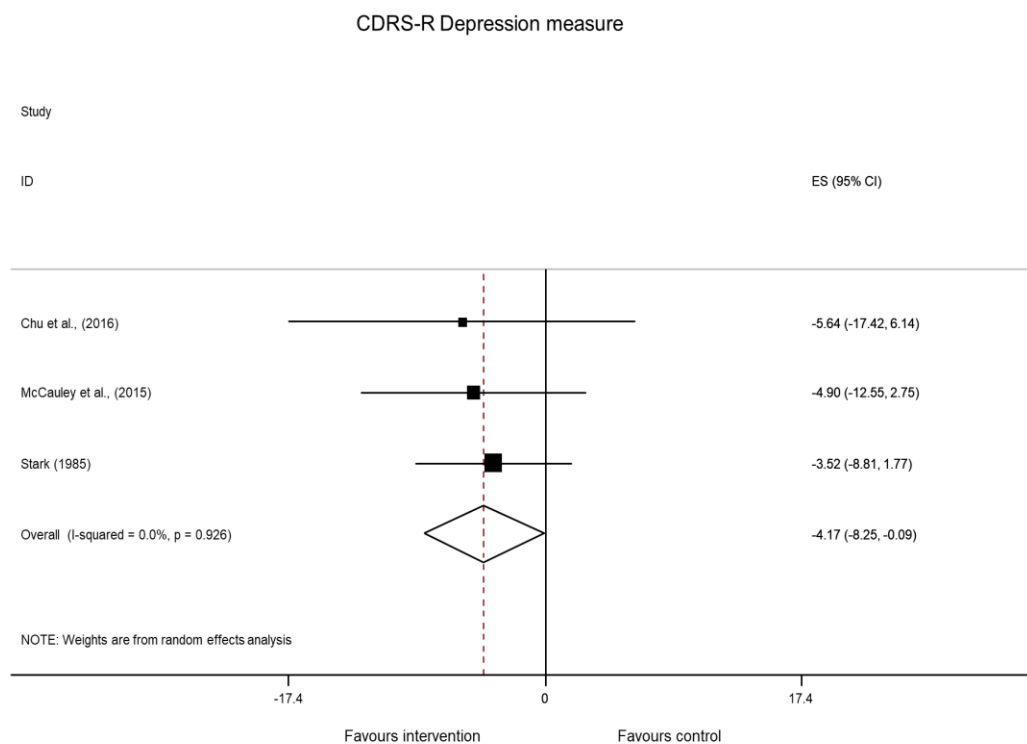


Figure 3: Random effects meta-analysis of the CDRS-R across included RCTs (n=3)

For other depression measures, in the study by Stark (1985) mean scores measured by the CDI reduced in the BA group from 22.40 (*SD*: 8.47) at pre-treatment to 9.11 (*SD*: 8.32) at end of treatment and to 7.43 (*SD*: 7.23) at follow-up. In the self-control therapy mean CDI scores reduced from 21.60 (*SD*: 5.48) at pre-treatment to 8.09 (*SD*: 6.65) at end of treatment and to 5.36 (*SD*: 5.04) at follow-up whilst scores in the wait-list group reduced from 20.00 (*SD*: 10.71) at pre-treatment to 19.45 (*SD*: 10.31) at end of treatment and then to 7.40 (*SD*: 5.68) at follow-up. The results of an ANCOVA test demonstrated that these between group differences were statistically significant ($p < .01$) at the end of treatment. Thus, those receiving treatment had a greater reduction in depression scores at this point than those in the wait-list group.

In the study by Stark (1985) mean depression scores measured by the CDS also reduced in the BA group from 71.10 (*SD*: 10.38) at pre-treatment to 55.24 (*SD*: 12.18) at end of treatment and to 50.03 (*SD*: 13.23) at follow-up. In the self-control therapy group CDS scores reduced from 72.40 (*SD*: 10.31) at pre-treatment to 50.29 (*SD*: 8.63) at end of treatment and then to 46.46 (*SD*: 8.31) at follow-up. For the wait-list group, mean CDS scores reduced from 66.00 (*SD*: 18.80) at pre-treatment to 62.61 (*SD*: 7.14) at end of treatment and then to 48.20 (*SD*: 13.29) at follow-up. These differences however fell short of conventional levels of statistical significance ($p < .07$).

On the CES-D in the study by Chu et al. (2016) rates of depression reduced in the BA group from 21.00 (*SD*: 2.15) to 16.38 (*SD*: 2.30) compared to a reduction from 20.22 (*SD*: 2.73) to 19.07 (*SD*: 3.15) in the wait-list group. However once again statistical tests were not performed due to a small sample size and lack of control.

The final continuous measure employed by McCauley et al. (2015) was the SMFQ. In the BA group mean scores reduced from 16.1 (*SD*: 6.1) at pre-treatment to 6.3 (*SD*: 7.4) at end of treatment in comparison to a reduction from 15.6 (*SD*: 6.2) at pre-treatment to 6.5 (*SD*: 6.5) at end of treatment in the TAU group. These differences in groups were however not significant ($p = .53$).

In addition to the continuous measures reported, McCauley et al. (2015) conducted the -K-SADS diagnostic interview with participants. Results demonstrated that 77% of BA participants no longer met diagnostic criteria for depression at end of treatment compared to 25% in the TAU group.

2.4.1.2 Within-participant designs

In the study by Riley and Gaynor (2014) all participants received non-directive therapy (NDT) initially and, if not demonstrating reductions in depression ratings, subsequently received behavioural therapy (BT). Following NDT 36% of participants demonstrated a clinically significant reduction on both the CDRS-R and the CDI. Of those who received BT 57% demonstrated a clinically significant change at the end of treatment.

Collectively these participants did not show a significant change in depression scores from pre-treatment to post-NDT on either the CDRS-R ($M= 59.57$ [13.29] to $M= 58.86$ [17.08]: $Z= -0.09$, $p=.93$) or the CDI ($M= 25.57$ [10.21] to $M= 24.71$ [8.48]: $Z=-0.51$, $p=.61$). There was however a significant difference on both measures from post-NDT to post-BT (CDRS-R: $M = 41.57$ [11.79]: $Z = -2.37$, $p= .02$; CDI: $M = 16.29$ [10.24]: $Z = -2.37$, $p=.02$). These results demonstrate that although participants who received BT did not show a significant change in depressive symptoms following NDT, a significant change was seen in 64% following BT.

In the study by Douleh (2013) all participants received MI initially and, if not demonstrating reductions in depression ratings, subsequently received four FA sessions. If depression was still evident following this, participants received behavioural therapy (Values-based behavioural activation: VBBA). Following MI 64% of participants demonstrated a clinically significant reduction in depression ratings and were stepped-out of treatment. For this group, mean CDRS-R scores reduced from 52.6 ($SD: 4.56$) at baseline to 27.2 ($SD: 3.90$) following MI. At the final follow-up point (20 weeks post-baseline) the mean CDRS-R score was 21.67 ($SD: 4.16$). Scores on the BDI-II also reduced in this group from 12.8 ($SD: 6.38$) at baseline to 4.40 ($SD: 5.13$) post MI and then to .67 ($SD: .58$) at follow-up.

A further 21% of participants entered the FA treatment phase and subsequently had reduced depression ratings. For this group, mean CDRS-R scores reduced from 65.33 ($SD: 11.85$) at baseline to 23 ($SD: 3.46$) post-FA and then to 21.5 ($SD: .71$) at follow-up. On the BDI-II mean depression scores reduced from 27.33 ($SD: 13.32$) at baseline to 5.33 ($SD: 2.51$) post-FA and then to .5 ($SD: .71$) at the final follow-up.

Only one participant received VBBA with the remaining 36% of the sample withdrawing from treatment. For this individual, CDRS-R depression scores reduced from 53 at

baseline to 31 post VBBA and then to 25 at follow-up. Reductions on the BDI-II were also reported, reducing from 31 at baseline to 14 post-VBBA and to 11 at follow-up.

2.4.1.3 Case studies/series

Across all included case studies/series reductions in depression scores were evident following receipt of a behavioural intervention. Jacob et al. (2013) and Wallis et al. (2012) reported reduced scores on the BDI-II for all participants from baseline to study completion with those in the latter of these two studies attaining depressive scores in the 'normal' range. Jacob et al. (2013) also reported reductions in depressive scores on the CDRS-R and the K-SADS with two of the three participants no longer meeting the criteria for a depressive disorder following treatment and the remaining individual being moderately depressed. Similarly, Ritschel et al. (2011) reported significant reductions in depressive scores on both the BDI-II and CDRS-R with 66% of participants being in the 'normal' range following treatment completion and thus similar to a non-clinical sample. In the study by Weersing et al. (2008) both included participants demonstrated a decrease in depression scores on the CDI from baseline to six months follow-up and in the study by Chu et al. (2009) significant reductions in depression scores on the CES-D were reported for two of the five participants. For one participant their depression score remained the same and for another it increased however neither of these findings were significant. The remaining participant withdrew from treatment, not completing follow-up measures.

2.4.2 Behavioural Activation effectiveness and other outcomes

Beside depression, this review also sought to examine the effectiveness of BA and anxiety symptoms, cost-effectiveness, QoL and school attendance.

2.4.2.1 RCTs

All three RCTs collected data about anxiety. Chu et al. (2016) reported greater reductions in anxiety scores for those receiving BA (29.67 (*SD*: 2.23) to 21.05 (*SD*: 2.41)) compared to those in the wait-list group (28.51 (*SD*: 3.36) to 26.93 (*SD*: 4.56)) from pre- to post-treatment measured by the SCARED. Again, owing to the study's small sample size analyses were not performed and therefore the significance of these results cannot be inferred. Using the RCMAS, Stark (1985) reported statistically

significant reductions in anxiety from pre to post testing in those receiving either BA or self-control therapy ($p < .01$) and no improvement for those in the wait-list condition. Individuals who received self-control therapy demonstrated the highest reductions in anxiety at post-testing. Whilst anxiety was measured at baseline in the study by McCauley et al. (2015) using the MASC, this measure was not repeated following treatment.

None of the included RCTs reported on the cost-effectiveness of BA nor its impact on QoL or school attendance.

2.4.2.2 Within-participant designs and case studies/series

Two of the case studies/series included anxiety measures (Chu et al., 2009; Weersing et al., 2008). Based on the SCARED, both participants in the study by Weersing et al. (2008) demonstrated reduced anxiety scores following BA. For one participant, anxiety scores reduced across all time points following treatment however, for the other, anxiety scores had increased at six months follow-up. In the study by Chu et al. (2009), two of the five included participants demonstrated reduced anxiety scores following BA measured by the MASC. For the remaining three participants, one demonstrated an increased anxiety score, for one it remained the same whilst the other withdrew from treatment not completing follow-up measures. Neither within-participant design studies assessed BA and anxiety.

Only one included study (Riley & Gaynor, 2014) examined BA and QoL. Using the FQOLS, a significant increase in QoL was found by the conclusion of BA ($M = 21.29$ [7.68]; $Z = -2.21$, $p = .03$). None of the included within-participant designs or case studies/series reported on the cost-effectiveness of BA nor its impact on school attendance.

2.4.3 Online Behavioural Activation

Although the ten included studies provided information about the effectiveness of BA for young people with depression, none delivered BA in an online format. Therefore, the second objective of this review, whether BA can be effectively delivered in an online form, could not be investigated.

2.4.4 Addendum to the results

The literature search for this review was completed in 2015 with the associated paper published in 2017 (Tindall et al., 2017). Since the review's completion additional work examining the delivery of BA for young people with depression has been reported. As presented in Chapter One (see 1.2.5), this has included several studies conducted by Pass, Reynolds and colleagues at the University of Reading, UK, and the first European feasibility RCT of BA use for adolescents with depression (Kitchen et al., 2020).

The work by the researchers at the University of Reading has included the adaptation of BATD/BATD-R (Lejuez et al. 2011; 2001) for adolescents (Pass & Reynolds, 2014) and the subsequent case studies (Pass, Hodgson et al., 2018; Pass et al., 2016; Pass, et al., 2015) and pilot and feasibility work (Pass, Sancho et al., 2018; Pass et al., 2017) to examine its acceptability. This collective research has yielded important findings within this context, providing support for both the effectiveness and acceptability of BA as a treatment for adolescents with low mood and/or depression and is therefore referenced throughout this thesis. However, as much of this work was completed and published after the review presented here, it was not included. One study (Pass et al., 2015) although available, did not meet the inclusion criteria as the participant involved scored below the clinical threshold for depression at baseline. Several studies (e.g. Pass, Hodgson et al., 2018; Pass et al., 2016) would have met the criteria for inclusion in the review had they been completed at the time. As these studies demonstrated improved depression scores from baseline to follow-up, they would have added support to BA as a treatment for depression as presented within the narrative synthesis. However, as the research conducted by the University of Reading did not adopt an RCT design, it would not have been included within the meta-analysis and so the reported results would have remained unchanged.

The study by Kitchen et al. (2020) also did not meet the eligibility criteria for inclusion in this review, being an ongoing study at the time of its completion with no outcome measures to report at that point. Owing to its RCT methodology, had its completion coincided with the time frame for the review it would have been included. As Kitchen et al. (2020) reported better outcomes for those in receipt of BA compared to those receiving TAU at both three- and six-months follow-up, the findings would have added support to those presented in this chapter, thus strengthening the support for BA as a treatment for depression in adolescents.

2.5 Discussion

2.5.1 Summary of results

This systematic review aimed to assess the effectiveness of BA in the treatment of young people with low mood and/or depression and investigate whether BA delivered in an online format is effective within this treatment context. Overall, ten studies met the inclusion criteria for the review – three RCTs, two within-participant designs and five case studies/series. Much variation existed between studies regarding their sample characteristics, settings, length and content of the behavioural interventions delivered and the outcome measures employed. Variations in the methodological quality of included studies was also evident.

The narrative synthesis demonstrated the effectiveness of BA in reducing depression in young people with all included studies reporting reductions following a behavioural intervention. These reductions were reported using multiple depression measures across studies, several of which suggested that a number of participants no longer met specific diagnostic criteria for depression following therapy. Further support was demonstrated in the meta-analysis examining the scores on the CDRS-R from pre-to-post treatment in the three included RCTs. The effect of BA on CDRS-R scores was moderate with a pooled mean difference of -4.17 (95% CI: -8.25, -0.09) which demonstrates a statistically significant difference in CDRS-R scores in favour of BA. This finding is particularly important since the CDRS-R is the most widely used measure of child and adolescent depression severity in research trials internationally (Kim et al., 2014; Plener et al., 2012) and demonstrates good internal consistency, reliability and validity (Mayes et al., 2010). Furthermore, these findings are similar to those previously reported in adult studies where BA has been found to be superior to control conditions (e.g., Mazzuchelli et al., 2009; Ekers et al., 2008).

Besides depression, several of the included studies examined the effectiveness of BA on two of the secondary outcome measures – anxiety and QoL. Four studies (Chu et al., 2016; 2009; Weersing et al., 2008; Stark, 1985) reported reductions in anxiety following BA whilst one study (Riley & Gaynor, 2014) demonstrated a significant increase in QoL by the conclusion of behavioural therapy. These findings provide preliminary evidence that BA may also be effective in reducing anxiety and increasing QoL for young people experiencing depression.

The second aim of this systematic review was to investigate whether BA delivered in an online format is effective in the treatment of young people with depression. As none of the ten included studies adopted an online format, this aim could not be addressed. In addition, none examined the impact of BA on school attendance nor investigated its cost-effectiveness.

2.5.2 Evaluation of the review methodology

2.5.2.1 Strengths of review methodology

This systematic review was based upon a comprehensive protocol which was registered on PROSPERO, an international online database for the protocols of systematic reviews within the health sciences. Through this registration, any unplanned duplicates of the review could be avoided. The protocol detailed the proposed inclusion criteria, search strategy, data sources, data extraction method and quality assessment tools. As part of its development the search strategy was checked and approved by an information specialist based within CRD at the University of York. This ensured that it contained all variations of the three constructs under review with each connected by the correct Boolean principles. The relevance checking proforma and data extraction form were developed, trialed and modified (where necessary) at this stage to ensure that correct and sufficient information would be collected throughout the review. The review's protocol was adhered to throughout and any necessary changes were registered on PROSPERO within a timely manner.

An additional strength of the review was the employment of three quality assessment tools which allowed a thorough examination of the included studies' quality to be conducted. Furthermore, and as described earlier (see 2.2.5) through employing both the Cochrane risk of bias tool and the Moncrieff scale to assess the quality of the RCTs, comparisons could be made between a general assessment measure, and one specifically designed for the subject area. The similarities generated from these tools suggested both the reliability and validity of their use within this context.

2.5.2.2 Limitations of review methodology

Despite the review's strengths and it generating important information relating to the effectiveness of BA in treating depression in young people, a number of methodological limitations require consideration when interpreting its findings.

Originally only RCTs were to be considered for inclusion yet preliminary searches identified few studies that adopted this methodology type. The initial search was therefore broadened to include studies with pre and post-test designs that reported numerical data. RCTs are the recommended study design for examining the effectiveness of health-related interventions and are often regarded as the 'gold' standard within such contexts (Bench, Day & Metcalfe, 2013; Rodgers et al., 2012; NICE, 2010). Therefore, the inclusion of other study designs was not desirable. In addition, when the PICO criteria were widened to include alternative designs, how to assess the methodological quality of the studies had to be reconsidered. Owing to this the SCED scale was added. Although this was initially designed for studies employing single participants, its use extends to case series/studies and it was successful in examining the quality of such studies in this review. However, a quality assessment tool specifically for use with the two within-participant designs could not be found and thus the Moncrieff scale had to be applied. Although this allowed the methodological quality of these studies to be examined, several domains were not relevant and so neither study could attain the maximum score on the scale.

The limited number of included RCTs also meant that only one meta-analysis could be completed. Although a pooled mean difference could be calculated, the results of which supported the effectiveness of BA for the treatment of depression, caution is required. Several discrepancies were noted in the study by Chu et al. (2016) including an imbalance in baseline scores and the standard error for depression scores in the post wait-list group on the CDRS-R being reported as 0. Although the author was contacted, no response was received. These discrepancies and the subsequent adjustment made may have affected the accuracy of the meta-analysis results which would not have been a completely true representation of the study findings. In addition, through the inclusion of only three studies in the meta-analysis, explorations of publication bias could not be conducted.

2.5.3 Quality of the evidence

2.5.3.1 Strengths of included studies

Although initially only RCTs were to be included, widening the review to include other study designs allowed comparisons to be made between the varied methodologies employed and the results obtained. This also meant that there were differences across study characteristics including the participants recruited, the study settings, the behavioural intervention used, and, relative to the included RCTs, the comparators examined. As a result, the effectiveness of BA could be examined in depth, with observations made regarding its application with individuals aged 8 to 18 years and within varied settings (primary care, secondary care and schools). A variety of outcome measures were also adopted, which resulted in a substantial amount of data between the studies, both quantitative and qualitative being presented. Despite this variation, 70% of included studies measured depression levels using the CDRS-R, allowing comparisons in findings to be made.

All three included RCTs (Chu et al., 2016; McCauley et al., 2015; Stark, 1985) demonstrated low risk of bias on several areas assessed using the Cochrane risk of bias tool and all attained maximum quality scores on several Moncrieff scale domains. The areas deemed to have high methodological quality included the allocation methods used, providing clear descriptions of treatments, using clear diagnostic criteria, the recording of exclusion criteria, clearly describing outcome measures, conducting ITT analyses, presenting results with the inclusion of data for the re-analysis of main outcomes and providing clear justifications for any conclusions made. Whilst the within-participant design scores were substantially lower on the Moncrieff scale than the RCTs, this was unsurprising since several domains were not applicable to their design. Despite this, high methodological quality was presumed for several of the domains including specifying objectives *a priori*, providing clear descriptions of treatments, using clear diagnostic criteria and clearly describing outcome measures. Furthermore, three of the case studies/series (Jacob et al., 2013; Ritschel et al., 2011; Weersing et al., 2008) attained over half of the total points on the SCED scale.

2.5.3.2 Limitations of included studies

Although the methodological quality of included studies was good overall, all had methodological flaws which may have affected the results presented.

In two of the three RCTS (Chu et al., 2016; Stark 1985) it was unclear whether allocation concealment had occurred. This may have led to the inclusion of observer bias and may have particularly affected the study by Chu et al. (2016) given the imbalance of depression severity scores observed at baseline. In addition, neither of these studies reported power calculations which questions whether their sample sizes were sufficient enough to detect a difference between groups. Despite receiving the highest score on both the Cochrane risk of bias tool (alongside Chu et al., 2016) and the Moncrieff scale, the study by McCauley et al. (2015) also had several methodological flaws. Here, aims were not specified *a priori*, compliance was only partially reported and, although assessor blinding was conducted, no information about the method employed was supplied. In addition, with no information presented about participant sampling, the sample representativeness was unclear. None of the included RCTs received maximum scores on the Moncrieff scale for assessments of compliance or the statistical analyses they employed. Similar methodological flaws, including failing to conduct power calculations, not reporting on side-effects and not blinding assessors were also evident in the two within-participant design studies.

When examining the methodological quality of the case studies/series using the SCED all five studies attained a score of zero for baseline data collection. Although baseline depression assessments had been undertaken all were conducted at a single time point. Therefore, no information was collected, nor subsequently presented, about the stability or variability of an individual's depression before receiving the intervention. Other methodological constraints regarding data collection included providing insufficient participant demographic information (Wallis et al., 2012), failing to adequately define the target behaviour under investigation (Wallis et al., 2012), providing insufficient data from during the treatment phase (Chu et al., 2009) and not providing raw scores (Chu et al., 2009). Three of the studies (Jacob et al., 2013; Wallis et al., 2012; Chu et al., 2009) also failed to employ independent assessors which may have biased the reported results. These studies, alongside that of Weersing et al. (2008) also attained zero for their statistical analyses which were either insufficient or had not been undertaken at all. Finally, two of the five case studies/series (Jacob et al., 2013; Wallis et al., 2012) only supplied information about one target behaviour which questioned the generalisability of the reported findings.

Besides the methodological limitations identified, other factors may have affected the review results. The sample sizes of the included studies were low with the maximum recruited in any study being 60 (McCauley et al., 2015). This was the only study to

employ power calculations, therefore it is unclear whether the remaining RCTs or within-participant design studies recruited sufficient participant numbers to suggest an intervention effect. For two studies a transdiagnostic approach was taken (Chu et al., 2009; Weersing et al., 2008) with the behavioural interventions employed developed to treat both depression and anxiety. Although comorbidity between anxiety and depression is common, and thus anxiety was included as a secondary outcome measure, the primary focus was on the effectiveness of BA for treating depression. Therefore, distinguishing what specific elements of BA were effective for treating depression from those treating anxiety was difficult as the two were reported collectively within these studies. Finally, several studies did not complete statistical analyses meaning that findings could only be inferred.

2.5.4 Interpretation of the results

Both the narrative synthesis and meta-analysis add support to the effectiveness of BA in treating young people with depression. However, the meta-analysis results need to be considered with caution owing to the inclusion of only three studies and the discrepancies and subsequent adjustments made regarding the study by Chu et al. (2016). As only one meta-analysis was conducted, a forest plot is presented. Although this provides a graphical representation of all depression scores obtained across the three RCTs, pooled mean differences could not be calculated given the nature of the analysis. Furthermore, the limited number of studies meant that explorations into any heterogeneity found could not be conducted.

Although the I^2 statistic suggested no statistical heterogeneity was present across the three RCTs, clinical heterogeneity was observed across the trials particularly regarding their settings and participant samples. Whilst the trials by Chu et al. (2015) and Stark (1985) were conducted within school-based settings, that by McCauley et al. (2016) took place in secondary care. Furthermore, eligibility to enter the trial by Stark (1985) was determined using a depression screening tool (the CDI), whilst eligibility for entry into the remaining studies were assessed using a diagnostic interview (CDRS-R or ADIS-IV; Chu et al., 2016) or a combination of both screening and diagnostic measures (CDRS-R, SMFQ; McCauley et al., 2015). Although a random effects meta-analysis was conducted through acknowledging the presence of heterogeneity, caution in the interpretation of the findings is needed.

A review of the methodological quality of the included RCTs demonstrated that two studies (Chu et al., 2016; Stark, 1985) did not report on allocation concealment. Research suggests that omitting to use allocation concealment may inflate effect sizes in favour of positive results (Wood et al., 2008; Schulz & Grimes, 2002). This may have affected the results produced in the meta-analysis. Furthermore, the same two studies failed to conduct power calculations for their included samples which may have resulted in them over or under-estimating the treatment effects they present.

Given the factors described above, the primary focus, when examining the findings of this review, should be placed upon the narrative synthesis.

2.5.5 Recommendations for future research

Despite BA being a NICE recommended treatment for adults with depression, the paucity of research examining its use for young people has been demonstrated. Three RCTs were initially identified with only seven further studies being included when the PICO criteria were expanded. In addition, the studies that were included exhibited several common methodological flaws. More research is therefore required within this context which should also seek to improve methodological standards and address the limitations of the studies within this review. In particular, future studies should maintain allocation concealment, conduct power calculations to determine adequate sample sizes, complete and report on sufficient statistical analyses and collect baseline data at multiple time-points.

This review specifically looked at the effectiveness of BA on the treatment of depression in young people with additional analyses specified *a priori* including anxiety, QoL, school attendance and cost-effectiveness. Although limited information was supplied about anxiety and QoL and nothing was reported relating to school attendance, multiple other measures (including symptom severity, self-esteem and hopelessness) were reported across the included studies but not discussed within this review. Outcome measures such as these, could be addressed in future research to further explore BA use with young people. Further information is also required about the impact of BA on school attendance and whether it is a cost-effective intervention.

Most studies within this review examined BA use with an adolescent sample (i.e. those aged 11 to 17) with only two studies incorporating a child sample (Riley & Gaynor, 2014 – 8 to 12 years; Stark, 1985 – 9 to 12 years). Whilst this strengthens the

rationale for placing focus upon an adolescent population for this thesis it also highlights the limited amount of research examining BA for children thus suggesting an additional area for future research.

Finally, the review also aimed to investigate whether BA delivered in an online format is effective for young people with low mood and/or depression. As discussed in Chapter One (see 1.3.1) much research suggests that young people experiencing depression may be treated more effectively using computer-administered therapies. However, none of the included studies incorporated BA delivered in an online format, highlighting the need for future research to address this.

2.5.6 Conclusions

This review was conducted to examine the effectiveness of BA for the treatment of young people with depression, with ten studies meeting the inclusion criteria. These studies provided initial evidence that BA may be effective within this context although more research is required. Particular focus needs to be placed on issues surrounding the cost-effectiveness of BA, its impact on QoL and whether it can be successfully delivered in an online format to young people. Several methodological constraints relating to included studies mean that the results need to be interpreted with caution with such constraints addressed in any future research.

2.6 Chapter summary and next steps

This chapter has reported the findings from a systematic review and meta-analysis conducted to examine the effectiveness of BA for treating depression in young people. This has provided useful information as part of the assessment of background knowledge and evidence aligning to phase one of co-design as described by Eyles et al. (2016). The next chapter presents the findings from a qualitative study which explored the views and preferences of adolescents and healthcare professionals about the development of a new online BA therapy for adolescents with low mood and/or depression.

Chapter Three: Perceptions and opinions on an online Behavioural Activation programme for the treatment of depression in adolescents: A qualitative approach

This chapter presents the findings from qualitative work exploring the perceptions and opinions of adolescents and healthcare professionals about the development of a new online BA therapy. The chapter opens with the rationale for conducting qualitative work in this context with the findings of a series of focus groups and individual interviews reported. Aligning to phases two and three of co-design (Eyles et al., 2016) this chapter provides important information to inform the development of a new online therapy from a target user and healthcare professional perspective.

3.1 Introduction

3.1.1 Background and rationale

The systematic review and meta-analysis (Chapter Two, Tindall et al., 2017) added support to the contention that BA may be an effective treatment for young people, particularly adolescents, with depression. Whilst the reported studies highlighted some of the BA components that are useful in treating young people with depression, none delivered BA in an online format. Given the benefits of online therapy deliveries (Chapter One), an online version of BA may provide an alternative treatment option in a format that ameliorates several barriers faced by young people when accessing support. A fundamental part of developing new treatments is ensuring they meet the needs of those for whom they are designed with qualitative research within this context required.

Including young people in the development of young-person focused therapy is important to ensure that the developmental needs of users are considered and used to enhance treatment effectiveness (Saunter, Heyne & Westenberg, 2009). However, many depression and anxiety treatments for young people are simply downward extensions of adult therapies or upward extensions of treatments for children with a 'one-size-fits-all' approach often reflected in their design and delivery (Holmbeck et al., 2006; Hudson et al., 2002; Weisz & Hawley, 2002). Whilst young people should be the best sources of information relating to themselves, their needs and capacities are not

always considered with this information frequently collected from adults including parents and paediatric healthcare professionals (Irwin & Johnson, 2005). Omitting to collect information first-hand may result in the misinterpretation of young peoples' needs and/or a focus on the needs of adult representatives instead (Fox & Berrick, 2007).

Where research has incorporated young peoples' views, disparities have been evident between their perceptions and those of healthcare professionals. When examining the experiences of care systems, Fox and Berrick (2007) reported that the key points highlighted by young people contrasted with the priorities of care providers. Furthermore, according to Forsner, Jansson and Sørli (2005), who examined the illness experiences with seven children who had been hospitalised, illnesses were found to have different meanings for young people compared to professional caregivers. Whilst young people had subjective and personal knowledge of illnesses derived from their own experiences, healthcare professionals based their knowledge on easily measured objective symptoms. There is therefore a need to include the perspectives of both healthcare professionals and young people in the development of an online BA programme. In particular to identify the problems that need to be addressed. According to Thabrew et al. (2018) as part of the co-design approach, like adopted during this research, this can be achieved by seeking to understand the lived experiences of users.

3.1.2 Study aims

This qualitative work explored the views and preferences of adolescents and healthcare professionals about what they perceived to be the important components of an online BA programme for adolescents experiencing low mood and/or depression.

3.1.2.1 Primary objective/question

The primary objective was to explore adolescent and healthcare professional views on the content of an online BA programme for adolescents with depression.

3.1.2.2 Secondary objectives/questions

The research also examined views regarding:

- The programme's presentation (e.g. level of interactivity, colourfulness, etc.)
- The programme's delivery (i.e. setting, session number/ length, most appropriate client groups)
- What additional support may be required alongside programme delivery
- The programme's most suitable position within the care pathway
- Parental involvement, if any, required

3.2 Methodology

3.2.1 Study design

This research adopted an exploratory qualitative design incorporating both an inductive and deductive analysis and closely followed a pre-written and ethically approved protocol (Appendix B).

Two focus groups, one with adolescents from a community sample and one with healthcare professionals with experience of working with young people with low mood and/or depression, were conducted. In addition, semi-structured interviews were completed with adolescents experiencing depression and currently accessing CAMHS.

3.2.1.1 Focus Groups

A focus group is a 'carefully planned discussion designed to obtain perceptions on a defined area of interest in a permissive, non-threatening way' (Krueger, 1994, p.46). Through employing focus groups an insight into the experiences, observations and opinions of participants about an online BA programme could be gained (Massey, 2011). Furthermore, these insights could be obtained from participants on an individual basis as well as part of a wider group (Massey, 2011).

3.2.1.2 Individual interviews

To maintain confidentiality, adolescents with current experiences of depression and accessing support were recruited via their CAMHS clinicians and invited to attend individual interviews. It was important to gain the views of individuals who have

accessed services although attendance to a focus group would inevitably lead to the disclosure of a depression diagnosis.

3.2.2 A qualitative approach

Through employing a qualitative methodology, a deeper understanding of a particular social phenomena can be obtained from the perspective of those experiencing it (Vaismoradi, Turunen, & Bondas, 2013; Silverman, 2000). Owing to this and acknowledging the importance of incorporating the needs of target users into intervention design, a qualitative methodology was deemed essential to inform the development of the new online BA therapy. The interpretivist paradigm, applied in the present work, incorporates numerous philosophical perspectives (McEvoy & Richards, 2006). One perspective is critical realism which aims to develop deeper levels of explanation and understanding (McEvoy & Richards, 2006). According to Braun and Clarke (2006) critical realists acknowledge not only how individuals make meaning of their experiences but also how social contexts can impinge on those meanings. Therefore, a critical realist approach was employed.

3.2.3 Participants, sampling and recruitment

Three participant groups were employed – adolescents from a community sample, adolescents from a service-user sample and healthcare professionals with experience of working with young people with low mood and/or depression. Participants were recruited from four NHS Trusts or localities within each and identified through a combination of purposive and snowball sampling approaches. Initially purposeful sampling was adopted to ensure that those best placed to discuss the programme development and able to provide rich information with individual meaning were recruited. Furthermore, it was hoped that through purposeful sampling, a variety of individual characteristics would be represented such as varied ages and genders for all participants, different depression severities and comorbidities (if applicable) for adolescent participants and a variety of experiences and roles within the area of interest for healthcare professionals. However, due to recruitment challenges, a snowball sampling approach was adopted where necessary as well as adaptations made to the techniques employed in recruiting to both adolescent samples. Ethical approval was obtained for all amendments made.

Group 1: Adolescents: Community sample

Since research suggests that 65% of young people experiencing a depressive disorder do not seek help (Gladstone et al., 2015), a community sample of adolescents was invited to a focus group. Initially, school wellbeing workers were asked to identify individuals who they believed might be interested in participating and supply them with study information. Those interested, were asked to inform their school wellbeing worker who would notify the researcher. The researcher would then arrange to meet the individual and their parent/guardian within school, answer any questions, and obtain consent accordingly. No individuals were identified via this method and so recruitment was extended using a snowball approach. One of the healthcare professional participants put the researcher in contact with a local school within their NHS Trust remit. Here a group of adolescents was identified to attend a focus group using a purposive sampling approach which stratified them by age and gender to ensure the representativeness of the sample.

Group two: Adolescents: Service-user sample

A sample of adolescents receiving CAMHS support for low mood and/or depression were recruited to attend face-to-face, semi-structured interviews with the researcher. Recruiting from both a community and a healthcare sample allowed maximum variation in the views collected. It was important to ensure that the individuals participating were similar to those who the eventual programme was designed for. Therefore, males and females aged between 11 and 16 were recruited. Initially, healthcare professionals working within one CAMH service were asked to refer anyone who they believed would be interested in participating. As with the community sample recruitment approach using school wellbeing workers, healthcare professionals were asked to distribute study information to individuals and their parent/guardian and inform the lead researcher of anyone who expressed interest. The lead researcher would then arrange to visit the individual and their parent/guardian within CAMHS, answer any questions, and obtain consent accordingly. Again, no participants were identified this way and so several different approaches were adopted to enhance recruitment. Firstly, a consultant child and adolescent psychiatrist, based within a local CAMHS inpatient unit in another NHS Trust was identified from the professional contacts of the lead researcher and asked to support recruitment. They identified several individuals to participate and provided them with study information. The researcher arranged to meet interested and eligible individuals at the inpatient unit and conducted interviews with

them. Furthermore, another NHS Trust was added as a site where the same approach was taken with individuals recruited from a CAMHS outpatient clinic.

To further supplement recruitment, the school wellbeing workers were re-approached and asked to identify individuals to participate in a face-to-face interview using the same approach they had adopted when trying to recruit to the community sample.

Group 3: Healthcare professionals

A sample of healthcare professionals with experience of working with young people with low mood and/or depression were invited to a focus group. These professionals were recruited through CAMHS within two of the included NHS Trusts and the professional networks of the lead researcher. Any professionals meeting the inclusion criterion were invited to attend to obtain a varied sample. Due to the limited availability of healthcare professionals, anyone unable to attend a focus group was invited to an individual, face-to-face, semi-structured interview if more convenient.

A standardised email (Appendix B) was sent to healthcare professionals outlining the study aims and inviting them to a focus group (or interview where applicable). The researcher arranged to meet any healthcare professional who expressed interest, answered any questions and obtained consent accordingly. Unlike the adolescent recruitment, this method was successful and resulted in the identification and participation of sufficient healthcare professionals. However, had an insufficient number expressed interest, a snowballing sampling approach would have been employed.

3.2.3.3 Exclusion Criteria

Non-English-speaking participants were excluded. Due to the small scope of the study, with limited resources, providing translated versions of study questionnaires and interview schedules was not feasible.

3.2.4 Sample size

As between five and ten individuals are recommended for a focus group to allow sufficient demographic variability (Krueger & Casey, 2015), the study aimed to recruit

ten individuals to each group. The study also aimed to interview up to ten adolescents who were accessing support for low mood and/or depression. According to Saunders et al. (2018) data saturation is the point at which further data collection and analysis is deemed unnecessary. It was decided that interviews would cease before ten if data saturation was attained beforehand. It was hoped that this number of participants, representing varied ages, genders, depression severity (where applicable) and professional experience (where applicable) would provide a rich sample of participants.

3.2.5 Consent process

All individuals who expressed interest were given an information leaflet to read with at least 24 hours allowed to elapse before consent was sought. The information leaflets outlined the research aims, explained what participation entailed and provided information about the withdrawal process and data storage arrangements. Furthermore, all prospective participants were informed that the focus groups and interviews would be digitally audio-recorded and transcribed with participant codes used during transcription to maintain confidentiality. As all adolescent participants were aged ≤ 16 years, they needed to provide assent alongside consent from a parent/guardian. If a parent/guardian consented but their son/daughter did not, they were not recruited and vice versa.

Three different versions of the information leaflet and consent form (Appendix B) were distributed; one for healthcare professionals, one for adolescents, and one for the parent/guardian of any prospective participants.

The information leaflets for adolescents and their parent/guardian contained information about both focus groups and interviews with sections outlining what each would entail. Demarcation was deemed to be somewhat stigmatising for those recruited through CAMHS and experiencing low mood and/or depression. Therefore, regardless of recruitment strategy, all adolescent participants received the same study documentation. When approached about participation the recruiting individual informed individuals of what participation would involve (interview or focus group) based on their experiences of accessing support.

All study documentation for adolescent participants was written in a language that was deemed age-appropriate and was reviewed by a patient and public involvement group (PPI), comprising young people, who clarified this.

3.2.6 Procedure

All focus groups and interviews were conducted within the schools and CAMH sites where recruitment had occurred and were arranged at times convenient to participants. All were conducted by the lead researcher who had undergone qualitative training for this study.

Prior to all interviews and focus groups, attendees completed a short questionnaire providing basic demographic information (age, sex, ethnicity, etc.) alongside information about their experiences of depression (if any). Healthcare professionals provided information about their education level, profession, years in practice, employment setting, age range, the number of young people they were seeing with depression per month and perceived computer proficiency (Appendix B). Each questionnaire was given an identifier code as to maintain participant confidentiality.

All interviews and focus groups were audio-recorded digitally (with permission) and transcribed verbatim by the lead researcher.

All interviews and focus groups closely followed one of two interview schedules, (one used with adolescent participants and one with healthcare professionals (Appendix B) to ensure consistency. Interview schedules, developed by the lead researcher, wider study team and a qualitative expert (PT), comprised semi-structured, open-ended questions and were based upon broader topic guides. Through asking open-ended questions using a semi-structured approach it was hoped that participants would be encouraged to provide detailed views and opinions about the programme development. Although the topic guides (Appendix B) were not piloted before the research, they were examined by the PPI group who confirmed they were suitable for use within this context. During all interviews and focus groups participants were asked about issues regarding the content and presentation to be included in a new BA programme. Adolescent participants were also asked about their opinions of parental input whilst healthcare professionals were asked about the programme's positioning in the care pathway.

3.2.6.1 Interview and focus group activities

During focus groups and interviews, participants completed two bespoke activities (Appendix B) specifically developed for the research. Activity one, completed by all, involved participants indicating what they thought should be included in the new programme from a list of options. This list was based upon the BA components identified by Kanter et al. (2010) and the systematic review findings (Chapter Two) but was presented in a way to enhance understanding. Therefore, whilst some activity components were simply presented using the terminology akin to Kanter's intervention categories (e.g. 'activity scheduling'), other, more ambiguous terms (e.g. 'skills training'), were broken down into more specific components (e.g. 'problem-solving' and 'communication'). The second activity, completed by adolescent participants only, was used as an additional tool to collect delivery-specific information. Here, individuals ranked ten factors that they felt would make the programme more attractive to young people (e.g. interactivity, colourfulness, etc.) in order of importance. In both activities, individuals were encouraged to suggest additional activities or components for inclusion in the new programme. The activities were included to make participation more enjoyable and allow individuals to provide information in varied ways.

Collecting information through interviews, focus groups, demographic questionnaires and activities allowed methodological triangulation (Denzin, 2009).

3.2.7 Data analysis

Data were analysed using thematic analysis which was selected to allow rich and detailed insights about a given topic (Braun & Clarke, 2006). The analysis was both inductive and deductive with the themes/subthemes generated from both the raw data provided by participants and from theory and previous research (Fereday & Muir-Cochrane, 2006). Thematic analysis comprises six phases (Braun & Clarke, 2006):

- 1. Familiarisation with the data** (i.e. Transcription, reading and rereading, noting initial ideas)
- 2. Generating initial codes** (i.e. Coding points of interest, collating relevant data)
- 3. Searching for themes** (i.e. Collating codes into themes, collating data relevant to each theme)

4. **Reviewing themes** (i.e. Checking the themes work regarding both the coded extracts and the entire data set, generating a thematic “map” of the analysis)
5. **Defining and naming themes** (i.e. Refinement of specifics of each theme, generating clear definitions and theme names)
6. **Producing the report** (i.e. Selecting extract examples, final analysis of selected extracts, reporting of the analysis)

Through closely following these six phases, themes were identified from what participants perceived to be the important components of an online BA programme for use with adolescents experiencing low mood and/or depression. According to Braun and Clarke ‘a theme captures something important about the data in relation to the research question and represents some level of patterned response or meaning within the data set’ (2006; p. 10). Therefore, the themes identified were formulated from information discussed within the interviews and focus groups that was deemed important to the overall research question. (See Appendix B for tables depicting how emergent themes became final themes).

A second individual from the research team, an expert in qualitative research (PT), examined all codes from a selection of the interview and focus group transcripts to ensure both the credibility and reliability of the analysis.

All analyses were completed by hand using Microsoft Word; no specific qualitative software packages were employed.

3.2.7.1 Reflexivity

Although a PhD student during the completion of this qualitative study, the lead researcher has a background in conducting research with young people, including those with experience of low mood and/or depression. Consideration for this was given during both the collection and analysis of data through incorporating methodological triangulation and employing a second researcher to examine the codes from a selection of transcripts. These methods aimed to minimise the impact that any experiences of the lead researcher in the field of child and adolescent mental health may have had on the final conclusions drawn.

3.2.8 Ethical considerations

Following ethical approval from the Health Sciences Research Governance Committee (HSRGC) at the University of York, this research was granted ethical approval by the East Midlands - Leicester South Research Ethics Committee (REC) and the Health Research Authority (HRA) in November 2016 (Reference: 16/EM/0420) (see Appendix B for HSRGC and REC approval letters). Over the course of the study six non-substantial amendments were made and approved between April 2017 and March 2019. These amendments related to expanding the recruitment of the wellbeing workers to include service-users also, the addition of three additional NHS Trusts as recruitment sites and the extension of the study end date from 30.04.2017 to 30.06.2019.

3.2.8.1 Data storage and quality assurance

All transcripts, notes and audio-files were allocated a code for each participant to safeguard confidentiality. Study data and any personal data collected were stored securely in separate locations. Electronic data were password protected and stored on secure servers at the University of York with access only available to members of the research team. Immediately following transcription all audio-files were erased. At the end of the research the interview transcripts were archived for ten years as required by the study sponsor (University of York). The University of York's data protection policy was adhered to at all times with all personal data collected treated in accordance with General Data Protection Regulations (GDPR) and the Data Protection Act (2018).

3.2.8.2 Confidentiality

Confidentiality was maintained for all participants. Full information about the purpose and uses of participants' contributions were outlined in the participant information leaflet and clarified at the beginning of all interviews and focus groups. All participant information collected was kept confidentially as described above (see 3.2.8.1). Participants could withdraw at any time without having to give a reason, however any information provided up until the point of withdrawal was retained as agreed during the consent process.

3.2.8.3 Risks and burdens to participants

The interviews and focus groups aimed to elicit information about what individuals believed should be included in an online BA programme and did not ask participants any personal or sensitive questions. Therefore, it was not anticipated that participation would cause distress or result in any adverse events. However, it was possible that some participants may have chosen to discuss issues relating to their own experiences (if any) of low mood and/or depression which may have been upsetting. Individuals trained to deal with distressed young people were available immediately to provide support in such circumstances. These included school wellbeing workers (if participation occurred in schools) and CAMHS clinicians (if participation occurred within CAMHS). In addition, one of the academic supervisors involved in this research (BW) is highly experienced in dealing with distressed young people and was well placed to provide support or refer to other support services, as necessary.

Adolescent participants could have a parent/guardian present with them when attending either an interview or focus group if they wished. However, parents/guardians were informed that, in these instances, the confidentiality of discussions as well as other attendees' identities (if applicable) needed to be maintained.

Although there were no direct benefits of participation, the research provided participants with the opportunity to give their opinions and inform the development of an online BA programme.

3.3 Results

Following the presentation of demographic information, for ease of reporting, the findings are presented in three sections; 1) results from the adolescent community sample focus group, 2) results from adolescent service-user interviews and 3) the information obtained from the healthcare professionals.

3.3.1 Demographics

Overall, twenty-seven individuals comprising adolescents from a community sample, adolescents from a service-user sample and healthcare professionals attended

interviews and focus groups with the lead researcher. Participant demographic information is presented in Table 8.

3.3.1.1 Adolescent participant demographics

Community sample

Nine adolescents from a secondary school in a northern city in England attended a focus group. The sample comprised five males and four females aged between 13 and 15 years ($M= 13.8$, $SD= .83$). Eight described themselves as 'white', and one as 'Black-African'. Two participants had experienced low mood and/or depression for which both had received support - one had seen a social worker whilst the other did not disclose information about this.

Service-user sample

Nine adolescents from two CAMH services who had experienced low mood and/or depression attended face-to-face interviews. The sample comprised eight females and one male aged between 13 and 16 years ($M= 15.2$, $SD=1.09$). All described themselves as 'white' and had received support for their low mood and/or depression from CAMHS. Four had attended group CBT, one was taking antidepressant medication and the remaining four did not provide information as to the support they had received.

3.3.1.2 Healthcare professional demographics

Nine healthcare professionals were recruited from two NHS Trusts, with eight attending a focus group and one a face-to-face interview. The sample comprised seven females and two males with two aged between 18 and 30, two between 31 and 50 and the remainder aged 51 to 70. All identified themselves as 'white' and had varied educational backgrounds ranging from completion of secondary education to the attainment of a doctorate degree. Four participants were nurses, two were clinical psychologists (one a trainee), and the remainder an art therapist, a student mental health worker and a support worker. Three participants had between zero and five years of experience, one between 11 and 15 years and the remaining five had all been in practice for over 20 years. When asked about their proficiency with computers, two described themselves as fair, four as good and the remaining three as very good.

Table 8: Participant characteristics

	Adolescents: Community Sample	Adolescents: Service- Use Sample	Healthcare Professional Sample
Participants (n)	n=9	n=9	n=9
Gender n (%)			
Male	5 (55)	1 (11)	2 (22)
Female	4 (45)	8 (89)	7 (78)
Ethnicity n (%)			
White-British	8 (88)	9 (100)	8 (88)
White-Irish	-	-	1 (11)
Black-African	1 (11)	-	-
Adolescent participants only			
Age (mean (SD), range)	13.8 (.83), 13-15	15.2 (1.09), 13-16	-
Experience of Low mood/ Depression n (%)			
Yes	2 (22)	9 (100)	-
No	7 (78)	-	-
Healthcare professional participants only			
Age group (years), n (%)	-	-	
18 to 30			2 (22)
31 to 50			2 (22)
51 to 70			5 (56)
Highest Education level, n (%)	-	-	
Secondary education			1 (11)
Trade/technical/vocational			1 (11)
Professional degree			1 (11)
Batchelor's degree			1 (11)
Master's degree			3 (34)
Doctorate			2 (22)
Job role, n (%)	-	-	
Nurse			4 (45)
Clinical Psychologist			2 (22)
Student Mental Health Worker			1 (11)
Support Worker			1 (11)
Art Therapist			1 (11)
Practice years, n (%)	-	-	
0-5			3 (33)
11-15			1 (11)
20+			5 (56)
Computer proficiency, n (%)	-	-	
Fair			2 (22)
Good			4 (45)
Very good			3 (33)

3.3.2 Adolescent participants' perceptions

3.3.2.1 The community sample

Three main themes were identified: supporting autonomy, addressing treatment concerns and adolescent appropriate treatment. Several subthemes were identified as belonging to each main theme. Figure 4 illustrates the themes and subthemes derived from the community sample focus group.

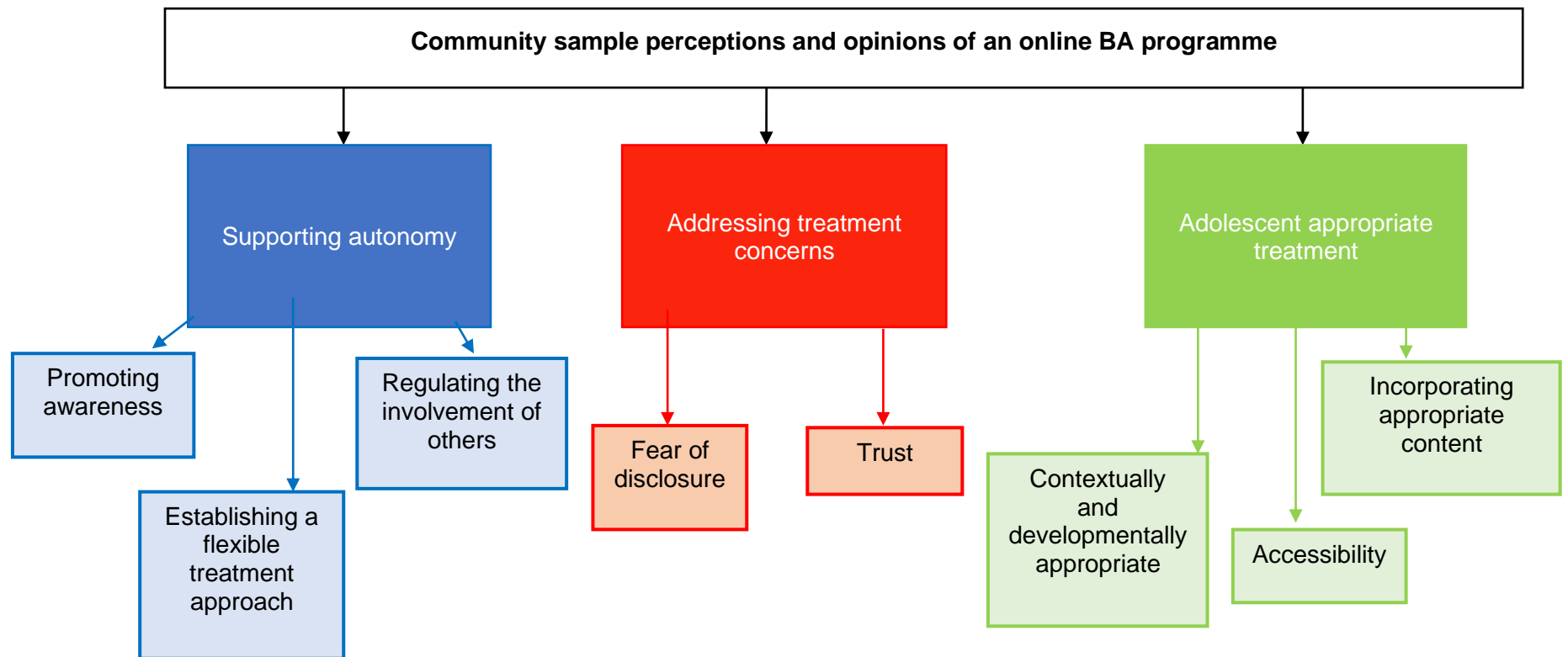


Figure 4: Community sample perceptions and opinions of the new programme – themes and subthemes from a thematic analysis

Theme 1: Supporting autonomy

The community sample wanted opportunities for autonomy regarding treatment provision. Three subthemes were identified as belonging to this theme – promoting awareness, establishing a flexible treatment approach and regulating the involvement of others.

Promoting awareness

Only two in the community sample had experience of accessing support – one for help with bullying and another for dealing with their parents' divorce. In general, many did not feel they could get any help, if required, and did not know who to speak to about receiving any:

“I think that’s why a lot of kids nowadays are feeling more pressured into committing suicide and things like that because it’s like ‘oh I can’t get any help’ because they don’t know what to do” [CP02, Male, 13 years old]

One individual assumed that if they were feeling low, their parents would seek help on their behalf:

“I thought it was like if you’re feeling depressed your parents would know about it and set you up with a therapist and stuff like that” [CP06, male, 14 years old]

None of the participants had accessed any online support, with most unaware of its availability thus highlighting the need for increased awareness of its existence and information about how to access it:

“I didn’t even know that you can go online, I just thought it was always face-to-face” [CP08, male, 15 years old]

Establishing a flexible treatment approach

Individuals wanted opportunities for autonomy if using the new programme and described how an element of flexibility was required to enable them to make decisions. A common discussion related to them being able to choose what content to view based on whether they deemed it necessary. Examples included deciding whether to disclose information about experiences of low mood and/or depression, selecting which

activities to participate in and deciding whether to complete additional follow-up sessions if available. They also wanted to be able to both save and delete content thus having the programme retain information if they were unable to complete a session in one sitting yet also have the ability to delete anything entered in error.

The participants felt that users should be able to choose how long they spent on sessions and how frequently they logged on instead of this being prescriptive. They felt that this approach would enable users to complete sessions at times most convenient and when they most needed support. They also wanted control over how long they used the programme with one individual suggesting that different options could be available to users based on whether they found it helpful:

“Maybe at the start you could choose for like one session and then go back and think ‘this is actually helping, I’d like to extend this to like a week or a month’”.

[CP02, male, 13 years old]

It was however stated that, if flexibility with session length was not possible, around 30 minutes per session was reasonable.

Other areas where individuals wanted an element of control were including an audio option so programme content could be read aloud, and the programme providing the contact details of healthcare professionals who they could contact if they felt it necessary.

Regulating the involvement of others

At various points, the participants discussed the position of themselves relative to their own care. They wanted to be independent in issues relating to accessing treatment and able to make decisions:

“If it was me, I’d just want them to talk to me instead of going through parents and that” **[CP09, female, 13 years old]**

The main area of concern related to the role that their parents would have if they wanted to access support, with many highlighting that they would not want them to be involved if they were using an online therapy for help with low mood and/or depression:

“I think parents should just stay out of it” [CP02, male, 13 years old]

One individual suggested that some young people may access online therapy through not being able to talk to their parents:

“There’s a reason why they wouldn’t talk to their parents if they are going on this website” [CP01, male, 13 years old]

Several reported how parental involvement could be detrimental to improving their mood with particular concerns that parents would not understand young-person specific issues:

“I’m not being disrespectful to them, but they’ll think they know everything about kids and stuff, but they really like, they don’t” [CP01, male, 13 years old]

Despite wanting to be responsible for their own care the participants acknowledged that others may have to be informed if they were experiencing low mood and/or depression to provide support. One individual suggested having a nominated friend involved in the new programme instead of a parent with several others preferring this idea:

“I’d rather be talked to by my mate than by my parents” [CP05, female, 14 years old]

Despite friends being the preferred choice for involvement, there were concerns that friends may worry too much, may not take things seriously or could be patronising. Furthermore, it was felt that disclosing information to a friend may be hard and may put too much pressure on that friend.

Interestingly, although the participants expressed their concerns at having other people, even their friends, involved in their care, they did identify some ways in which this involvement may work, for example with reporting risk. Although they wanted to be responsible for their own care, they did feel that parents should be informed if an individual’s low mood was deemed ‘serious’ (e.g. they reported suicidal thoughts).

*“Parents should only be involved if it’s serious and you’re talking about suicide”
[CP03, female, 13 years old]*

Consequently, it was felt that the new programme should contain some information dedicated to parents, although this should be minimal. Suggestions included providing parents with information about low mood and/or depression or links to external information. The participants were clear that they wanted the sharing of this information to be optional so they could retain autonomy but choose to receive parental support if required. Specifically, one individual felt that it could be beneficial to educate parents on how to respond to their son/daughter if they experienced low mood and/or depression:

“So, like if their kid does have depression, they would know how to handle it and know what to say and what not to say” [CP02, male, 13 years old]

Theme 2: Addressing treatment concerns

The second theme identified related to addressing treatment concerns. Two subthemes were identified as belonging to this main theme – fear of disclosure and trust.

Fear of disclosure

At times, several concerns were raised about the implications of accessing support, particularly how individuals would subsequently be treated. Both of the participants who had previously accessed support discussed how the information they disclosed had been reported back to their parents. They described this as a negative experience and stated that consequently they did not return for future sessions. Several others expressed concern about this specifically how they would be perceived by their parents:

“Even if it was found by your parents, people don’t take it seriously and think you’re just doing it so you get the attention” [CP04, female, 14 years old]

One individual felt that if they had low mood and informed their parents, they would have a number of restrictions placed upon them which would be detrimental:

“...your mum and dad would be like ‘right I’m not letting you out the house, I’m not letting you do this, I’m not letting you do that’ because that kind of puts you down more” [CP01, male, 13 years old]

These concerns were not limited to parents with some worrying about healthcare professional involvement, particularly GPs. One individual reported how they would feel uncomfortable disclosing low mood to their GP through worry about how they may handle the situation:

“You wouldn’t want your doctor knowing because your doctor would probably skip and jump to conclusions and probably put you on antidepressants and stuff like that” [CP02, male, 13 years old]

For another, this opinion related to feeling uncomfortable disclosing to a GP who had known them since childhood:

“It’s really awkward as well isn’t it, say you’ve had the same doctor since you were like three and then all of a sudden, you’ve come out saying ‘I feel real depressed, I’m real low’ and they’re like ‘oh right, well’” [CP01, male, 13 years old]

For some, delivering therapy in an online format that *‘you can go on by yourself’* addressed some of these concerns. However, one individual felt that, even using an online therapy would lead to others finding out and them being treated differently. This individual had specific concerns about being treated differently in school where they felt that they would be watched and *‘they’ll give you special care’* and *‘put you in a room with yourself’*. In addition, they worried that if they were to feel particularly low and accessed online therapy people might show up at their house to tell them *‘don’t kill yourself’*.

Owing to concerns about the perceived implications of accessing support, several discussions centred around the importance of confidentiality. Concern about confidentiality was described as something that could deter young people from accessing face-to-face support with some expressing a preference for online therapy with increased anonymity and perceived privacy. One individual described how, if therapy was delivered on a computer *‘no one has to know then do they’*.

Despite associating online therapies with increased confidentiality, the participants made several suggestions of how this could be upheld in the new programme. These included embedding good security with programme access being password protected and requiring a personal username to log on. An automatic log off after a short period of inactivity was proposed to ensure that anything accessed or inputted could not be

viewed by others if a user forgot to log off. It was also suggested that the new programme needed to refrain from asking users to enter any personal details or contact information (or at least make it optional) to increase confidentiality.

Several discussed the importance of discretion, for example regarding what the new programme could be called:

"I think the name should be discreet as well so it shouldn't be anything like 'depression'" [CP07, male, 14 years old]

Participants felt it was very important that the name of the new programme did not reveal what it was about and made suggestions including '*what do I do next?*' or '*control*'. One individual suggested combining words associated with the programme and creating a name that was suggestive of something else:

"It could be something that like shortens two of the words like BE-ACT and if someone asks what that means you could just say 'oh I am learning how to act'"
[CP06, male, 14 years old]

Discretion was also wanted for the programme's presentation and how it would be advertised. It was recommended that, if available as an app, it should appear on a device as a simple number or letter as not to be identified and it would not send notifications to users, which may be seen by others, as to retain privacy. For programme advertising, the consensus was for this to be done through social media which was described as both popular with young people and free to use. One requisite of this was that privacy and discretion had to be retained. For example, if there was a link embedded on social media (e.g. Facebook, Instagram, etc.) it would not be publicised that an individual had clicked on it as they described was often the case.

Trust

Trust when accessing therapy was regarded as important. Two participants had discussed negative experiences relating to trust and described how this had reduced the likelihood of them accessing future support. It was therefore outlined that adolescents would only disclose how they felt if they had built up trust and this was retained. One individual highlighted how they did not trust their GP because '*you don't really know them*'. This same participant stated that '*anyone can set up a website*' and

therefore building trust with an online therapy could be particularly difficult. Therefore, this individual felt that therapy delivered face-to-face may be better:

“You just don’t want to gain trust with somebody that you haven’t met or don’t know so I think it’s probably best to do it in person” [CP01, male, 13 years old]

Although this participant had concerns about establishing trust in online therapy deliveries, others disagreed. One individual felt that, if someone was particularly low, they would ‘lose a lot of trust in everyone’ and therefore establishing trust would be an issue regardless of how therapy was delivered. They felt that as long as there was assurance that a website had been set up by someone reputable then trust could be gained. Interestingly another participant felt that the anonymity of completing therapy in an online format actually meant that establishing trust was not an issue and stated that they would probably disclose more information if therapy was delivered in a computerised format:

“If you don’t have to put any of your details in, I don’t think it would be a real big problem because if you don’t think no one knows who you are, and they aren’t going to find out who you are then I don’t think trust is a problem” [CP08, male, 15 years old]

Theme 3: Adolescent appropriate treatment

The third theme identified was adolescent appropriate treatment. Three subthemes were identified as belonging to this main theme - contextually and developmentally appropriate, incorporating appropriate content and suitable accessibility.

Contextually and developmentally appropriate

The community sample felt that the adolescent period was where an online therapy could be of most importance, particularly for those already experiencing low mood and/or depression. They outlined specific stressors including the transition to secondary school, changes to curriculum and workload and working towards and completing GCSEs:

“Obviously you’re doing your GCSEs and you’ve got to have a strict schedule and that means like you can’t do as many things and that means you’ll be more

worried, if you did have depression you'd be more worried about like that as well so it just, it just builds up to like loads of things" [CP02, male, 13 years old]

When suggesting specific age ranges for the end user several proposals were made with some suggesting a narrow target age range (between 13 and 17 years), and others a wider group (between 11 and 18 years). A consensus emerged that different presentations of the new programme were required to suit users' abilities with chronological age not necessarily a good indicator of ability:

"A low level sixteen-year-old might have the same ability as a high level twelve-year-old" [CP05, female, 14 years old]

Overall, they felt that two or three different presentations were needed to suit the target age range with developmental level guiding the programme presentation and chronological age guiding the content (i.e. to ensure the therapy did not place greater pressures on young people at already stressful times e.g. during exam periods).

Incorporating appropriate content

Much discussion focused upon the content that should be included in the new programme and how it should be presented. During the focus group, participants also completed two activities (see 3.2.6.1) with the findings of these and the associated discussion reported together. The inclusion of activities meant that this particular subtheme was more deductive than the rest, comprising both raw data provided by the participants and information from theory and previous research.

As shown in Table 9, the most highly rated activities for inclusion in the new programme were communication, goal setting, activity scheduling and identifying barriers, with the first two of these being identified by all of the community sample. Particularly, individuals felt that including information about communication would help them to develop their social skills and proposed that as part of activity scheduling the new programme could contain links to clubs or activities that they could become involved in:

"Maybe you could put like links to like clubs that there are so maybe like a sports club or if you want, maybe like a music club or anything like that" [CP02, male, 13 years old]

The least favoured component was recording activities and moods. For some, there was concern that this could result in them providing information that others may see. Consequently, one individual suggested that, if included, this should simply involve ticking boxes. Although most were against recording activities and mood in the new programme, some wanted to see this included to enable them to see connections between periods of time and mood:

“You could maybe put in the programme like what day it is so like say every day you have like a bad day, say there is a coincidence that you have a bad Wednesday we’ll say or something, like it could be because you’ve had loads of bad lessons that day or it could be that you’re in a lesson with bad people” [CP01, male, 13 years old]

All remaining components presented in activity one, were selected by some participants. Several wanted to see videos and games/puzzles included but were keen to highlight that neither should be too ‘childish’. Participants felt that any videos needed to be non-patronising, modern, not include animation which they deemed as too childish and needed to show depression in a serious way. They felt that it was important to include actors who they could identify with, who had knowledge of depression and therefore could provide an accurate reflection of what experiencing depression is like and not be ‘too upbeat’.

Several participants selected homework for inclusion yet had two conditions. They did not feel the word ‘homework’ was appropriate and made alternative suggestions:

Participant (CP07): *“I wouldn’t call it homework though”*

Interviewer: *“What word would you use if you were not calling it homework?”*

Participant (CP05): *“Challenges or something”*

Interviewer: *“Challenges?”*

Participant (CP06): *“Goals to achieve”*

[CP07, male, 14 years; CP05, female, 14 years; CP06, male, 14 years]

Furthermore, due to other demands on their time, homework could not involve copious amounts of work. The completion of an activity was deemed to be acceptable but lots of writing was not.

Most participants also wanted to see problem-solving, reading about depression and quizzes included. They suggested that information about depression could include

coping strategies, provide statistics about depression and could describe current treatments whilst problem-solving could involve a healthcare professional giving advice. Although some wanted quizzes included, they wanted these to be brief (five minutes or less).

When talking generally about activities for inclusion, the participants wanted the new programme to contain elements of fun. They felt that without this, adolescents would not access it and suggested including some items not referencing low mood and/or depression to achieve this. Participants also wanted the programme to be sensitive and relaxed, providing adequate information – not too much that users would be overwhelmed nor too little that they would not take it seriously. Furthermore, they did not want it to be too direct with the potential of '*scaring people off*' using it.

A final area of discussion regarding activities related to relevance. Suggestions included enabling users to skip any information they did not deem relevant and making the new programme sophisticated enough to process inputs and respond accordingly (e.g. only presenting information applicable to user's experiences):


"They wouldn't want to see all of the activities if they were feeling that bad, all they want to know is how to cope with it and how to get help" [CP02, male, 13 years old]

Table 9: Community sample activity one – Activities endorsed for inclusion in the new programme

ACTIVITY	PARTICIPANT ID								
	CP01	CP02	CP03	CP04	CP05	CP06	CP07	CP08	CP09
Activity Scheduling	✓	✓	✓		✓	✓	✓	✓	✓
Problem-solving	✓	✓	✓		✓		✓	✓	
Reading about depression	✓	✓	✓	✓				✓	
Learning about coping skills		✓	✓	✓	✓	✓		✓	
Goal setting	✓	✓	✓	✓	✓	✓	✓	✓	✓
Recording activities/moods	✓	✓	✓			✓			
Identifying barriers	✓	✓	✓	✓	✓	✓	✓	✓	
Relaxation	✓	✓	✓	✓	✓	✓		✓	
Monitoring feelings	✓	✓			✓		✓		✓
Practicing new skills		✓	✓		✓	✓	✓	✓	
Games/puzzles	✓	✓	✓	✓	✓	✓			✓
Watching videos	✓	✓			✓		✓		✓
Homework				✓		✓	✓	✓	✓
Quizzes	✓	✓	✓	✓	✓	✓			✓
Relapse Prevention		✓	✓	✓	✓		✓	✓	
Communication	✓	✓	✓	✓	✓	✓	✓	✓	✓

In the second activity, various factors relating to the new programme were ranked in order of perceived importance. Participants assigned a number from one to ten to each item with one representing what they deemed the most important and ten the least. One individual completed the task incorrectly by using several numbers more than once. Table 10 shows the overall ranking for each component by the remaining eight participants. As presented, the community sample rated the colourfulness of the new programme as the most important component to make it most attractive. This was closely followed by it containing lots of information about depression and having additional follow-up sessions. Handouts that could be printed off following each session were rated as the least important. The new programme containing videos to watch and homework activities to complete were also deemed of lower importance.

Table 10: Community sample activity two – programme component ranking

	Rank	Programme components
<p>Most important</p>  <p>Least important</p>	1	The programme's colourfulness
	2	The programme having lots of information about depression
	3	The programme having additional follow-up sessions to do in the future
	4	The programme having games and puzzles to play and complete
	5	Level of interactivity (e.g. being able to type answers into the programme)
	6	Gaining rewards for completing certain parts of the programme
	7	The programme being available to complete anywhere
	8	The programme having homework exercises to do
	9	The programme containing videos to watch
	10	Having handouts that you can print off and take away

Accessibility

An important element in the design of the new programme was to ensure its accessibility - something the community sample participants expressed concern about. They highlighted that some adolescents may not have the means to access an online programme and therefore proposed that it needed to be available everywhere to ensure equal access (e.g. within GP surgeries). This was particularly important as it was discussed how those without access to the new programme, will not have access to other forms of support presented in an online format and may be more vulnerable.

They also emphasised the importance of having access to the new programme at all times, both when most convenient to use and when most required. It was therefore emphasised that the programme content needed to be both downloadable and accessible to use on other devices including smartphones. This would allow content to be downloaded and accessible at times when an internet connection was unavailable:

“Download the links so you can access it offline so then you could go to your notes and click the link and it would just all be there like all of your progress”

[CP02, male, 13 years old]

In addition, individuals wanted to ensure that the new programme would not require users to have to ‘*sign up now*’ or trawl through large amounts of terms and conditions which they felt would dissuade young people from using it.

3.3.2.2 The service-user sample

Four main themes were identified from the service-user interviews: Constructive safe space, developmentally appropriate formatting, accessibility and regulating parental involvement. Within each of these themes several subthemes were identified. Figure 5 illustrates the themes and subthemes derived from the service-user interviews.

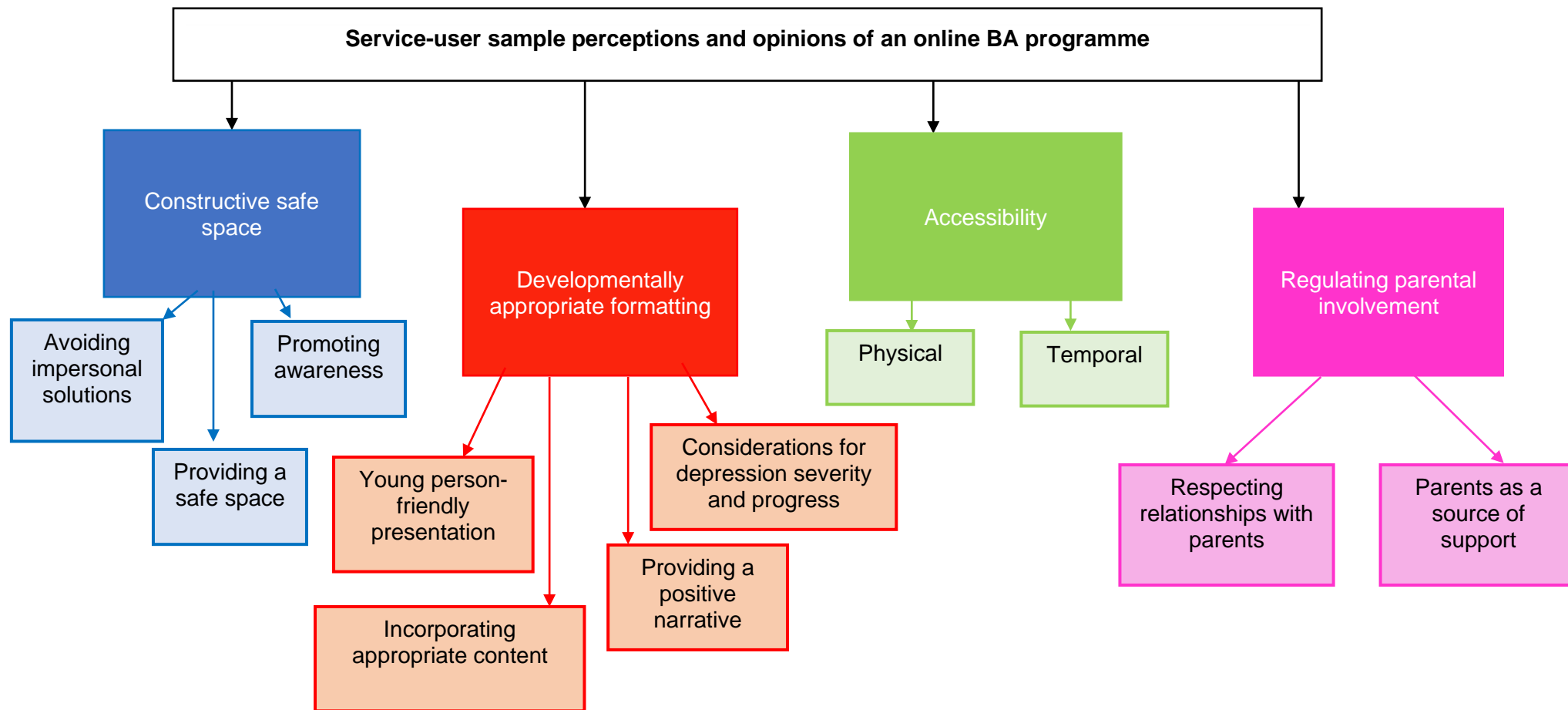


Figure 5: Service-user sample perceptions and opinions of the new programme – themes and subthemes from a thematic analysis

Theme 1: Constructive safe space

Avoiding impersonal solutions

Of the nine service-users, four had accessed online support, searching the internet and browsing websites, generally when they were feeling particularly low and alternative support was unavailable. Although two had found online help useful, shortcomings of the approach were described including a lack of personal rapport, automated responses described as 'robotic' and a feeling that information was more directed at parents:

"I found the [name of website] one to be a lot of phone numbers and it was a lot more directed towards parents than the child" [SU04, female, 16 years old]

Providing a safe space

The service-users had all received face-to-face support for low mood and/or depression, with the majority describing how hard they had found this, particularly talking with another person about their feelings.

"I remember that was one of the hardest things– first ever going to therapy was, like your fear of you don't know this person and you're about to tell them your life story" [SU04, female, 16 years old]

"A lot of young people don't like talk, they're shy, or they don't like talking to people, they don't like being face-to-face, they like being hidden" [SU06, female, 16 years old]

Like the community sample, their main concern related to how they would be perceived with several reporting feelings of embarrassment or worry that others would not understand.

"Sometimes you wouldn't want to talk to other people and find it kind of difficult just sharing stuff because you don't always really think they will understand, and you might feel a little bit embarrassed or something" [SU02, female, 16 years old]

Given their experiences, the service-users felt that an online treatment approach addressed some of these difficulties. Particularly, providing adolescents with anonymity that allowed them to talk freely without judgement:

“It’s sometimes quite hard to express your feelings and talk to someone in real life whereas there’s less fear of judgement and stuff over the internet” [SU08, female, 15 years old]

“There’s no judgement there, you can’t see any judgement, so you just sort of feel comfortable” [SU09, female, 15 years old]

It was also felt that an online approach allowed adolescents to receive support in a format that they were both familiar with and comfortable using.

“I was born into the generation where we are all sort of focussed around technology and our safe space is talking through a phone, through a screen because that seems easier than talking to people” [SU09, female, 15 years old]

One individual reported that they had looked for help online at the onset of their low mood as they felt the internet provided a ‘safe place’:

“Because I didn’t really know what to do so my first go-to was internet, safe place” [SU09, female, 15 years old]

Other perceived benefits of providing help online included allowing adolescents access to support without having to ask for it and the opportunity to receive it within their own surroundings where they felt most comfortable.

Promoting awareness

Irrespective of whether they had accessed online help, none of the service-users had ever had it recommended to them nor been directed to it as part of therapy with some unaware that it existed. Owing to this, all discussed the importance of making adolescents aware of its availability highlighting the need for advertisement to be wide ranging and delivered through varied channels to inform as many individuals as possible. The three main places proposed for advertising the programme were healthcare settings (CAMHS, GPs, NHS website), schools and social media:

“Instagram accounts, Facebook accounts, twitter accounts, just like social media just to get it around, CAMHS sessions, schools, say like the crisis team” [SU05, female, 14 years old]

Theme 2: Developmentally appropriate formatting

The second theme identified related to ensuring the new programme was formatted in a way to make it developmentally appropriate. Several subthemes were identified: young person-friendly presentation, providing a positive narrative, incorporating appropriate content and considerations for depression severity and progress.

Young person-friendly presentation

The service-users were aware that the new programme was being designed for adolescents aged between 11 and 16 and made suggestions as to how information needed to be presented to accommodate all users in this age range. Whilst some felt that there were few differences between 11- and 16-year-olds, others felt that different versions of the new programme were required - the consensus was that two versions were needed. A simpler version was proposed for younger users, those aged 11 to 13 with more in-depth information presented for older individuals aged 14 to 16. Some felt that, not only did the content of the new programme need to be different based on users' age but the presentation of information also:

“For the younger one you could possibly make it a bit more simplified, make the aesthetics more colourful so that it's more intriguing, have more puzzles and stuff to make it more engaging whereas you could go into a bit more detail maybe like depression on a scientific level or whatever if like increasing understanding would help, you could go more into that with the older version” [SU08, female, 15 years old]

Additional presentation-related suggestions included making the new programme fun, relaxed and non-patronising. A common discussion also related to the programme's complexity with the service-users highlighting how it needed to be simple to avoid users disengaging with several reasons for this provided. Firstly, if the new programme contained too much information individuals would find it boring and not want to use it. Secondly, the participants felt that the more complex the information, the less likely adolescents would be to understand it which could make them feel even worse:

“If an eleven-year-old who is anxious, low mood, stressing out about themselves is answering questions or reading words that they don’t understand, it is only going to make it worse for them” [SU09, female, 15 years old]

Finally, it was highlighted that many adolescents tend to procrastinate, especially if they have low mood and/or depression and will be even less interested in engaging. Therefore, the simpler and more focused the new programme, the more likely individuals would be to use it.

Many service-users felt that the new programme needed to be tailored to suit user needs - particularly their learning preferences. It was highlighted how people have different learning styles with some preferring more visual information and others a more verbal approach. Presenting information in a variety of modes was therefore suggested with users able to select their preferred approach:

“If I’m on a website or something, I get proper annoyed if I can’t personalise it to my, like the way I learn and things like that. I like to read through things but some websites they use very little words and a bunch of pictures so there should be like different modes for each activity for the people using it” [SU07, female, 13 years old]

Incorporating appropriate content

One of the main areas discussed within the interviews related to the content of the new programme, with the two activities completed prompting further discussions. Like the community sample analysis, this subtheme was consequently more deductive than the rest. The activity results and the information about content obtained from the interviews are reported together.

As shown in Table 11, the most highly rated activities for inclusion in the new programme were learning about coping, practicing new skills, games/puzzles and having information about relapse prevention which were each selected by all service-users. For practicing new skills one participant discussed how they had found exercise useful in coping with their low mood. This individual had taken up boxing although had also found simple exercises like going for a short walk helpful, finding it to be relaxing and providing a focus rather than ruminating. They were therefore keen for information about exercise to be presented in the new programme.

Although only some participants selected mood monitoring for inclusion, several had previously used it and found it helpful, particularly valuing being able to monitor their feelings over time and see improvements even if they were not necessarily noticing changes:

“I’ve found that really useful because although I didn’t feel like enormously better, when I saw it on the graph I was like there has evidently been some positive changes” [SU08, female, 15 years old]

During activity one some suggested additional content for the programme including providing information about other conditions (e.g. eating disorders), having a chat option so users could talk to similar others, having useful contact telephone numbers and adding in satisfying videos (videos designed to reduce anxiety and aid relaxation). Participants also wanted information that demonstrated to users that they were not alone in their experiences:

“There isn’t that much information with things like thinking you’re alone and nobody else struggles, people get isolated and it would be nice to know sometimes, maybe, that you’re not alone” [SU02, female, 16 years old]

“If they had got a similar problem sort of thing, knowing what it feels like they kind of get it” [SU06, female, 16 years old]

Homework was considered the least important for inclusion, with the requisite that, if included, it had to be minimal to increase adherence and avoid people “getting bored”.

Some wanted the option to print content to give users something to do when not on the computer. Examples of printable content included information about coping, mood monitoring and timetables. One individual proposed presenting all programme content in a booklet that each user could be given at the start. Despite this, several did not see the need for content to be printed if it could be downloaded. Generally, they felt that it would be easier for all information to be kept in one place – on the computer and not in handouts that could be misplaced. One individual felt that printing information both defeated the object of an online delivery and would have a negative environmental impact.

Finally, some felt that it would be good if the new programme included notifications to both check progress and remind users to complete sessions.

“You could do like one notification after like a certain amount of time of not using it like a month or something like that and it’s just like “hi, how are you doing?””

[SU04) female,16 years old]

These individuals felt that through notifications, users would not have to remember when to complete sessions. However, they felt that how and when to receive notifications should be optional.


Table 11: Service-user activity one – Activities endorsed for inclusion in the new programme

ACTIVITY	PARTICIPANT ID								
	SU01	SU02	SU03	SU04	SU05	SU06	SU07	SU08	SU09
Activity Scheduling	✓		✓	✓	✓	✓	✓	✓	✓
Problem-solving		✓	✓	✓	✓	✓	✓	✓	✓
Reading about depression	✓	✓	✓	✓		✓	✓		
Learning about coping skills	✓	✓	✓	✓	✓	✓	✓	✓	✓
Goal setting	✓		✓		✓			✓	✓
Recording activities/moods				✓	✓		✓	✓	✓
Identifying barriers		✓	✓	✓	✓		✓	✓	
Relaxation	✓		✓		✓	✓	✓		✓
Monitoring feelings			✓	✓	✓		✓	✓	
Practicing new skills	✓	✓	✓	✓	✓	✓	✓	✓	✓
Games/puzzles	✓	✓	✓	✓	✓	✓	✓	✓	✓
Watching videos	✓					✓	✓	✓	
Homework					✓		✓	✓	
Quizzes			✓	✓	✓	✓	✓	✓	✓
Relapse Prevention	✓	✓	✓	✓	✓	✓	✓	✓	✓
Communication		✓	✓	✓	✓		✓	✓	✓

In activity two (Table 12), where individuals ranked factors in order of importance, the programme’s level of interactivity was rated as the most important component to make it most attractive. This was followed by the new programme being available to

complete anywhere. Gaining rewards and having games/puzzles to complete were rated as equally important as were the new programme's colourfulness and it including videos. The component rated least important was homework. The service-users also identified the new programme having handouts that could be printed off as unimportant.

Table 12: Service-user sample results of activity two – programme component ranking

	Rank	Programme components
<p>Most important</p>  <p>Least important</p>	1	Level of interactivity (e.g. being able to type answers into the programme)
	2	The programme being available to complete anywhere
	3	The programme having lots of information about depression
	4	The programme having additional follow-up sessions to do in the future
	5 and 6	Gaining rewards for completing certain parts of the programme
		The programme having games and puzzles to play and complete
	7 and 8	The programme's colourfulness
		The programme containing videos to watch
	9	Having handouts that you can print off and take away
	10	The programme having homework exercises to do

Providing a positive narrative

Although most service-users selected reading about depression for inclusion in the new programme (Table 11), several had concerns about this. It was felt that, although it may be useful to have information about low mood and/or depression, reading this information could make some programme users feel worse:

“I don’t think that one [reading about depression] because like it will make people worry, I think... I don’t think that someone with it like needs to know what it is because they’d know but I don’t know if it helps other people or not it just doesn’t help me” [SU05, female, 14 years old]

Consequently, several suggested that whilst this information could be included, it would not help everybody and therefore should be optional. Ways to present this information included via slides or a PowerPoint presentation with information about why adolescents experience depression alongside methods to improve mood.

Similar concerns were discussed about both recording activities/moods and watching videos. Again, although benefits of these components were identified, there was concern that, at times, these could be more detrimental than helpful. Therefore, for recording activities/moods, the participants suggested presenting this in a more positive way and not including the recording of any negative information.

“With the recording activities and moods I would maybe say, maybe not recording the ones that make you feel bad, just because reminding you of the negative possibly” [SU04, female, 16 years old]

This same individual also worried that watching videos could make users feel guilty that their experiences were not as bad as others:

“I know the videos are to show that people have overcome it but the only other thing I would say is that I remember looking at people and stuff like that and then I’d feel bad because I’d feel like “well they’ve got it worse than me so I’m just being dramatic for no reason” [SU04, female, 16 years old]

Considerations for depression severity and progress

The service-users described how the presentation of certain components needed to be informed by a user’s depression severity and the progress they made when using the programme. There were no particular points during any of the interviews where depression severity was discussed at length, instead participants made recommendations as to how the new programme should be presented and then highlighted that flexibility would be required to take these issues into account. For example, all service-users made suggestions about the length of the new programme both in relation to its session number and the time taken to complete each. Although

they had clear ideas about the new programme's length several were keen to highlight that this needed to be somewhat guided by depression severity and therefore users could spend more or less time on the programme relative to how they were feeling:

"If someone's just got low mood it could just be a couple of weeks or all week and then if someone's got kind of middle ground, as an example, then they could maybe be for a month and then if they're really severe it could be maybe a couple of months" [SU03, Male, 16 years old]

One individual described how overall programme completion should be guided by progress and therefore, if a user was feeling better no more sessions would be required. Furthermore, it was suggested that anyone experiencing a relapse should be able to complete either a follow-up session or repeat the entire programme.

Depression severity was also discussed regarding whether different presentations of the new programme were required. As demonstrated earlier (see young person-friendly presentation) much discussion about different presentations of the new programme related to age. However, some highlighted how programme presentations needed to be made relative to depression severity also:

"I don't think it really relates to age, I think it relates to how far or how worse, or how much you are affected, it's not really about the age it's more about how much you are affected by low mood or depression or things like that" [SU06, female, 16 years old]

Theme 3: Accessibility

The third theme identified related to the accessibility of the programme - both physically and temporally.

Physical accessibility

Several commented that a benefit of online deliveries was the ease of accessing support. It was felt that online help would be seen and used by more adolescents including those too anxious to obtain any support and those who struggled to access services through issues with transport. Owing to this, the service-users wanted the new programme to be accessible everywhere. They felt that some adolescents would be deterred from using the programme if it was only available in certain locations (e.g. GP

surgeries, CAMHS) through not wanting to travel nor enter locations such as these. This was deemed especially important for those who were anxious or who did not want to talk face-to-face:

"I think probably better everywhere so that the people who don't want to go to talk to someone will be able to use it" [SU04, female, 16 years old]

The service-users also felt that if it were to be positioned in locations such as CAMHS or GP surgeries, programme access would be limited by the waiting lists often in place in these locations. Therefore, those in need of immediate support would not be able to access it when they really required it. They felt this was particularly important for those just noticing the signs of low mood and/or depression:

"I think it should be everywhere. If someone is starting to notice, as an example, if they're just starting to notice they're kind of getting a bit more low and not enjoying stuff they could quickly jump go onto it and go ah and click on a new technique" [SU03, Male, 16 years old]

Some described how an online therapy delivery could address issues with access and waiting times within current CAMHS:

"The process of getting into CAMHS and stuff is like a bit of a pain with like waiting lists and then maybe not having enough sessions and getting discharged before you're ready and stuff because the fact that there are so many people that need to use the service but if it's internet as many people can use it as they need I'm guessing" [SU08, female, 15 years old]

A consensus emerged that '*nowadays everybody has access to the internet*' and therefore, delivering therapy in an online format would not disadvantage anyone. It was however reiterated that ensuring all content was downloadable and therefore accessible at any time would be useful. One individual stated that, if this were the case those without internet access readily available could log onto the new programme in locations providing free WIFI (e.g. supermarkets), download content and read it later.

Despite participants wanting the programme to be available everywhere, there was less agreement about who should have access. Several felt that the new programme should be available to use by anyone, and questioned its value if this were not the case:

“Yeah there’s not much point doing it, like it only being available to some people”
[SU08, female, 15 years old]

Others felt that, to monitor risk, individuals should only be able to use the new programme if given a username and password to access it. Therefore, it was suggested that clinicians could send the relevant information about the new programme to any patients that they felt it would be suitable for, or their parents:

“Maybe it could be like a link that is sent to parents of a child, or to a child through email or social media or something... send it to who it concerns and then they have the ability to log in anywhere but it’s not everywhere”. **[SU09, female, 15 years old]**

Temporal accessibility

Several discussions focused upon the programme’s temporal accessibility particularly session number and length and the time left between finishing one session and starting the next.

Suggestions for session number ranged from between six and 12. The consensus was that this would be dependent on user needs with the number of sessions accessed guided by the support required. Most service-users felt that some form of follow-up was required to allow users to review their progress and ensure that therapy did not simply stop:

“You could do monthly follow-ups for maybe six months or whatever because it might be a bit daunting like, just to get left and be like ‘right there’s all your strategies just get on with it” **[SU08, female, 15 years old]**

Again, there was variation in how a follow-up could be included with some considering a single session one month after therapy completion to be sufficient and others believing several follow-up sessions were required. Suggestions for additional follow-ups ranged from having them monthly for two months following programme completion to monthly for six months. One individual wanted follow-ups to be optional and aimed at those who might not have processed all programme content:

“I’d just have it optional, just in case because obviously there might be some young people that have not picked some of it up” **[SU05, female, 14 years old]**

Suggestions for the programme's length ranged from 15 minutes to one hour with the majority recommending between 30 and 45 minutes. It was felt that if programme topics could not be completed in this time, they could be covered over multiple sessions to keep session lengths shorter. Several discussed the need to consider the attention spans of adolescents when determining session length:

"I know with me like I kind of click off, like after half an hour so anything after half an hour wouldn't be any good, I wouldn't take it in" **[SU02, female, 16 years old]**

One individual considered the differences between receiving therapy face-to-face and therapy in an online format. They felt that focus may be lost more easily if accessing therapy online which may be less engaging than when delivered face-to-face:

"We have an hour and a half of CBT here {CAMHS site} but here you're sat in a room and it's maybe more engaging than the internet one would be so you could lose focus like more easily if you're just on your phone or at home or whatever" **[SU06, female, 16 years old]**

Generally, it was felt that if longer than a week lapsed between sessions users may forget what they had been doing in the previous session. One session per week, with time to practice skills learned in-between was deemed appropriate by some:

"I think weekly is probably good because you've got time to practice the skills and stuff in between" **[SU08, female, 15 years old]**

Others disagreed and felt that a higher frequency of sessions was needed with completing two sessions per week or having sessions on alternate days suggested. One individual felt that users should decide how many sessions they do each week and when. In addition, continued access to the programme following its completion was deemed important to allow users to repeat anything if required.

Theme 4: Regulating parental involvement

The final theme identified related to regulating parental involvement in the new programme. Two subthemes were identified as belonging to this main theme: respecting relationships with parents and parents as a source of support.

Respecting relationships with parents

Several service-users discussed how they would not want any parental involvement in the completion of the new programme. They felt that adolescents not close to their parents may find it difficult to complete the programme with them involved. Particularly, that some may feel uncomfortable talking about things with their parents present and a worry that, if they were to disclose information in front of them, awkward situations could arise:

“Some people might not have a close, close relationship with their parent, so they won’t feel comfortable talking about how they really feel or how they really think in a situation if their parent is there...they won’t really want to talk about it because they feel like they’re going to have an awkward conversation with the parent about it.” [SU09, female, 15 years old]

“At times I don’t get on with my parents and I find it really awkward talking to my mum about stuff because she just doesn’t understand” [SU02, female, 16 years old]

It was therefore felt that some users would not engage with the new programme if a parent was present.

One service-user highlighted that some adolescents may not tell their parents when they feel down and therefore, more individuals would seek help if their parents were not involved. Thus, some felt that the issue of parental involvement should be decided by the programme user:

“I feel it should be sort of a matter of personal choice so like the child can decide if they want their parent involved or not” [SU09, female, 15 years old]

However, it was highlighted that allowing users choice as to whether to involve their parents again needed to take into consideration the severity of their low mood and/or depression:

“I think parental involvement depends on if the patient wants it and also depending on severity again, if they’re severely depressed and at the point of suicidal thoughts, it may be often that parents are going to have to know all of it but if they’re just low and getting there, you know just low depression maybe they have more of the choice there” [SU03, female, 16 years old]

Another individual felt that parents needed to be informed if their child was using the new programme but simply to demonstrate they were using the computer in an appropriate way thus avoiding being told '*get off the computer*'.

Parents as a source of support

In contrast, several service-users wanted some parental involvement, feeling that this could help with the successful completion of the new programme. In particular, some suggested that, if involved, parents could gain a better understanding of how their child was feeling, learn techniques to help them and thus be able to provide more suitable support:

"They could become more aware of how their child's feeling" [SU01, female, 16 years old]

"Maybe sessions for the parents that don't know what to do when their child is sort of in that situation, give them information about how to deal with it, how to explain the child's emotions to them or something like that and sort of ways of coping as a parent whose child is going through low mood or something like that because it can have a negative effect on the parent as well" [SU09, female, 15 years old]

To implement parental involvement, giving parents handouts providing information about low mood and/or depression and coping techniques, was proposed. Furthermore, several suggested that parents could complete some programme sessions themselves however, how to implement this varied. Some felt that parents should complete the new programme together with their son/daughter so they could monitor their progress:

"If the parent goes through it with the child then they can kind of see what they're going through and adapt to that I guess" [SU04, female, 16 years old]

"Just do it together so they would know what you're doing or how you're doing" [SU06, female, 16 years old]

One individual felt that parents may be able to assist with completing some of the session activities as they would be able to provide information that the user may have

forgotten. The example given was activity scheduling where it was highlighted that parents may be best placed to remind adolescents of things that they previously enjoyed before experiencing low mood and/or depression.

Other service-users suggested that the new programme should contain some parent-only sessions so parents could learn more about low mood and/or depression and how to provide support, but not be present to see anything their son/daughter inputted:

“There should be at least one session, so it can help the parents understand how it is helping the child, so at least one session to explain what is happening, what will happen, how it will help” [SU07, female, 13 years old]

“I think there should be like, like a little bit of it, I don’t know, like a little segment of it that’s just for parents and then a bit that’s just for teenagers” [SU01, female, 16 years old]

Other variations to this included having parent-only and adolescent-only sessions alongside sessions to complete together or the option for parents to join users at the end of each session to see what they had been doing.

3.3.3 Healthcare professionals’ perceptions

Six main themes were identified from the focus group and individual interview with the healthcare professionals. These were familiarity and experience of BA and online therapies, essential elements required for a successful BA programme, developmental considerations and flexibility of the programme, depression severity and care pathway positioning, risk monitoring and systemic approach and collaborative working. Within all but one of these themes (risk monitoring) several subthemes were identified. Figure 6 illustrates the themes and subthemes identified.

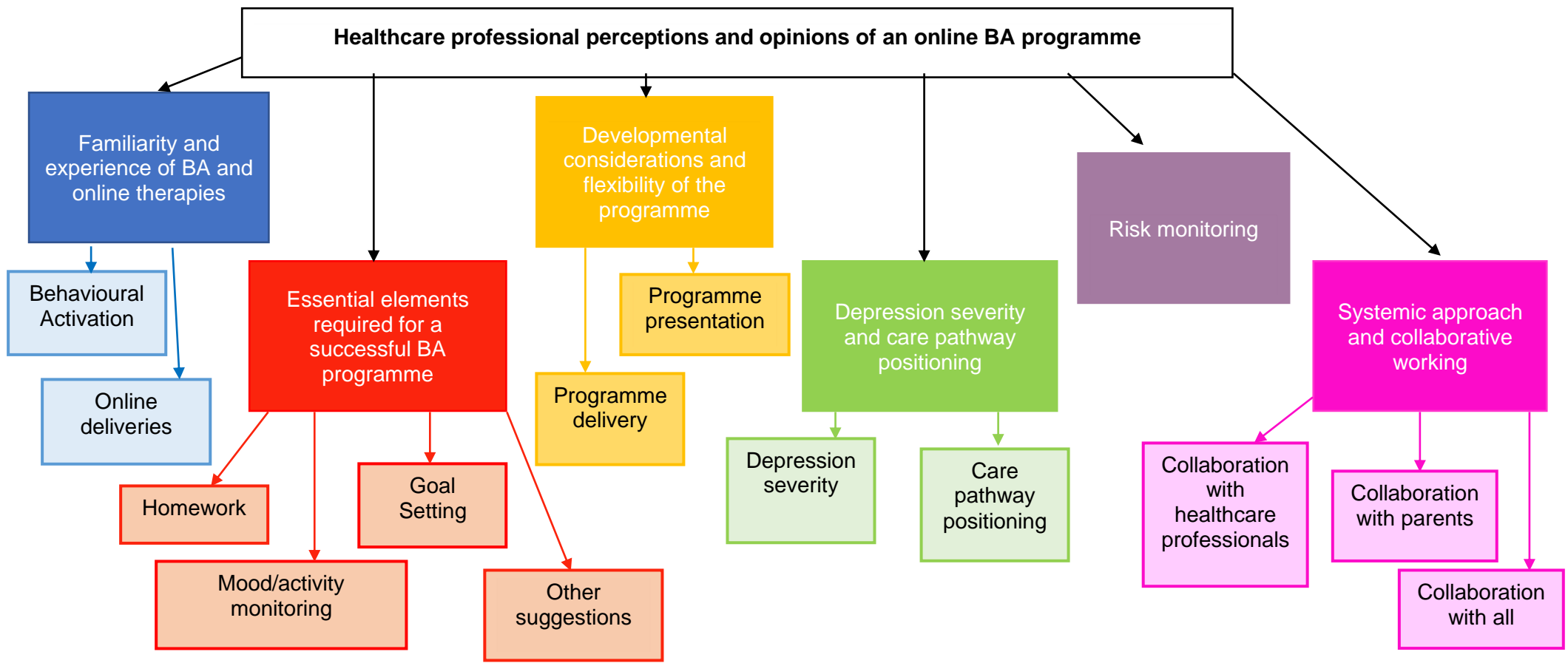


Figure 6: Healthcare professional perceptions and opinions of the new programme – Themes and subthemes from a thematic analysis

Theme 1: Familiarity and experience of BA and online therapies

The first theme related to the healthcare professionals' previous experience of both BA and the delivery of online therapies.

Experience of BA

Most of the healthcare professionals were familiar with components of BA having used several, mainly mood and activity monitoring, in therapy. However, some were either not aware of the term BA or had not previously referred to the therapy they delivered as this:

"(W)hen you break these things down, yeah, we do do a lot of these things, but we don't name it" [HP06, male]

Those familiar with BA discussed how therapy of this type tended to be bespoke when used with young people. They reported how, with no manual to follow, their knowledge of BA was often based upon an adult model which they had adapted themselves for use with young people:

"The only one I am aware of is an adult model, the Oxford model for behavioural activation which is in adults and historically in CAMHS we've always adapted things from adults...we tend to make it up with the young person and agree it" [HP06, male]

Online deliveries

All healthcare professionals were familiar with the increased use of online therapies, with some having referred individuals to online resources whilst awaiting face-to-face therapy. Several discussed the value of delivering therapy in an online format to adolescents:

"...but then I'm not into computers so I probably avoided it but with the people we are talking about we need to move with the times and that is how they interact so we've got to get with it really" [HP01, female]

"One of my teenagers in the group, in fact two of them, were really, really anxious and social anxiety and he uses, he showed me an app that he uses, a

mindfulness app and it really works for him, and the young girl, they said that they, when they were showing me the mindfulness app, yeah it was really interesting” [HP02, female]

Particular benefits of online deliveries were identified including allowing a more structured approach to therapy and providing opportunities for young people to talk without being watched. However, some shortcomings of the approach were recognised alongside. The healthcare professionals reported that they did not feel that online therapy delivery was suitable for all and had avoided its use if they felt the risks were too high. Several had concerns that it could in fact have a negative impact upon the treatment outcomes of some:

“(W)hat if you’ve got somebody, a young person who was very, very low mood, they’re on their own and can access it would that make them feel better? Would that make them feel worse? So, if they are very, very low, we’d have to get it right, because if they were very, very low and they couldn’t do what they were being asked on the computer, would that then make them feel worse? And would they be suicidal? I’m thinking worst scenario I know” [HP05, female]

The main concern related to the lack of therapist presence during treatment delivery. It was felt that, despite their benefits, online deliveries could not provide everything a real-life therapist could:

“Instilling the hope, the computer cannot instil hope” [HP06, male]

Some expressed concern about what would happen to users if they felt particularly low following online treatment sessions:

“Because it’s OK being able to type in it but then that computer turns off at the end of it and you are suicidal then where do you go?” [HP05, female]

Finally, issues relating to the accessibility and portability of online therapies were discussed with the healthcare professionals highlighting the importance of making them accessible to all young people.

Theme 2: Essential elements required for a successful BA programme

A second theme identified related to what healthcare professionals perceived to be the essential elements needed for a successful new programme. Like the adolescent participants the healthcare professionals completed activity one, selecting the activities they felt should be included in the new programme from a list. The activity findings and the focus group/interview discussion are reported together with the activity results reported first. Three of the components that featured in the activity (goal setting, mood/activity monitoring, homework) were identified as subthemes, alongside a fourth subtheme 'other suggestions', during the thematic analysis and will be discussed individually in more detail following the presentation of the activity findings.

As shown in Table 13 the activities most selected by the healthcare professionals for inclusion in the new programme were goal setting, activity scheduling, coping skills, mood/activity recording and monitoring feelings. Some also wanted the inclusion of homework, practicing new skills and providing information about communication. Most also selected information about depression, problem-solving and quizzes for inclusion. However, one individual felt that the person-centredness and individualised nature of problem-solving would make it difficult to implement in an online format and another stipulated that any quizzes needed to be optional with completion having no impact upon therapy outcome. Furthermore, although most wanted information about depression to be provided, they felt this should be minimal. The remaining activities (identifying barriers, relaxation, games/puzzles, videos and relapse prevention) were selected for inclusion by most healthcare professionals.

Goal setting

The majority felt that goal setting should be included in the new programme with one healthcare professional describing it as a '*vital*' component in assisting therapists to gauge therapy direction. One individual proposed that if included, it needed to be based upon goal-based outcomes, whilst another proposed that goal setting should be achieved via shared decision making and using option grids. Despite most endorsing a goal setting component, like problem-solving, concerns were raised about how it could be implemented owing to its individualised and person-centred approach.

Mood/activity recording

All selected mood/activity recording for inclusion making it the most selected choice. The healthcare professionals felt that recording moods allowed therapists to generate a clearer picture of how a person was feeling and thus tailor treatment accordingly. Particularly, they felt it was important for adolescents to monitor their moods regularly as to identify factors impacting upon it.

“It’s like that noticing when you’re feeling happy, what’s happening, what are you doing” [HP01, female]

Homework

Only some healthcare professionals selected homework for inclusion in the new programme with concern that there would be minimal compliance. Those who selected it felt that it was important for users to participate between therapy sessions but did not feel the term ‘homework’ should be used (although no alternative suggestions were made). It was suggested that if homework were included, it would need to be monitored with reminders required to support engagement.

Other suggestions

Besides making suggestions about the new programme’s content, the healthcare professionals also discussed issues relating to its presentation. They were keen to ensure that the new programme would be inclusive of as many adolescents as possible, highlighting the need to make it accessible to those with autism, dyslexia and learning difficulties for example. Ways to achieve this included providing a combination of pictorial and text information and enabling users to adjust programme settings (e.g. background colour) to enhance ease of use.

It was also felt that there needed to be a way for users to enquire about things they did not understand. Suggestions included ensuring key points were reviewed each session to clarify meanings and the inclusion of a chat box where users could type questions and healthcare professionals could respond.

Furthermore, one individual highlighted the importance of emphasising to adolescents that they are the experts on themselves and it is them that need to make any changes to improve mood. Therefore, whilst an online therapy delivery could involve therapists

providing support alongside it was ultimately users' responsibility to ensure they were accessing and completing sessions successfully.

Table 13: Healthcare professional activity one – Activities endorsed for inclusion in the new programme

ACTIVITY	PARTICIPANT ID								
	HP01	HP02	HP03	HP04	HP05	HP06	HP07	HP08	HP09
Activity scheduling	✓	✓	✓		✓	✓	✓	✓	✓
Problem-solving	✓	✓				✓	✓	✓	✓
Reading about depression	✓	✓	✓	✓		✓			✓
Learning about coping skills	✓	✓		✓	✓	✓	✓	✓	✓
Goal setting	✓	✓	✓			✓	✓	✓	✓
Recording activities/mood	✓	✓	✓	✓	✓	✓	✓	✓	✓
Identifying barriers	✓	✓	✓			✓	✓	✓	✓
Relaxation	✓	✓		✓	✓	✓		✓	✓
Monitoring feelings	✓	✓		✓	✓	✓	✓	✓	✓
Practicing new skills	✓	✓						✓	✓
Games/puzzles	✓	✓	✓	✓			✓	✓	✓
Watching videos	✓	✓		✓	✓		✓	✓	✓
Homework	✓	✓				✓		✓	
Quizzes	✓	✓	✓	✓			✓	✓	
Relapse Prevention	✓	✓	✓		✓	✓	✓	✓	
Communication	✓	✓					✓	✓	

Theme 3: Developmental considerations and flexibility of the programme

The third theme identified related to developmental considerations and the new programme's flexibility. Here, two subthemes were identified: programme presentation and programme delivery.

Programme presentation

The healthcare professionals felt that more than one programme presentation was required. However, they highlighted how the ability of many young people is often incorrectly inferred from their age and therefore felt that basing varied presentations upon the developmental level of the user would be more appropriate.

Some expressed concerns that adolescents may not understand certain words, and others, particularly if lacking energy would struggle with lots of text. Suggestions to address these concerns included breaking words down to aid understanding, using combinations of words and pictures and embedding an audio option so content could be read aloud.

“Something where you can choose so it’s written but you can press the button on the computer at the bottom where it says ‘read it to me’” [HP05, female]

Programme delivery

The consensus amongst the healthcare professionals was that the number of sessions and their frequency needed to be tailored to the user. They felt that, in particular, this needed to consider users’ energy levels and highlighted that if the timings were incorrect there could be a negative impact upon therapy delivery. However, they stated that around eight to 12 sessions, delivered weekly, would be sufficient:

“I think from a kind of CBT model it’s kind of weekly because you’ve got to keep that momentum going and if you leave it much longer, maybe two weeks but you know, if they’re logging on and doing it themselves I think weekly is quite realistic and you’ve got time then in the week to do your stuff in between haven’t you” [HP01, female]

The healthcare professionals wanted session length to also have some flexibility with suggestions including basing this upon depression severity, developmental level or the number of questions users had. However, the consensus was that sessions should not exceed an hour, with between 30 and 45-minutes suggested as optimal:

“No more than an hour tops, absolute tops and that would probably be too long...between half an hour and maybe forty, forty-five minutes maybe” [HP01, female]

Another healthcare professional outlined how adolescents with low mood may not have large attention spans and therefore suggested basing the sessions upon graded exposure:

“I am just wondering with retaining the attention of young people with low mood particularly when it is on a computer how, yeah, I mean do you exponentially make the sessions longer and longer in the hope that behavioural activation improves their mood so you start off short and almost that itself being a bit of graded exposure so you could start off at ten minutes and then it goes to fifteen”
[HP09, male]

Theme 4: Depression severity and care pathway positioning

Another main theme identified related to who the new programme would be most suitable for with depression severity and care pathway positioning identified as sub-themes.

Depression severity

Overall healthcare professionals contended that the new programme would be best developed for those experiencing mild to moderate low mood and/or depression, with concerns that those with severe presentations may have difficulties using it:

“I think you’d be looking at mild to moderate. Yeah, because I suppose my, my thinking is even if it was severe and not with the initial difficulties that come along with it but the, the resistance to engage with an external computer programme initially, without that kind of work around instilling hope and motivation to change and stuff like that, so yeah mild to moderate” **[HP05, female]**

Therefore, they suggested it should be placed within tiers two (early help and targeted services) and three (specialised services) of CAMHS and at step two of the CYP-IAPT (children and young people’s improving accessing to psychological therapy) stepped-care model (low-intensity services).

Care pathway positioning

The healthcare professionals felt that the new programme could fit anywhere within the care pathway and provided examples of its positioning at pre, during and post-treatment points.

Firstly, it was suggested that the new programme could act as a preventative method and be used by those awaiting treatment within CAMHS. If successful, they felt it could reduce the number requiring face-to-face treatment and enable clinicians to allocate appointments to those with more significant needs:

“[I]n sub-CAMHS ‘watchful waiting, try this first’, carry out this specific programme under consultation with CAMHS or whatever, do this review and then come back’ kind of thing, it could be a step-up, step-down” [HP06, male]

One healthcare professional suggested that the new programme could be used as part of the CAMHS initial assessment appointment:

“(A)nd then that could be part of your assessment that you came, if you did have a CAMHS assessment appointment you could say ‘I’ve been doing all this”
[HP01, female]

The healthcare professionals also felt that the new programme could have a place during the treatment period, used as an additional therapy alongside CAMHS usual care. Here individuals could complete programme sessions between or during CAMHS appointments:

“(S)ometimes we do some group work with young people and it might be that in between the group work we could say ‘there’s always this that you can do” you know rather than having a one-to-one” [HP01, female]

If used during treatment, the healthcare professionals felt the new programme would provide individuals with a new medium to use as part of their care and provide therapists with a useful tool to help monitor progress.

Finally, the healthcare professionals proposed that the new programme could be used post-treatment as a *‘further treatment’* completed prior to discharge:

“I think it would be a great sort of next step before you discharge them, so they’d go through that sort of intense therapy, you know, and then once they’ve managed to reduce their, their depression they’d go on to do something like computerised and then discharge” [HP07, female]

Theme 5: Risk monitoring

All healthcare professionals highlighted the importance of risk monitoring when delivering therapy in an online format.

“(w)hat’s been highlighted here is that there has to be a safety mechanism” [HP06, male]

They described how it was essential to have plans in place for how to identify anyone at risk following therapy (e.g. suicidal) and how to deal with it. Healthcare professionals felt this was especially important if there was no parental involvement in therapy delivery. Several suggestions on how to achieve this were made including incorporating live chat or crisis numbers into the new programme. Another suggestion was to enable any adolescent feeling at risk to input details of this into the programme and request a call back from a healthcare professional. These ‘*contact points*’ would be organised and available in any localities where the new programme was implemented.

Although there was discussion surrounding how an online therapy could have some form of embedded risk monitoring (e.g. using an algorithm), the healthcare professionals placed great emphasis on adolescents taking control in these instances. They felt that individuals should take responsibility of their own conditions and agree to seek additional support if they deemed it necessary. One suggestion on how to achieve this was to have adolescents sign a contract prior to therapy:

“You could have it in the contract... so just something that they signed to say that ‘if you do feel at risk or you feel that you need to talk to someone that you are willing to contact the crisis team and speak to someone’, even the Samaritans” [HP07, female]

This would also be useful in ensuring that programme users are aware of where to seek help if needed.

Theme 6: Systemic approach and collaborative working.

The final theme identified related to adopting a systemic approach with collaborative working for the successful delivery of the new programme. Three subthemes were identified: collaboration with healthcare professionals, collaboration with parents and collaboration of all.

Collaboration with healthcare professionals

One of the main concerns that the healthcare professionals had with the new programme was its lack of human contact. They saw the therapeutic alliance as significantly important and felt that a connection between service-users and therapists was essential:

“I think for me though there is nothing more powerful than the connection between the therapist and the client, you know” [HP07, female]

Particularly, they felt that their presence as clinicians was needed to instil hope during the treatment process. Furthermore, with the variability in feelings inherent to low mood and/or depression they felt it essential as clinicians to be informed of their young client's progress and deteriorations and be available to provide support as required. Therefore, although the healthcare professionals supported the new programme's development, they wanted a balance between the computer and therapist in treatment delivery.

Collaboration with parents

A consensus emerged that parental involvement was essential for the successful delivery of the new programme. In the healthcare professionals' experience, therapies were more successful if parents were involved as they could learn how best to support their child. Through increased awareness of the difficulties their child was experiencing and the therapy they were receiving, healthcare professionals also felt that parents could be vigilant to any change (both internal and external) that may exacerbate their child's symptoms of low mood and/or depression. In addition, parental feedback on their child's progress could be used to adapt therapy if necessary and ensure it is meeting the adolescent's needs.

The healthcare professionals felt there were particular areas of therapy where parental involvement was needed, specifically for risk monitoring but also if guided imagery were used:

"[I]f you're using techniques like that [guided imagery] you very much do need parents on board because there may be things to discuss about what might be important for that young person that might not be expected" [HP08, female]

Finally, one individual felt that if parents were not involved with the care of their child, they would simply be passing the issue over to CAMHS to deal with:

"but if I am not involved [speaking as a parent] and it is a separate thing I am basically giving it to CAMHS or whoever and saying 'you deal with it and then when they are OK, they can come back to me'" [HP05, female]

The healthcare professionals acknowledged that establishing parental involvement within therapy can be difficult and therefore outlined how parental support within the new programme would need to be adapted based upon user-parent relationships.

Collaboration of all

Finally, the healthcare professionals highlighted the importance of adopting a systemic approach to therapy delivery, with the inclusion of all agencies co-working to ensure treatment success. They felt that everyone had a role to play in the delivery of therapy and it was important to be flexible and have a clear definition of roles:

"Everybody has a role to play from the preventative early intervention, the mild end, the moderate end, the severe end so it will be quite clear who does what, when and how, and then that maxes our public money, so we're not stop starting" [HP06, male]

Although the healthcare professionals were mindful of adolescents' privacy, they also highlighted the importance of communication to ensure therapy is as successful as possible:

"I say to parents 'look they come into the group however if you see a deterioration, if they're coming to see me if I'm making things worse, if they're having any, you know anything's changing massively, please call me, please

make a phone call and we can sort this', we want to know if things change, that's maybe all that it needs to have is to say to parents 'they're on this, they're doing this but we need to know if things are changing or if situations external to that are changing which then impact on it" [HP05, female]

Through the collaboration of all, the healthcare professionals felt that adolescents would have a variety of places to contact for support if they were feeling low and there would be multi-level monitoring in place throughout treatment completion, something especially important if risk was presumed.

3.4 Discussion

3.4.1 Summary of results

Twenty-seven individuals, a combination of adolescents from a community sample, adolescents from a service-user sample and healthcare professionals, participated in interviews and focus groups. From these, information was collected from varied perspectives to inform the development of a new online BA therapy.

3.4.1.1 The community sample views

Few in the community sample were aware of the availability of online support, with none having accessed any, but saw the benefits of this therapy approach particularly during heightened periods of stress.

Communication, goal setting, activity scheduling and identifying barriers were the most favoured activities for inclusion in the new programme whilst mood/activity recording was the least. Conditions for including many of the activities were imposed such as them being relevant, reflecting user abilities and not being patronising or childish. The community sample wanted the programme to contain an element of fun and therefore include some items not about low mood and/or depression. To make the programme most attractive, they wanted it to be colourful, present information about depression and include additional follow-up sessions. They felt that two or three different programme presentations were required.

Confidentiality was frequently discussed with suggestions made for good security, automatic log offs, no personal information requests and the programme being discrete. Additionally, they wanted the programme to include choice and be flexible

with optional content and the ability to control the time spent on sessions and the frequency of access. Around 30 minutes per session was deemed reasonable. Participants also wanted the option to both save and delete programme inputs.

Although the community sample expressed concern about the involvement of others, wanting instead to retain autonomy and responsibility for their own care, they suggested that although parental involvement should be optional, parents could be informed if a user's low mood was deemed 'serious'. They also proposed including the contact details of healthcare professionals in the programme for additional support if required.

3.4.1.2 The service-user views

Several service-users had accessed online support, but none had been recommended it as a treatment option. Regardless of whether they had accessed online help, all were positive about it as a treatment approach identifying benefits including its anonymity, familiarity, accessibility and availability.

Learning about coping, practicing new skills, games/puzzles and information about relapse prevention were the most favoured activities for inclusion in the new programme whilst homework was the least. Some wanted the programme to include notifications containing session reminders and progress checks and have both downloadable and printable content. Including information about other conditions, a chat option to show users they were not alone in their experiences and useful telephone numbers were suggested. Furthermore, service-users wanted the programme to be fun, interactive, relaxed and non-patronising and felt that adolescents would be more likely to use it if it was simple and focused. Again, they felt that more than one programme presentation was required with a simpler version available for younger users.

Opinions varied regarding the programme's session structure with suggestions ranging from between six and 12 sessions, lasting 15 minutes to one hour. All service-users felt that the time between sessions should not exceed one week whilst the majority felt some form of follow-up was required. Several felt that the programme's presentation should be determined by depression severity and treatment outcomes.

The service-users wanted the programme to be available everywhere thus accessible when and where needed. Some felt that the programme should be available to use by

all whilst others proposed that, to monitor risk, only those given a username and password should access it.

Opinions about parental involvement were mixed; some worried that users might feel uncomfortable and not engage whilst others felt that parental involvement could enhance treatment success with parents gaining understanding and learning techniques to support their son/daughter. Suggestions for involving parents included providing information handouts, having parent-specific sessions and encouraging parents to join in with sessions/activities. Some felt that parental involvement should be optional.

3.4.1.3 The healthcare professionals' views

Most healthcare professionals were unaware of the term BA but had used components of it in practice. Therapy of this type tended to be bespoke when used with young people, often adapted from an adult model. Whilst the healthcare professionals acknowledged the benefits of an online therapy approach, they did not deem it suitable for all. Their main concern was risk monitoring with suggestions to address this including incorporating live chat, crisis numbers and call backs from healthcare professionals if needed. Emphasis was placed on adolescents taking control and agreeing to seek support if required.

Mood/activity recording, goal setting, activity scheduling, coping skills, and monitoring feelings were the most favoured activities for programme inclusion whilst homework, practicing new skills and providing information about communication were the least. It was felt that the programme length needed to be tailored to each user, being flexible to depression severity, individual needs and energy levels. Eight to 12 sessions, lasting between 30 and 45 minutes and delivered weekly were regarded as sufficient.

The healthcare professionals wanted the programme to be as inclusive as possible and felt that different programme presentations were required with language, in particular, adapted across these. They felt that the new programme would best suit those with mild to moderate low mood and/or depression and placed within tiers two and three of CAMHS and step two of the CYP-IAPT stepped-care model but could fit anywhere on the care pathway.

A consensus emerged that parental involvement was essential and the importance of a systemic approach to therapy delivery was highlighted, with healthcare professionals

and parents, co-working to ensure treatment success. Through this collaboration, it was felt that users would have a variety of contact points for support and multi-level monitoring would be in place throughout treatment.

3.4.1.4 Comparisons of the three participant groups' views

Regardless of whether a participant was an adolescent or healthcare professional, their views were similar regarding several issues about the new programme's development. All felt that more than one presentation was required to suit the target age-range, and all had concerns about homework, stipulating that if included, it needed to be minimal and presented using a different term. In addition, despite some individual differences, the three groups generally felt that programme sessions should last approximately 30 to 45 minutes. Across both adolescent groups additional similarities were found. These included regarding handouts and homework as the least important components to make the programme attractive, wanting the new programme to be available everywhere with access at all times and highlighting the need for the new programme to be simple to avoid dissuading individuals from using it.

Despite these similarities, several differences were apparent both between the adolescent samples and the healthcare professionals and also between the two samples of adolescent participants. One of the most favoured activities for inclusion reported by the service-users was practicing new skills yet this was one of the components rated as the least favoured by the healthcare professionals. Different views across all three groups about the involvement of others, particularly parents, were also apparent. Here, like reported in a systematic review examining the experiences of young people using tech-assisted CBT (McCashin et al., 2019), the involvement of parents was regarded both positively and negatively. Those in the community sample were wary about involving others including both parents and healthcare professionals and whilst suggesting friends as an alternative, expressed some concern about this also. Although ideally this group would have preferred no involvement from other people they did discuss how, in instances of risk parents could be informed. Although not the case for all, several service-users were more positive about involving others, highlighting how including parents in the new programme could enhance treatment effectiveness. It was however suggested that this involvement should be optional. In contrast to the adolescent participants' views the healthcare professionals regarded the involvement of others in an online therapy as essential and contended that parents, alongside healthcare professionals, needed to take an active role in the completion of the new programme.

Differences in opinion were also evident between the two adolescent samples. Whilst the community sample rated the programme's colourfulness, it providing information about depression and including follow-up sessions as the most important in making it more attractive, the service-users selected the programme's interactivity and it being available everywhere as the most important. There was also variation in the views about the programme's availability with the community sample believing it should be available to all whilst several service-users, concerned about risk monitoring, wanted access limited to those identified by healthcare professionals.

3.4.2 Evaluation of the qualitative methodology

3.4.2.1 Strengths of methodology

This qualitative study has provided valuable information to inform the development of the new programme. Through purposive sampling, the views of multiple individuals with diverse experiences of mental health interventions were obtained which increased the likelihood that the new programme would meet the needs of its target users. Furthermore, through employing thematic analysis rich and detailed accounts of the data were obtained.

Through adopting a semi-structured approach within the interviews and focus groups, discussions could be guided by issues relating to the topic of interest whilst allowing flexibility for participants to discuss, and elaborate on, specific factors that they deemed most important. In addition, the semi-structured approach can elicit information that has not been considered *a priori* (Gill et al., 2008). This was evident within this qualitative work where useful information was gathered as a result of developing discussions as opposed to participants directly responding to questions. Through employing focus groups, not only were the opinions of individuals obtained but also the opinions of individuals when part of a larger group (Massey, 2011). The employment of individual interviews allowed those with experience of accessing services to participate whilst maintaining their confidentiality and allowing them to discuss their experiences without concern about personal information disclosure.

Attaining the proposed sample size was an additional strength. There were nine attendees in each of the focus groups which was consistent with recommendations (Krueger & Casey, 2015). With too few participants, discussions may have been limited with the credibility and dependability of the findings compromised. Nine

individuals were also recruited to attend face-to-face interviews which aligned to the sample size initially proposed. Following the interviews data saturation was considered to have been reached and therefore a sufficient amount of data had been obtained deeming further data collection or analyses unnecessary (Saunders et al., 2018).

3.4.2.2 Limitations of methodology

Despite its strengths, several limitations require the results to be interpreted with caution. Significant challenges when trying to engage adolescents to be part of the service-user sample resulted in the recruitment approach being amended both regarding the methods employed and the geographical location of recruitment. Whilst a sufficient number of adolescents were recruited to the service-user sample, these amendments delayed recruitment completion with a 16-month gap between the first service-user interview and the last. Although, it is not perceived that this delay will have affected the views expressed by participants, completion of the analysis was significantly delayed.

Furthermore, several factors may have affected the transferability of the findings. Through employing an opt-in method, the adolescent participants were more likely to be those motivated to engage and thus might not have expressed views demonstrative of the general age-range population. In the service-user sample only one participant was male. As research suggests that males are less likely to access mental health services (Rickwood, Mazzer & Telford, 2015), this is unsurprising however it meant that the views of males were under-represented within this sample. In addition, although recruitment occurred within four NHS trusts these were all located in close proximity and were all culturally similar with the overall participant sample not being ethnically diverse. Therefore, the views expressed by the individuals within this qualitative work might not be typical of other healthcare professionals based within, nor adolescents receiving support for low mood and/or depression from, other NHS trusts.

3.4.3 Implications for the development of a Behavioural Activation programme

Despite the study's identified limitations, this work has generated several important findings with implications for the development of an online BA programme.

Across the three participant groups all endorsed an online therapy delivery with particular benefits of the approach including enhanced anonymity, treatment accessibility and awareness identified. These findings were concordant with previous

research in the area (e.g. Pretorius et al., 2019; Fleming et al., 2014; Stallard et al., 2010). When presented with potential content for inclusion in the new programme, based upon techniques commonly delivered within BA (Kanter et al., 2010) and the systematic review findings (Chapter Two, Tindall et al., 2017), all content was selected by at least one third of participants in each group. Furthermore, activity scheduling and activity monitoring, the two approaches consistently delivered within BA (Kanter et al., 2010), were selected for inclusion by most participants. These findings support the contention that BA may have the potential to be an effective treatment in this context.

Although the healthcare professionals were aware of the availability of online therapies, the adolescent groups were predominantly not with none having been directed to this kind of support. It has been reported elsewhere that young people need to be made more aware of the availability of online support and where to access it (Bradley et al., 2012). The findings of this qualitative study add support to this assertion, highlighting the need to sufficiently promote the support available to adolescents.

In Chapter One the rationale for developing an unguided treatment approach was presented (see 1.3.2). This was in response to the findings of several systematic reviews (e.g. Karyotaki et al., 2021; Rasing et al., 2020) and RCTs (e.g. Dear et al., 2018; Titov et al., 2016; 2015) that suggested comparable clinical outcomes to guided treatment deliveries. Furthermore, additional benefits of adopting an unguided approach in ameliorating several barriers associated with treatment provision (e.g. limited treatment availability and accessibility, young people's reluctance to engage one-to-one with a therapist) were suggested (e.g. Karyotaki et al., 2021; Rasing et al., 2020). Several findings from the qualitative work have further supported this rationale. Despite different experiences, the adolescent participants expressed concerns relating to accessing support particularly worrying about information disclosure and how they would be treated and perceived as a result. These concerns were not limited to parents but also included healthcare professionals. Owing to this, confidentiality and anonymity were frequently discussed as important, and an online therapy delivery was considered to allay some of these concerns as well as allowing them to access therapy at times when most needed and in their own surroundings where they feel most comfortable. Whilst these findings were not discussed with direct reference to the adoption of an unguided treatment approach, they did imply that this approach would be favoured over a guided delivery where discussions with healthcare professionals would be required, and anonymity would not be possible. However, whilst the views expressed by the adolescents suggest support for an unguided approach, this was not always the case for the healthcare professionals. Although keen to promote the concept of adolescent's

taking responsibility for their own health, at various points in this qualitative work, emphasis was placed upon the importance of involving healthcare professionals in the delivery of online interventions, predominantly as a mechanism to monitor risk. Similar concerns were reported in several of the studies included in the review by Rasing et al. (2020), where professionals questioned whether online interventions could effectively monitor the risk of self-harm and suicidal ideation regardless of the approach adopted (guided, blended or unguided). This highlights the requirement for any online programme development, particularly ones with an unguided delivery approach, to have an effective risk monitoring procedure embedded.

Like previous research, (e.g. Fox & Berrick, 2007; Forsner et al., 2005) this work has demonstrated the differences in the experiences, opinions and priorities across the participant groups regarding the development of a new treatment. This highlights the need to use the opinions of multiple stakeholders within this context. Whilst considering the views of adolescents in their own care is essential to avoid the misinterpretation of their needs (Fox & Berrick, 2007), the views of healthcare professionals also need acknowledgement. The information gathered from healthcare professionals in this qualitative work was invaluable for informing the development of a new treatment with those who participated providing salient information from a clinical perspective. Particularly, it provided useful information about the new programme's practical application, its position within the care pathway and highlighted the need to consider risk monitoring with an online approach.

What is especially interesting are the differences found between the perceptions of the two adolescent groups. All adolescent participants were from similar age ranges, ethnic groups and lived within relative geographical proximity yet there were clear differences in their opinions based upon whether or not they had received support for low mood and/or depression. Whilst it is undoubtedly important to tailor treatments to target users, this highlights the importance of considering the needs of those for whom the programme may be useful but who do not routinely access treatments. As previously discussed, (see 1.3) 65% of young people with low mood and/or depression do not access care (Gladstone et al., 2015) often due to issues with stigma, negative attitudes about help-seeking, accessibility and their reluctance to engage one-to-one with a therapist (Gulliver et al., 2010; Rickwood et al., 2005). Although the community sample in this qualitative work was small, they provided an insight into the opinions of a group of individuals who had very limited experience of CAMHS and who may have not accessed services because of the aforementioned issues.

These findings therefore demonstrate the need to involve all stakeholders in the development of new interventions to ensure they meet the needs of the target user. This systemic approach needs to incorporate the views of those with experience of the treatment who are the experts on what works and what does not, those who have not accessed treatment who are the experts on the barriers and how these may be overcome and healthcare professionals who are the experts on the practical application of therapy and its integration into services.

3.4.4 Conclusions

Information about what both adolescents and healthcare professionals believe should be included in an online version of BA were obtained through focus groups and interviews. Although there were similarities in the opinions of the three groups, differences highlighted the need to adopt a systemic approach in the development of new interventions. In the context of an adolescent therapy, the opinions of adolescents, both with experience of accessing mental health support and those without and healthcare professionals need to be incorporated.

3.5 Chapter summary and next steps

This chapter has presented the results from focus groups and interviews with adolescents and healthcare professionals to inform the development of a new online BA therapy for adolescents experiencing low mood and/or depression. This aligns to phases two and three of co-design (Eyles et al., 2016). The next chapter consolidates the findings from the first three chapters of this thesis, alongside considering the specific changes and challenges of the adolescent period to describe the development of a new online BA programme.

Chapter Four: Adapting Behavioural Activation for adolescent use: A synthesis of evidence

Aligning to phase four of co-design (Eyles et al., 2016) this chapter consolidates the findings from the preceding chapters and demonstrates how they have been operationalised into the development of an online BA programme for adolescents. Specific focus is placed upon how these findings influenced the final programme's content, structure and presentation/delivery. Any areas about adolescent development identified as important for consideration in the programme design, following expert advice and a review of adolescent biopsychosocial literature, are explored and discussed throughout the chapter as appropriate. Where key findings from previous chapters could not be incorporated into the new programme or where compromises were required, the rationale for these decisions is provided. The chapter concludes with information about the computerisation of the programme.

4.1 Introduction

4.1.1 The importance of considering adolescent development in therapy design

As discussed in Chapter One, the adolescent period encompasses more biological, psychological and social changes than any other time of life except infancy (Lerner et al., 2018; Viner et al., 2012; Steinberg, 2005). It is therefore essential that the developmental characteristics of this period are considered during both the design and delivery of treatments addressed at this age group to enhance effectiveness (Auby, 2020; Saunter et al., 2009). These developmentally appropriate treatments should "...take into account the unique developmental issues and problems characteristic of adolescence..." (Wagner 2003, p. 1349).

Although the importance of developmental factors in designing treatments is increasingly recognised (Garber et al., 2016; Suveg et al., 2007; Cicchetti & Rogosch, 2002) and more developmentally appropriate treatments are emerging, discrepancies in treatments developed for adolescents still exist with few including the developmental issues of this life stage in their design and evaluation (Holmbeck, et al., 2006). In a review by Weisz and Hawley (2002) only one in 14 empirically supported treatments for ADHD, depression, anxiety and conduct problems was specifically designed for adolescents. The remaining treatments were either downward extensions of treatments for adults (n=6) or upward extensions of treatments for children (n=7). This

approach to 'borrow' treatments from other patient groups has also been reported in several CBT treatment protocols (e.g. Holmbeck et al., 2006; D'Amico et al., 2005). Consequently, the characteristics of treatments applied to adolescents may not meet their specific developmental needs in relation to the language, materials, activities and tempo of the treatment (Saunter et al., 2009). According to Garber et al. (2016), this is particularly evident regarding depression treatments with limited attention given to adolescents' developmental demands.

Besides extending both child and adult treatments for adolescent use it has been suggested that the 'developmental level uniformity myth' (Holmbeck et al., 2006; Kendall, Lerner & Craighead, 1984) may be inadvertently endorsed by therapists. Here, clinicians can view children and adolescents of different ages as homogenous, disregarding developmental level and assuming that a single treatment approach will meet the needs of individuals at various developmental stages. This 'one-size-fits-all' approach may negatively impact treatment outcomes (Garber et al., 2016; Holmbeck et al., 2006) including adherence (Taddeo, Egedy & Frappier, 2008). For example, treatments may be considered to be too simplistic or too advanced if developmental level is disregarded (Garber et al., 2016).

A variety of behavioural strategies are employed when delivering BA (Chapter One), with Kanter et al. (2010) identifying eight categories of interventions and several 'ancillary' therapy components frequently delivered alongside them. Across BA deliveries, variations exist in both the combination of strategies employed and how they are applied. (Kanter et al., 2010). This is evident when looking at contemporary BA deliveries including *BA* (Martell et al., 2001) and Brief Behavioral Treatment for Depression (BATD/BATD-R; Lejuez et al., 2011, 2001). Although both of these are based upon traditional BA models and share several similar characteristics, there are evident variations in their approaches (see 1.2.3).

When examining the components inherent to BA much information has been based upon adult populations with emerging BA interventions for adolescents generally being based upon adult models. For example, Brief BA (Pass & Reynolds, 2014) is based upon BATD/BATD-R (Lejuez et al., 2011; 2001) and the Adolescent Behavioural Activation Program (A-BAP: McCauley et al., (2015)) is based upon *BA* (Martell et al., 2001). Both of these treatment approaches therefore use many of the techniques designed originally for use with adults. In the development of Brief BA (Pass & Reynolds, 2014) the authors contended that elements of BA fit well with the developmental period of adolescence particularly it's simple approach and low

cognitive demand (Pass et al., 2015). This was supported by McCauley et al. (2015) who suggested that BA's focus on behavioural strategies may be regarded as more acceptable by some adolescents. Through making adaptations to adult BA models to make them more engaging and relevant to young people, BA has demonstrated its acceptability with adolescents (e.g. Pass, Sancho et al., 2018; Pass, et al., 2017).

Developing a BA treatment for adolescents and selecting components for inclusion, unavoidably has to involve taking into consideration existing evidence and when this is largely in the adult field it is inevitable that there will be some 'downward extending' of components. Although not ideal, to develop a new therapy that is synonymous to BA, the components of the models that have been deemed effective require consideration. However, when designing BA for adolescents it is imperative that the treatment components are carefully selected, delivered and presented, with the user group in mind and based upon what would be most effective for them as opposed to making inferences from what is known about adults. Adopting this approach, regarded as empathy-based design, (see 1.4.2) allows weaknesses in digital interventions (e.g. low adherence and high attrition) to be addressed during their development (Scholten & Granic, 2019). Therefore, in producing a BA programme delivered in an online format for adolescents, to focus upon *who* the intervention was intended for, consideration of the developmental needs of the target audience was required at the outset of its design.

To determine which developmental factors were important for consideration within this context, expert advice was sought (including from a child and adolescent psychiatrist (BW) and an expert in adolescent development (LF)). This provided an overview of potential areas of relevance with further reading identifying additional factors for consideration. The area of biopsychosocial development is extensive and far broader than the constraints of this thesis. Thus, all of the changes impacting upon adolescence could not be covered in this chapter nor examined in detail. Instead, consideration is given to the developmental changes deemed to be most pertinent within the context of developing a psychological treatment, in particular psychosocial development.

4.1.2 Defining the programme user

As presented in Chapter One, this work has focused upon the development of a new online BA programme for adolescents aged 11 to 16 with low mood and/or depression. During the qualitative study (Chapter Three) additional information was collected,

particularly from healthcare professionals about programme user characteristics. They suggested developing a programme of this type for individuals with mild to moderate low mood and/or depression, expressing concerns that those with more severe presentations would have difficulties using an online therapy. Similar findings have been reported elsewhere (e.g. Rasing et al., 2020). Furthermore, where NICE guidelines have recommended digital deliveries of CBT this has been in relation to young people experiencing mild depression (NICE, 2019). The new BA programme was therefore designed for use with adolescents experiencing mild to moderate low mood and/or depression.

4.1.3 The stages of programme development (BALM)

The first and current version of the online BA programme was completed in 2019. The programme's development was iterative and involved the complex task of incorporating the findings from the preceding chapters, with consideration for important factors associated with adolescent development, into a workable and user-appropriate therapy within time and financial constraints. Although there were many elements to the programme development, the three key areas considered at the outset were its content, structure and presentation/delivery. Adopting a staged approach, programme content was established first followed by its structure and finally its presentation/delivery.

How the findings from the preceding chapters were incorporated varied, whilst those from all three chapters influenced the programme's content and structure, its presentation/delivery were predominantly guided by the qualitative study (Chapter Three). This approach resulted in a completed draft of the therapy package, in paper-format which could be further refined ahead of computerisation. Each of these three stages of programme development are described in turn.

4.2 Stage one: Selecting the programme content

Selecting the programme content was originally guided by examining the BA approaches developed for adult use. This included Kanter et al's (2010) eight categories of BA interventions and ancillary therapy components as well as variations to these approaches as described in both *BA* (Martell et al., 2001) and *BATD/BATD-R* (Lejuez et al., 2011; 2001). Although this provided key information about the components deemed effective for inclusion in BA, based upon adult treatment, these components could not simply be reproduced within the new programme with the

assumption that they would be effective for adolescents also. This prompted an examination of what components of adult therapy can be effective when used with young people and how they can be adapted to make their application appropriate. The findings from the systematic review (Chapter Two) provided useful information for this purpose. A wide range of terms were included in the review's search strategy to ensure that studies delivering techniques fundamental to BA, but presented under a different name, were identified. Although elements of the interventions delivered within the ten included studies were presented briefly in Chapter Two, they were not discussed in detail.

Within the ten included study papers, to varying degrees, information about the BA treatments delivered was provided and the majority had an associated treatment manual. Sufficient information about the interventions delivered within trials is not always provided, making comparisons within systematic reviews and meta-analyses difficult (e.g. Hollis et al., 2017; Hoffman, Erueti & Glasziou, 2013). Therefore, to gather as much information as possible, where papers included a treatment manual, copies were requested from the authors— four were received. The amount of information relating to the BA interventions discussed within the systematic review varied, with the reporting of some interventions being limited and requiring caution with their interpretation.

All but one (Stark, 1985) of the studies within the review were conducted post 2000 and therefore the majority were based upon the more contemporary approaches to BA; *BA* by Martell et al. (2001) (e.g. McCauley et al., 2015; Ritschel et al., 2011), *BATD/BATD-R* by Lejuez et al., (2011; 2001) (e.g. Wallis et al., 2012) or a combination of both (e.g. Chu et al., 2016; 2009; Douleh, 2013). The BA components used with young people relative to the eight categories of interventions as outlined in the review by Kanter et al. (2010) are presented in Table 14.

Table 14: The BA components delivered within included systematic review papers relative to Kanter et al. (2010) intervention categories

	Activity Monitoring	Assessment of goals and values	Activity Scheduling	Skills Training	Contingency Management	Procedures Targeting Verbal Behaviours	Procedures Targeting Avoidance	Relaxation Training
Chu et al. (2016; 2009)	✓	✓	✓	✓	X	✓	✓	X
Douleh (2013)	✓	✓	✓	Unknown	Unknown	✓	Unknown	Unknown
Jacob et al. (2013)	✓	✓	✓	✓	Unknown	✓	✓	X
McCauley et al. (2015)	✓	✓	✓	✓	✓	✓	✓	✓
Riley and Gaynor (2014)	✓	X	✓	✓	✓	X	X	X
Ritschel et al. (2011)	✓	✓	✓	✓	✓	✓	✓	X
Stark (1985)	✓	X	✓	✓	✓	X	X	X
Wallis et al. (2012)	✓	✓	✓	✓	X	✓	✓	✓ Optional
Weersing et al. (2008)	✓	✓	✓	✓	X	✓	✓	✓

Only one of the BA studies within the systematic review (McCauley et al., 2015) used all of the BA interventions identified by Kanter et al. (2010) (Table 14). When examining the studies combined, all included activity scheduling and activity monitoring with the remaining intervention types delivered in only a selection. This is consistent with the findings of Kanter et al. (2010) regarding BA deliveries with adults. Further examination also demonstrated that additional components of therapy were included in BA when delivered with young people. Given the varied approaches to BA more information was required to inform the components for inclusion in the new programme.

As presented in Chapter Three, twenty-seven individuals participated in focus groups and interviews between 2016 and 2019 to inform the new BA programme's development. Information about its content was collected in both discussions with participants and the completion of two activities (see 3.2.6.1; Appendix B). The first activity required participants to select what they perceived to be the important components for inclusion. The second activity, completed by adolescent participants only, included ranking several factors to increase the programme's attractiveness, some of which related to programme content.

The next part of this chapter provides an overview of the content selected for inclusion in the new programme through consolidating what is known about the BA components as delivered with both adults and young people and the findings from the qualitative work. Information as to the rationale for either including or avoiding any treatment component is provided. Content is presented in four groups:

- i) Content relative to the eight BA intervention types as described by Kanter et al. (2010)
- ii) Content described by Kanter et al. (2010) as ancillary
- iii) Additional 'adolescent specific' therapy components identified within the systematic review when BA has been delivered with young people
- iv) Additional content recommendations from the qualitative work.

4.2.1 Programme content relative to the eight BA interventions (Kanter et al., 2010)

When reviewing Kanter et al's (2010) eight BA intervention types it is apparent that some therapy components can be placed in more than one category. For the purpose

of this chapter, and to avoid repetition each component is positioned within the category where it is presumed to have the best fit.

4.2.1.1 Activity Monitoring

Kanter et al. (2010) described activity monitoring as typically serving two functions; informing activation through identifying baseline activity levels and associated moods and demonstrating to individuals the meaningful relationships that exist between their activity and mood. All ten of the studies within the systematic review included activity monitoring within their BA deliveries with a variety of techniques employed.

Across the studies, activity monitoring was introduced early and generally lasted for the duration of therapy. In early sessions young people were encouraged to consider the connections between their activities and moods; identifying both things that made them feel good and those that negatively affected the way they were feeling. In the study by McCauley et al. (2015) emphasis was placed upon adolescents distinguishing between goal-directed and mood-directed behaviour thus understanding the importance of engaging in activities to help improve mood rather than waiting for mood to improve before engaging. Generally, across studies individuals recorded their daily activities and moods using a diary sheet, an activity repeated regularly and often completed outside therapy as homework. This information was then presented in charts or graphs and used within therapy to observe patterns and guide activation.

In the qualitative study all healthcare professionals wanted activity monitoring to be included in the new programme, yet, whilst identifying the benefits of this component, some adolescent participants expressed concerns, specifically the potential adverse impact on mood if individuals were asked to record negative information. Consequently, some proposed that only the recording of positive activities and moods should be included. Concerns were also expressed about this component and disclosure with suggestions made that its implementation should only involve 'ticking boxes'.

Activity monitoring is one of the fundamental components of BA (Kanter et al., 2010) and was included in all of the interventions referenced within the systematic review. Its inclusion in the new programme was therefore regarded as important despite being unpopular with several participants of the qualitative study. However, the concerns expressed were considered when it was implemented. Using diary sheets, users are asked to record activities engaged in both at the start of the programme when reporting

current engagement and later when scheduling new activities. Tick boxes are provided where users select a joy rating (from 0: not enjoyable at all, to 10: really enjoyable) and a mood rating (from 0: feeling really low/negative, to 10: feeling really happy/positive) for each activity recorded. These methods, alongside reiterating that all information entered would remain strictly confidential, aimed to allay concerns about disclosure. Although some wanted only positive information to be recorded this was not possible. Recording activities and moods that are both positive and negative allows users to identify both what helps with their low mood as well as what leads to the worsening or maintaining of symptoms. Furthermore, omitting to consider negative information could also negate several of the programme's aims both in reducing avoidance and engaging in more goal-directed rather than mood-directed behaviours – both of which require this information to be considered. As programme users select all activities to engage in it is hoped that, whilst some activities may result in them feeling low, the majority will help to improve mood. Users can also amend the activities they engage in as appropriate.

4.2.1.2 Assessment of goals and values

Although termed 'assessment of goals and values' (see 1.2.2) not all studies within Kanter et al's (2010) review assessed both of these to guide activation. Similarly, in the interventions described in the systematic review, of those including the component, eight assessed goals but only three assessed values also.

In the studies including a goals assessment, similar approaches were taken. Generally, individuals were encouraged to set goals, both short-term and long-term and shown how to break these down into manageable steps. This was often achieved using a graded approach by identifying smaller 'sub-goals' to reach a larger goal. Guidance to maximise effectiveness was given across studies to ensure goals were both practical and attainable.

Kanter et al. (2010) referenced BATD/BATD-R (Lejuez et al., 2011; 2001) as an example of how a values assessment can be completed within BA. Here an individual's valued life domains (e.g. family, social relationships) are used to guide any goals set; ensuring that any activation plans formulated are relative to what they deem important. Three of the studies within the systematic review (McCauley et al., 2015; Douleh, 2013; Wallis et al., 2012) considered values as well. For example, in the study by Douleh (2013), assessment forms were completed where adolescents identified their values in several areas (e.g. family/caregiver relations, social relations,

learning/education), whilst the BA by McCauley et al. (2015) asked adolescents to plot the people and activities most important to them in concentric circles.

Most qualitative study participants endorsed a goal setting component, yet only the healthcare professionals discussed its implementation. They regarded it as a vital treatment component and suggested basing its presentation upon goal-based outcomes or using shared decision making or option grids in the new programme. Despite these suggestions, there was uncertainty as to whether goal setting could be successfully implemented in an online format.

Given the qualitative study findings and its successful delivery in previous BA interventions, goal setting was incorporated within the new programme. Owing to the healthcare professionals' concerns it was important that the goal setting included was simple and could be completed independently by programme users. A similar approach to those taken in face-to-face BA with young people was therefore adopted: individuals were encouraged to set both short-term and long-term goals, which could be broken down into manageable steps. Through linking this with the activity scheduling component, adolescents were therefore encouraged to schedule small, manageable activities that might help them to work towards the goals they have set. In addition, to support activity scheduling, and aligning with McCauley et al. (2015), adolescents were presented with information that demonstrated the difference between mood-directed and goal-directed behaviour.

Although only evident in three of the interventions in the systematic review, a values assessment was also incorporated into the new programme. Including this alongside goal setting was deemed important relative to several developmental changes occurring during the adolescent period. As discussed in more detail later (see 4.2.4.1), adolescence has been associated with increased egocentricity. Stallard (2019) highlighted how, during this time, adolescents may become preoccupied with their own views and struggle to consider alternatives. As a result, approaching therapy in a non-judgemental way with a willingness to consider new ideas may be difficult. Therefore, in relation to the delivery of CBT with adolescents, Stallard (2019) outlined the importance of acknowledging the views of individuals whilst encouraging them to consider new information relative to their beliefs or assumptions. Whilst the development of an online BA therapy for adolescents is different from a face-to-face delivery of CBT, as referenced by Stallard when making these assertions, adopting a reflective approach in the development of a new BA programme was important. In BA individuals are encouraged to increase engagement in adaptive activities whilst

reducing engagement in activities that can increase risk of or maintain depressive symptoms. Approaching this in a reflective way and encouraging individuals to achieve this through an assessment of the things important to them is likely to be more successful when BA is delivered with adolescents.

A similar approach to that described in BATD/BATD-R (Lejuez, et al., 2011; 2001) was taken with some modifications to ensure it was adolescent friendly (i.e. placing focus upon education-related values rather than employment). Such modifications have been seen in other deliveries of BA for young people (e.g. Douleh, 2013). This activity is used as a precursor to goal setting with adolescents asked to consider four life domains (relationships, education, hobbies/interests, health) and select both short and long-term goals relative to each. Like BATD/BATD-R (Lejuez, et al., 2011; 2001) this aimed to ensure that activation was relative to what users deemed important thus increasing the likelihood of engagement. This approach also provides structure to the goal setting component. Instead of individuals being asked to think of goals generally, they must consider them within the context of a life domain with examples provided for additional guidance. Adopting this approach, alongside allowing adolescents the flexibility to select the activities they participate in, when and in what order enables them to consider alternative ideas (e.g. increasing activity engagement) in relation to their individual assumptions and beliefs as suggested by Stallard (2019).

4.2.1.3 Activity scheduling

Activity scheduling was a treatment component consistently identified within the review by Kanter et al. (2010). As with activity monitoring, all ten of the studies within the systematic review used activity scheduling with young people encouraged to identify and complete activities between treatment sessions. Generally, a diary sheet was used by individuals to plan when they would engage in activities, ensuring they appropriately fitted around other commitments. Aligning with several adult BA interventions (Kanter et al., 2010), activity scheduling was often graded with some incorporating activity hierarchies. Here, as in BATD/BATD-R (Lejuez et al., 2011; 2001) adolescents were encouraged to work through a hierarchy of activities, completing simpler ones first and increasing complexity over time.

The amount of guidance provided for activity scheduling varied across studies. Whilst some simply reported that individuals selected appropriate activities and scheduled times to do them, others (e.g. Wallis et al., 2012; Stark, 1985) dedicated time to identifying specific activity details such as with whom and for how long an activity would

be completed, to maximise the chances of completion. Information to ensure selected activities complied with rules, finances and capabilities was also presented in some studies.

Most participants of the qualitative study endorsed the inclusion of activity scheduling in the new programme, yet only adolescent participants made suggestions about its implementation. Such suggestions included providing links to various clubs (e.g. sports, music) to offer ideas about different activities to engage in and ways to become involved and encouraging parental involvement to increase effectiveness.

Since activity scheduling is a key component of BA and owing to its endorsement in the qualitative work, it was included in the new programme. Users select 12 activities to complete and schedule times to do them over four-weeks using diary sheets. To maximise the effectiveness of activation and like other BA deliveries (e.g. BATD/BATD-R; Lejuez et al., 2011; 2001) activity scheduling is graded with users placing their activities into a hierarchy and completing them in order of complexity. Although empirical evidence is available to support activity scheduling (Kanter et al., 2010) this does not extend to nuanced approaches like graded task assignments nor the use of hierarchies. Despite this, through employing a graded approach it was hoped that individuals would be able to gradually work through activities, increasing them in difficulty as their confidence grows. To minimise user burden, additional details such as with whom and for how long activities are to be completed are not required.

Deciding which activities to participate in is solely the responsibility of the programme user, an approach that has been regarded favourably elsewhere (Davidson et al., 2014). Unlike some studies (e.g. McCauley et al., 2015) individuals are not provided with a list of activities to select from nor with links to clubs as suggested in the qualitative interviews. Instead, it is recommended that adolescents might find it useful to search the internet for possible activities to engage in. This encourages individuals to develop the skill of learning to pick things themselves rather than selecting from a list and, through not including links, the programme does not appear to endorse particular clubs/activities. However, consistent with the suggestion by some participants of the qualitative study, if a user wishes for a parent to support them in selecting activities they can do so. Suggestions for including peers in activity completion are also made to provide support and enhance adherence. Including others in programme completion is optional throughout.

The period of adolescence sees many individuals demonstrating an increased need for autonomy. This is often strongest between the ages of ten and 14 years and may be correlated with adolescents' increased reliance on peers (Steinberg & Monahan, 2007). As part of this many individuals want to assume increased responsibility for aspects of their own lives including their health, which by the end of the adolescent period they will largely, if not entirely be responsible for (Christie & Viner, 2005). Research suggests that parents are commonly involved in their child's treatment and may contribute to its success (Flessner & Piacentini, 2017; Kendall, 2006). However, whilst a child may benefit from parental involvement in treatment, an adolescent may prefer no involvement. In research examining the factors that promote and prevent willingness to seek psychological help, Sheffield, Fiorenza and Sofronoff (2004) found the main barrier to seeking help from formal sources of support reported by adolescents was a preference for them to manage their problems themselves. Allowing users to select the activities that they wish to participate in and decide whether to include others in programme completion supports their need for autonomy.

4.2.1.4 Skills training

Kanter et al. (2010) described skills training as therapy components used to help individuals develop the skills, both social and non-social, required to engage in effective behaviour. Non-social skills generally focus upon problem-solving whilst social skills are often associated with improving the skills required to obtain and maintain contact with social reinforcement.

Targeting non-social skills in BA can be achieved through activity scheduling, where skill building assignments are employed (Kanter et al., 2009) and via problem-solving. In the studies described by Kanter et al. (2010), where a problem-solving intervention was used, despite some variation, the majority generally used a structured step-by-step approach. Kanter et al. (2010) referenced the work of Nezu, Nezu and Perri (1989) as an example of a typical problem-solving sequence. This five-step approach requires individuals to (1) identify a problem, (2) brainstorm alternative solutions, (3) evaluate each solution, (4) consider what is needed to implement solutions and then (5) implement and evaluate them.

Most BA interventions described within the systematic review (Chapter Two), incorporated a problem-solving component, often based on a similar sequence to that by Nezu et al. (1989) but presented in a step-by-step acronym to follow. Examples included ACTION: Assess, Choose, Try, Integrate, Observe, New behaviour (Jacob et

al., 2013; Ritschel et al., 2011²), COPE: Calm and clarify, Options, Perform, Evaluate (McCauley et al., 2015) and STEPS: State problem, Think of solution, Evaluate each solution, Pick one, See if it works (Chu et al., 2016; 2009; Riley & Gaynor, 2014). Across included studies, problem-solving techniques were introduced to increase engagement in pleasant activities and reduce engagement in avoidant behaviours.

Problem-solving was selected for inclusion in the new programme by most participants of the qualitative study yet few discussed its implementation. Concerns were however expressed by healthcare professionals who, although supportive of its inclusion, felt that problem-solving may be difficult given its person-centredness and individualised nature.

Problem-solving was included in the new programme not only given its endorsement by participants of the qualitative study and its suggested value in helping individuals engage in effective behaviour (Kanter et al., 2010) but also owing to several developmental changes occurring during the adolescent period.

According to the theory of cognitive development by Piaget (1972), children's thinking moves through a series of stages as it develops. By early adolescence, individuals are transitioning from 'concrete' to more 'abstract' thinking (Taddeo et al., 2008), referred to as the formal operations stage (Piaget, 1972). During this stage, starting around the age of 11 years and concluding between the ages of 15 and 20 years, individuals develop the ability to think more logically and are able to not only formulate hypotheses but to test them systematically also (Arnett & Hughes, 2012). According to Tyler (2020^a) increases in more abstract and hypothetical thinking can elicit new ways of information processing including greater introspection, hypocrisy and pseudo-stupidity where adolescents overlook obvious solutions and approach problems in a complex way. Whilst the transition from concrete to more abstract thinking is addressed in more detail later (see 4.4.1.2), the emergence of pseudo-stupidity has particular relevance to problem-solving. In developing a problem-solving component, the propensity of adolescents to overlook obvious solutions and focus on complex ones often leading to failure had to be considered. Therefore, any problem-solving components designed for adolescents needed to encourage simple and logical steps to solving problems in order to enhance success. Thus, the problem-solving component is presented as a simple step-by-step guide that users can follow to identify problems and explore solutions.

² NB: although very similar the N of ACTION varies slightly between these studies - In Jacob et al. (2013) the N describes observation of the 'New' behaviour, Ritschel et al. (2011) use N to denote 'Never giving up'

Whilst this is bespoke and does not follow a particular acronym, the stages are similar to those outlined by Nezu et al. (1989) and the sequence in STEPS as used in the studies by Chu et al. (2016; 2009) and Riley and Gaynor (2014). This was added as a supplementary component and, although accessible at all times, users are specifically directed to this if having difficulty completing planned activities.

For studies within Kanter et al's (2010) review where focus was placed upon social skills training, various techniques (e.g. modelling, role-play, therapeutic feedback) were used to target deficits in, for example, assertiveness, communication and social interactions. Although most studies within the systematic review included a non-social skills component, generally problem-solving, fewer included a social skills component. Kanter et al. (2010) highlighted how *BA* (Martell et al., 2001) employed techniques which focused upon social skills but *BATD/BATD-R* (Lejuez et al., 2011; 2001) did not. Therefore, as several of the studies within the systematic review were based upon *BATD/BATD-R* this is unsurprising.

Where focus was placed upon social skills training, some employed techniques similar to those described by Kanter et al. (2010) whilst others adopted alternatives. Chu et al. (2016; 2009) included role-play, assertiveness tasks and mock social interactions to address issues with social anxiety whilst Riley and Gaynor (2014) used self-monitoring videos to allow individuals to observe and adapt self-presentation styles with the aim of making interactions with others more pleasant. In the study by Ritschel et al. (2011), the authors described how as part of mastery practice, young people who set themselves goals relative to social anxiety were encouraged to increase social contact, but specific techniques were not discussed.

The participants of the qualitative study were asked about the inclusion of communication in the new programme with differences in their opinions apparent. Whilst most adolescent participants wanted communication included few healthcare professionals did. It became apparent during discussions with adolescents that many found it difficult to communicate how they were feeling to others, particularly their parents and regarded the inclusion of information about communication as useful for improving their social skills. This finding may have been influenced by the relationship changes seen during adolescence.

Despite parents playing a dominant role during childhood, adolescence sees an increase in independence from the family (Stamato et al., 2018) and increased emphasis upon peer relationships (Curtis, 2015). Regardless of these changes, both

parents and peers can be important sources of support for adolescents. Family support and communication have been associated with decreased emotional and behavioural problems in adolescents (Paclikova et al., 2018; Heerde & Hemphill, 2018). In addition, perceived parental support has been linked to decreased risk of depressive symptom development (Santens et al., 2018), decreased likelihood of self-harm (Klemmera et al., 2017) and reported by some adolescents to be a main contributor in them ending engagement in risky behaviours (Stamato et al., 2018). Thus, the family unit has been identified as the most stable source of support during adolescence (Pössell et al., 2018). Peers also play an important role in supporting adolescents including providing an opportunity for developing and practicing social skills, opportunities for self-disclosure and help with the development of both self-worth and self-expression (Laible, Carlo & Raffaelli, 2000). In a survey-based study by Sheffield et al. (2004) adolescents with personal, emotional or behavioural problems selected friends and family as the largest sources of support compared to more formal support including school counsellors, doctors and psychiatrists.

According to Heerde and Hemphill (2018) young people are more likely to feel able to seek support from both family and peers where environments allow for open communication, respect, listening and problem-solving (Heerde & Hemphill, 2018). Therefore, the findings from the qualitative work and acknowledging the critical role parents and peers can play in supporting adolescents, including a section in the programme about communication was deemed essential. Aligning to the findings from the qualitative study that many adolescents do not feel comfortable talking to others, handouts are provided that can be given to others. These, with versions available for both parent/guardians and friends, provide additional information about low mood and/or depression, explain the BA treatment rationale and outline how best to provide support to an adolescent when they are using the programme. It was hoped that this information could be utilised where a programme user required support from others but did not feel confident in communicating their experiences. As the qualitative work demonstrated that communication was not favoured by all, this information is supplementary with users determining whether to access it.

4.2.1.5 Contingency management

Contingency management has been described as the techniques used to help individuals make changes to ensure that their engagement in improved behaviours is reinforced by their environment (Kanter et al., 2010). Featuring in both BA (Martell et al., 2001) and BATD/R (Lejuez et al., 2011; 2001), contingency management can

include both self-reinforcement and receiving reinforcement from others. In the adult studies that used them, these techniques included encouraging individuals to reward themselves for achieving a goal and making contracts with family or friends to reinforce desired behaviours. For example, in *BA* (Martell et al., 2001) individuals were encouraged to invite a significant other to a treatment session so they could identify ways in which they may be reinforcing depressed mood and adapt their responses accordingly.

Four of the studies within the systematic review (Chapter Two) used some form of contingency management. In three of these (Riley & Gaynor, 2014; Ritschel et al., 2011; Stark, 1985), the use of rewards was discussed in response to desired behaviour with small prizes (Stark, 1985) or stickers (Riley & Gaynor, 2014) provided as examples. In response to this 'gaining rewards' was included in the adolescent-only activity completed within the qualitative study. Both adolescent samples rated this similarly, positioning it 5th or 6th out of ten components and not discussing its implementation. Owing to this and the complexities associated with providing rewards when adopting an online therapy delivery, gaining rewards was omitted from the new programme.

The use of contracts was reported in two of the studies within the systematic review. In the study by Stark (1985) young people completed contracts to confirm that they would complete the work required each session whilst in the study by McCauley et al. (2015) parents detailed how they would support their child during *BA* treatment.

Although self-reinforcement is not included in the new programme, the reinforcement involving others is addressed. Whilst receiving social support from others can be beneficial (see 4.2.1.4), the period of adolescence also sees an increase in conflict between adolescents and both family and peers with negative impacts arising from both. Parent-teen conflict has been shown to significantly increase the risk of depression and suicide in young people (Ewing et al., 2015) whilst conflict in the wider family has been identified as a negative moderator of treatment outcome (e.g. Asarnow et al., 2009). It has been suggested that the relationship between parent-conflict and adolescent depression may be bidirectional (Rengasamy et al., 2013). Regarding peers, conflicts within these relationships may contribute to low mood and/or depression or exacerbate symptoms with peer problems commonly reported amongst clinically referred young people (Weisz & Hawley, 2002). In the delivery of *BA*, establishing a conducive environment to support behaviour change is essential and therefore addressing how conflicts can be avoided and/or resolved may positively

impact upon treatment outcomes. Therefore, alongside providing information about communication, the new programme provides users with supplementary information about conflict resolution and includes strategies that users can employ to make talking to others easier. Whilst the programme encourages individuals to strengthen their relationships with others to support positive behaviour change it is flexible to accommodate the changing relationship dynamics evident during the adolescent period. It could not be assumed that all adolescents would be experiencing conflict. Therefore, presenting information about conflict resolution as supplementary allowed access to those whom this information was deemed relevant whilst not disadvantaging others. Although unlike some previous deliveries of BA the new programme does not require individuals to make formal contracts with family or peers to reinforce behaviour, like *BA* (Martell et al., 2001) users can choose whether to include others in the completion of sessions.

4.2.1.6 Procedures targeting verbal behaviour

Kanter et al. (2010) identified procedures targeting verbal behaviours as techniques used to reduce the number of occurrences of negative covert verbal behaviours (i.e. cognitions) and increase positive ones. *BA* (Martell et al., 2001) provided an example of using this intervention type by assessing rumination (via functional analysis). Here, contextual triggers for depression and the responses to these triggers are identified with particular focus placed upon; (1) depression triggers, (2) depressive symptoms experienced, (3) responses to and attempts to cope with depression, (4) the impact of avoidance patterns and (5) disrupted routines. Through this, individuals are encouraged to recognise triggers to their depression and modify their behaviour or avoid such triggers accordingly. Within this context, rumination was regarded as an avoidant behaviour and therefore Martell et al. (2001) emphasised the importance of examining the specific triggers to rumination via functional analysis rather than addressing its content (Kanter et al., 2010).

Most studies within the systematic review employed techniques to target verbal behaviours in their BA deliveries also (see Table 14). Like in *BA* (Martell et al., 2001), several conducted a functional analysis with young people, including to assess ruminative thinking. Whilst rumination has been used as an example across studies, the use of functional analysis has not necessarily been limited to this but for all problematic behaviours (e.g. Ritschel et al., 2011). Martell et al. (2001) described how overall treatment is guided by the functional analysis conducted and therefore this component features early in treatment. This was true also of the studies identified in

the systematic review where a functional analysis was conducted. For example, in McCauley et al's (2015) BA early sessions examine the role of reinforcement in the maintenance of behaviour with specific focus placed upon evaluating the 'pay-off versus price' and the short and long-term consequences of behavioural choices. The studies by Chu et al. (2016; 2009) described functional analysis as one of the main components of their BA delivery with individuals asked to consider their avoidant behaviours and the effects of these early in treatment. Besides functional analysis, mindfulness was reported in two studies within the systematic review (Jacob et al., 2013; Ritschel et al., 2011) as an additional technique to target ruminative thinking.

Although the new programme's online format made completing functional analyses with users difficult, as functional analysis aims to identify factors that maintain depression and make changes accordingly, several of the techniques used within this context (e.g. problem-solving, techniques to reduce avoidance) are described elsewhere. Therefore, whilst the intervention type 'procedures targeting verbal behaviour' is included in the new programme, information about this is presented more so in other sections of this chapter. Pass et al. (2015) contended that with cognitive development ongoing during adolescence, many adolescents could find cognitive-based therapies challenging. Therefore, it is envisaged that covert verbal behaviours will be addressed via other included techniques used in the programme to increase activation and reduce avoidance rather than providing specific sections focusing upon cognitions.

4.2.1.7 Procedures targeting avoidance

Procedures targeting avoidance was included as one of the eight BA intervention types (Kanter et al., 2010) due to its empirical support despite only being identified in BA (Martell et al., 2001). Here the authors contended that individuals who have depression often engage in avoidant behaviours to ease the discomfort of their condition, avoidance which in turn can exacerbate their symptoms. Therefore, within BA (Martell et al., 2001) individuals are encouraged to identify avoidant behaviours and replace them with alternatives. Specifically, Martell et al. (2001) addressed avoidance using an acronym: TRAP/TRAC. Here, TRAP denotes 'Trigger', 'Response' and 'Avoidance Pattern'. Individuals are encouraged to identify their avoidant behaviours and replace them with 'Alternative Coping', changing TRAP into TRAC.

Although BA (Martell et al. 2001) was the only study identified in Kanter et al's (2010) review as including techniques to target avoidance, this was mentioned in seven of the studies within the systematic review, with five of these (Chu et al., 2016; 2009;

McCauley et al., 2015; Jacob et al., 2013; Ritschel et al., 2011) incorporating TRAP/TRAC. Alternative approaches to TRAP/TRAC included discussions about the fight-or-flight response (Weersing et al., 2008) or the reviewing of different scenarios with consideration for the impact of avoidance on each (Wallis et al., 2012).

During the qualitative study it was important to ascertain whether individuals felt the new programme should incorporate information that focused upon the identification of alternative coping. However, to aid understanding, this was presented to participants as two components: 'learning about coping skills' and 'identifying barriers', rather than the more complex term 'procedures targeting avoidance'. Whilst inclusion of these components was endorsed by the participants of the qualitative study there was little discussion about their implementation.

Based upon the qualitative findings and a review of previous BA approaches, including information about coping skills and encouraging individuals to identify barriers to activation within the new programme were deemed important. The inclusion of activity scheduling, to some degree achieved this through encouraging activity engagement and thereby reducing avoidance. Users are also encouraged to consider what might have prevented them from completing an activity and provided with information about how to avoid such barriers in future activation attempts. However, to maximise the effectiveness of activity scheduling, exploring the benefits of activation relative to avoidance within the context of depression was required. Therefore, in the new programme diagrams are presented that demonstrate the depression cycle and depict how avoidance can both exacerbate and maintain depressive symptoms. Examples are provided to allow users to see how different outcomes can arise relative to whether they adopt an avoidant way of coping or an alternative. To further support users in identifying avoidant behaviours and considering alternatives, TRAP/TRAC is also employed. It was hoped that this, alongside providing information to demonstrate the impact of avoidance on mood, would assist with activation. When introducing TRAP/TRAC some brief information is presented to users to explain the role of coping skills with both positive (e.g. talking to others) and negative examples (e.g. rumination) provided. However, this information is minimal as, whilst it was deemed important to provide some context for TRAP/TRAC, too much information or elaboration was considered unnecessary.

Including information about alternative coping in the new programme was further supported during the review of adolescent development. The period of adolescence has been associated with a higher propensity for engagement in risk-taking behaviours

(Steinberg, 2008) with research in this area providing several suggestions as to why. According to Steinberg (2008) increased risk-taking during adolescence is likely to be associated with biological changes occurring during puberty, particularly changes in dopaminergic activity which is involved in regulating affect and motivation. Spear (2000) contended that adolescent risk-taking might result from young people not getting sufficient stimulation from certain activities and therefore replacing these activities with risky behaviours whilst Dumont et al. (2004) suggested that temporary losses in buffering capacity during puberty could elicit higher levels of dopamine in the brain eliciting increased sensitivity and making rewarding stimuli to be experienced as more rewarding. However, Steinberg (2008) highlighted that knowledge about structural and functional changes in the brain exceed understanding about the links between these changes and adolescent behaviour and therefore should be regarded more as 'reasonable speculation', with causality unclear. Furthermore, not all adolescents will engage in risk taking behaviours with some during this period having a higher propensity for increased social avoidance, something which may be further mediated if experiencing depression (Miers et al., 2014).

Whilst the new programme does not specifically focus upon risk-taking, it is hoped that providing information about alternative coping strategies might reduce the likelihood of users adopting more avoidant approaches like engagement in risky behaviours. Although risk taking is not always bad, dissuading adolescents from engaging in negative risk-taking behaviours that could cause harm and encouraging them to identify more conducive coping skills was required. Informing adolescents of alternative coping skills, their benefits and how these could be applied through TRAP/TRAC could be a way of achieving this.

4.2.1.8 Relaxation training

Several studies in Kanter et al's (2010) review used some form of relaxation training - generally optional components used to target sleep difficulties. Three of the studies within the systematic review incorporated relaxation in their BA delivery, with variation in the amount of attention given to this. Weersing et al. (2008) placed a strong focus upon relaxation in helping with stress and anxiety, providing a relaxation CD as a supplementary material alongside therapy. Session two of their eight-week therapy predominantly focused upon stress reduction with techniques to improve mood (e.g. guided imagery, somatic relaxation) presented whilst breathing and muscle relaxation exercises were encouraged between sessions. Others (McCauley et al., 2015; Wallis et al., 2012) also used relaxation techniques but to a lesser extent. In the study by

Wallis et al. (2012) individuals were able to select the content of their final therapy session with relaxation techniques a possible option. Although there were no sessions dedicated to relaxation in the BA delivered by McCauley et al. (2015) as part of a problem-solving session adolescents were introduced to a technique (COPE) which included several relaxation techniques (i.e. counting, breathing, muscle relaxation) to help with problems or stressful situations.

Most participants of the qualitative study selected relaxation for inclusion in the new programme yet only one individual discussed its implementation, proposing the inclusion of 'satisfying videos' (videos based upon eliciting an autonomous sensory meridian response to help reduce anxiety and increase relaxation). As 'satisfying videos' are not a typical BA component they were not included in the final programme, nor were any additional relaxation techniques. Although this was identified as one of the BA intervention types by Kanter et al. (2010), with no clear guidance from participants of the qualitative study about its implementation and within the constraints of an online delivery, this component was omitted and may need to be revisited in future adaptations of the programme.

4.2.2 Content described by Kanter et al. (2010) as ancillary

Kanter et al. (2010) identified several 'ancillary' therapy components, commonly used within psychotherapies but not synonymous to BA. These included establishing a therapeutic relationship, providing the treatment rationale, maximising the effectiveness of homework, agenda setting and managing post-treatment events (e.g. providing information about relapse prevention). The studies within the systematic review (Chapter Two), adopted these techniques to varying degrees. All included some form of 'homework' or 'between-session' tasks such as mood monitoring or engaging in scheduled activities. Six of the studies also incorporated information about relapse prevention.

Given the online nature of the new programme it was not possible to incorporate techniques relating to developing a therapeutic relationship nor include young people in setting session agendas. However, information about the treatment rationale, homework assignments and relapse prevention were included.

4.2.2.1 Information about the treatment rationale

Information about the treatment rationale is provided in the new programme which includes a description of BA, an explanation of the approach' aims and introduces users to how the programme works. This was regarded as important given the increased need of adolescents to exercise autonomy, including about their own health which previously had been largely the responsibility of parents (Christie & Viner, 2005). It cannot be assumed that on reaching adolescence, individuals will be able to automatically understand issues relating to their health and make decisions accordingly. For example, Oetzel and Scherer (2003) highlighted how sometimes adolescents may disregard maladaptive symptoms yet at other times will overestimate psychological symptoms but not seek help through being ashamed. Despite many adolescents striving for autonomy, their desire to exercise it can lead to several issues including resistance, detachment and disengagement from treatment (Rubenstein, 2003; Stallard, 2002^a). According to Stallard (2002^b) these issues may result from frustration surrounding adolescents' inability to 'solve their own problems'. Therefore, in the new programme development, to support autonomy, it was important to ensure that users are provided with sufficient information about the treatment they will receive at the outset. This allows them to make an informed choice about whether to proceed thus exercising responsibility for their own health and treatment.

4.2.2.2 Homework

The qualitative study findings showed that homework was regarded of lesser importance than other therapy components. Although some healthcare professionals considered homework important for encouraging user participation between sessions others felt that if included there would be minimal compliance. The overall consensus was that if included, homework needed to be minimal, including simple exercises, and called something different; one participant suggested 'goals to achieve'.

Despite these concerns, in the delivery of CBT, correlations between homework compliance and clinical improvements have been found (e.g. Simons et al., 2012). Therefore, although unpopular, including homework in the new programme was deemed important. To ensure a balance between incorporating evidence-based components within therapy but being sensitive to target user opinions, consideration for both was required. Although the participants of the qualitative work would have generally preferred homework to have been omitted from the new programme, a compromise was reached with the homework developed guided by their stipulations.

Homework is therefore included but minimal, comprising simple exercises (e.g. activity monitoring and engagement) and, as per the participant suggestion is termed 'goals to achieve'.

4.2.2.3 Relapse prevention

Relapse prevention was selected for inclusion in the new programme by most participants of the qualitative study. Relapse rates in young people following low mood and/or depression are high with approximately 50% still depressed at 12 months (NICE, 2015) and 70% experiencing a relapse within five years (Cox et al., 2012). Providing information about relapse prevention can help with both maintaining treatment gains and developing future plans if problems re-occur (Ritterband et al., 2009). Owing to this and the endorsement by the participants of the qualitative study, relapse prevention was deemed an important component for inclusion in the new programme. To ensure that information was provided in sufficient detail, a full session is dedicated to this with users introduced to what relapses are and how to identify them and shown ways to both prevent and deal with relapses by continued activation. Pertinent topics from earlier sessions are revisited, with key points summarised.

4.2.3 Additional 'adolescent specific' therapy components

Besides the 'ancillary' components outlined by Kanter et al. (2010), the systematic review highlighted some additional treatment components that were incorporated when BA was delivered with young people. Again, these were not inherent to BA and included sessions developed specifically for, or to be completed with, parents and 'fun activities'.

4.2.3.1 Parental Involvement

Most studies within the systematic review incorporated parents within treatment sessions to some extent. Generally, parents were invited to attend between two and three pre-specified sessions (or parts thereof) throughout treatment alongside their son/daughter. Although some variation, parents typically joined early sessions when discussing the treatment rationale, and at treatment end in discussions about relapse prevention and how they could support the maintenance of treatment gains. Where a third session was attended this was often around the middle of therapy where problem-solving or goal setting were discussed. Some studies allowed for additional parental input if required (e.g. Jacob et al., 2013; Ritschel et al., 2011). In several studies (e.g.

McCauley et al., 2015; Riley & Gaynor, 2014) parent-only sessions (or segments of sessions) were included with therapy comprising a combination of child-only, parent-only and joint elements of treatment.

The important role of parents in the delivery of BA with young people was highlighted in several included studies. For example, in reinforcing appropriate behaviours and supporting therapy strategies (McCauley et al., 2015), by learning how to support activity scheduling and problem-solving (Riley & Gaynor, 2014), ensuring goals and activities were logistically and financially feasible and allowing parent-child communication difficulties to be addressed (Ritschel et al., 2011).

The qualitative study demonstrated clear differences in opinions about parental involvement in the new programme. Whilst some adolescent participants would have preferred no involvement, instead identifying friends as better in providing support, others were more positive, highlighting how including parents may enhance treatment effectiveness. Suggestions for involving parents included providing handouts about low mood and/or depression and coping techniques, having parent-only sessions or including parents in treatment sessions. It was however suggested that this involvement should be optional. In contrast, the healthcare professionals regarded parent involvement in the new programme as essential.

During the programme development, it was important to consider the valuable role that parents can play in providing support as previously discussed whilst also acknowledging the views of those who were less favourable of this. Research suggests that the need for autonomy amongst adolescents can be a barrier to seeking mental health support (Wilson & Deane, 2012). However, although many adolescents will strive for autonomy and welcome exercising control over health-related decisions this will not apply to all. Therefore, whilst psychological therapies should allow for autonomy, they need to also be sensitive to individual needs and allow adolescents to guide the level of responsibility they wish to take.

When examining the developmental demands of CBT for adolescents with depression, Garber et al. (2016) referenced the importance of considering the 'zone of proximal development' as defined by Vygotsky (1978). This relates to the difference between what an individual can learn independently and what they can achieve with guidance and support from others. Vygotsky, who regarded learning as a social process, contended that adolescents would benefit most from receiving assistance at first and then allowing this to decrease as competence increases (Arnett & Hughes, 2012).

Taking this into consideration, some users may find it helpful to have parental support in treatment sessions, particularly early on.

To address the needs of all users regarding parental involvement, a compromise was required with the new programme designed to be flexible. There are no components or whole treatment sessions designed for parents, instead users choose whether to involve a parent/guardian and if so, how. This may include asking parents to join sessions, inviting them to participate in activities (see 4.2.1.3) or simply discussing what they have been doing on the programme. Involvement is not a requisite of the treatment; some users may opt for no involvement or involvement might be changeable (e.g. during periods of conflict). Allowing users to decide whether to involve parents in treatment was further influenced by previous research examining the experiences of young people using tech-assisted CBT (McCashin et al., 2019) where parental involvement was perceived both positively and negatively. Owing to the age of the target user, parental consent is required for individuals to use the new programme and parents/guardians are informed of any potential risks arising during its use.

At various points during the new programme the benefit of involving others in treatment is discussed where users are encouraged to talk about using the programme and ask for support if required. As some participants of the qualitative study suggested that friends may be a better support to some than parents, both are mentioned. As discussed earlier (see 4.2.1.4), information handouts that can be given to parents and friends, are available to support this.

4.2.3.2 Fun activities

Incorporating a range of developmentally appropriate and 'fun' techniques have been identified as a means of engaging young people in treatments (Kingery et al., 2006). Fun activities, including videos, drawing, games/puzzles have been used as both mechanisms to deliver BA strategies (e.g. Stark, 1985) or as additional components to conclude treatment sessions (e.g. Riley & Gaynor, 2014). Although not employed in many of the studies within the systematic review, these activities were used to elicit enjoyment during therapy or provide an alternative treatment approach.

Most participants of the qualitative study selected games/puzzles and quizzes for inclusion in the new programme, however few discussed their implementation. Opinions about videos were mixed, whilst most healthcare professionals endorsed this component the adolescent participants regarded them less favourably, expressing

concerns that videos could make users feel guilty that their experiences were not as bad as others. They therefore suggested including only videos that showed positive experiences. Additional suggestions included ensuring they were not childish, patronising or containing animation.

Despite their inclusion in some studies within the systematic review and many participants of the qualitative study endorsing the inclusion of these components, games/puzzles, quizzes and videos were omitted from the new programme. Content inherent to BA had to be prioritised in the programme's development and therefore, due to both time and financial constraints these could not be included.

4.2.4 Additional recommendations of programme content from the qualitative work.

4.2.4.1 Psychoeducation

Psychoeducation has been identified as an important component in the management of depression in adolescents (Grover & Avashthi, 2019). Generally, this includes a focus upon the prevalence and symptomatology of a condition. 'Including information about low mood and/or depression' featured in the qualitative study activities and was selected for inclusion by most participants and rated of high importance in making the new programme attractive. Despite its endorsement, there were concerns that too much information may deter adolescents from using the programme and if information was complex users may not understand it and could feel worse. It was therefore proposed that any information about low mood and/or depression needed to be simple and minimal. Suggestions included providing depression statistics, information about coping strategies, descriptions of alternative treatments, information about why adolescents experience low mood and/or depression alongside methods to improve mood. To ameliorate several concerns, making this component optional was favoured.

Including some information about low mood and/or depression in the new programme was deemed important to provide some context for the symptoms that users were experiencing. However, this was written with consideration for the views expressed by the participants of the qualitative study as well as the findings from the review of adolescent development. The information provided is minimal, as not to overburden users, and as suggested includes some depression statistics and information about why some might experience depression, alongside information about typical depression symptoms. Aligning with the comments from participants of the qualitative

study, information about coping strategies is included, however, although briefly mentioned, little information is provided about alternative treatments. It was felt that this could add confusion when the programme is specifically delivering BA as the treatment approach. Making this information optional to view allows those not wanting to read about low mood and/or depression or finding it upsetting, to skip this content.

A review of adolescent development literature also highlighted the requirement to include not only information about how to identify and deal with symptoms of low mood and/or depression but also about normal psychological experiences (Oetzel & Sherer, 2003) to allow adolescents to gain a better insight into the condition. Graber (2013) reported how emotional changes, both positive and negative, will be experienced by all during puberty and therefore many individuals will report 'normative' experiences of low mood during this time. However, associations have been identified between puberty, particularly its time of onset, and more significant mental health issues such as depression which has an increased risk during the adolescent period (Crone & Dahl, 2012). Factors relating to brain maturation, the impact of environmental risk factors on the developing brain and maturational changes exposing underlying predispositions to depression have all been proposed as mediators in depression development during adolescence (Andersen & Teicher, 2008). As many young people do not present for support with low mood and/or depression due to concerns about stigma (Gulliver et al., 2010), highlighting that depression is common during adolescence may allow them to both rationalise why they may feel as they do and demonstrate that they are not alone in their experiences. Therefore, throughout the programme, users are reminded that feeling low at times can be a normal response in many situations but when this is chronic it can be negative.

An increase in egocentrism has also been identified during the adolescent period which was originally discussed by Piaget (1967) and later expanded by Elkind (1967). According to Elkind (1967) egocentrism comprises two aspects; (i) the imaginary audience where adolescents believe those around them are thinking about them, a belief that Elkind (1967) suggested could contribute to self-consciousness and (ii) the personal fable where, building on the imaginary audience, adolescents believe that others must be thinking about them because they are unique, special and invulnerable to harm (Schwartz, Maynard, & Uzelac, 2008). As part of the personal fable construct, adolescents can believe only they have experienced certain emotions and therefore others would not understand how they feel (Tyler, 2020^a). Elkind (1967) suggested that increases in egocentrism peak in early adolescence before declining during middle adolescence, however more recently Schwartz et al. (2008) reported egocentrism in

late adolescence suggesting its re-emergence later in the adolescent period. The authors concluded that egocentrism may be a response to environmental changes and new life events (Schwartz et al., 2008). The impact of the personal fable construct, particularly it leading to a view that others would not have experience of nor understand certain emotions, needed to be addressed in the new programme. Again, through providing information as part of psychoeducation about depression prevalence and its increase in adolescence, users might acknowledge that others may understand what they are experiencing, hopefully increasing the chances of them seeking additional support from others around them.

4.2.4.2 Information about other conditions

Several participants of the qualitative study wanted the new programme to include information about other conditions (e.g. eating disorders). Although some users might have comorbidities and find additional information useful, the new programme had to prioritise providing information about low mood and/or depression. Including information about other conditions in sufficient detail could not be completed within the remit of the programme nor within time and financial constraints. However, links to additional websites providing extra support are embedded in the programme. Whilst these were selected on the basis of their low mood and/or depression support, some contain information about other conditions also.

4.2.4.3 Interactive content

In the qualitative study several discussions were dedicated to the new programme's interactivity, particularly– interactions between programme users and (i) healthcare professionals, (ii) other users, (iii) the new programme itself.

i) Interaction with healthcare professionals

All participant groups outlined the need for the programme to provide interaction, to varying degrees, with additional clinical support. In a systematic review and meta-review of digital interventions for children and young people with mental health problems, Hollis et al. (2017) reported that some anxiety and depression therapies had poorer adherence where therapies had no human support. The authors concluded that human support, including guidance from therapists or contact with researchers, may enhance adherence. Providing interaction with healthcare professionals therefore

required consideration but needed to align to the new programme's unguided approach (see 1.3.2).

The healthcare professionals wanted users to be able to ask questions about things they did not understand when using the programme, suggesting a chat box to achieve this. Several adolescent participants wanted the option to receive advice from healthcare professionals about problem-solving and others wanted the programme to contain useful telephone numbers for accessing additional support. This information was incorporated into the new programme. A comments box, where users can type any questions was included and linked to a dedicated email account monitored by the research team daily. Programme-specific questions can be answered by the lead researcher with any therapy-specific questions passed to the clinical members of the research team or other clinicians where necessary and responses provided to users as soon as possible. Whilst problem-solving was referenced as an area where additional support might be required, the comments box is not specifically dedicated to any section. Instead, an icon for it features on all programme pages ensuring it is easily accessible if questions arise at any stage of programme use. A section of the homepage is also dedicated to providing information about additional sources of support including telephone numbers, email addresses and website links.

ii) Interaction with other users

Several participants of the qualitative study discussed how important it was to see that they were not alone in their experiences and suggested embedding a chat option in the new programme so they could communicate with similar others. Whilst acknowledged that this was important to some, a chat option that could be adequately monitored to ensure the safety of users and the maintenance of their anonymity was not possible within the remit of the programme.

(iii) Interaction with the new programme

Mohr et al. (2013) highlighted how one disadvantage of web-based interventions is their reliance on individuals using their initiative to access them. Therefore, many developers seek to include automated reminders to encourage both access to, and engagement with, treatment. In the development of a behaviour change model to guide the delivery of internet interventions, Ritterband et al. (2009) provided examples of the types of prompts that are often used in internet-based interventions to enhance adherence. These include both automated and personalised emails and telephone

calls which can be used across all users or in response to individual programme inputs (e.g. where a task has not been completed).

Several participants of the qualitative study wanted the new programme to send session reminders but stipulated that these needed to be optional owing to concerns that they could disclose programme use. As the new programme is unguided, does not include organising future appointments as with face-to-face therapy delivery and with research demonstrating that reminders can support programme adherence (e.g. Burns et al., 2011) notifications were included. Aligning to the qualitative study findings, notifications are sent when the final follow-up session is available for completion and where a user has not logged on for two weeks. Whilst the importance of increasing programme adherence was acknowledged, allowing adolescents to exercise autonomy and be responsible for their own health was considered. Therefore, at the programme start users are asked whether they would like to receive reminders and if so how (email or text message). All reminders are optional, automated, do not provide any information about what the programme is for and can be stopped at any time.

4.2.4.4 Aiding understanding

The healthcare professional participants wanted users to be able to understand the programme content and suggested the programme should break words down to aid understanding, review key words to clarify meanings and have an embedded glossary for reference. These suggestions were implemented where possible. A glossary is available on the homepage which provides definitions of key words and contains a link to an online dictionary that users can consult if required. Words considered more complex are also highlighted, with their definition appearing if selected and key points are repeated and revisited throughout the programme to maximise understanding. All programme users are also reminded that they can use the comments box to enquire about anything they do not understand.

4.2.4.5 Monitoring mood/feelings

In previous BA deliveries, recording information relating to feelings/moods has generally been presented in conjunction with activity monitoring with connections between the two recorded. However, in the delivery of an online BA therapy, the recording of feelings as a standalone component was considered important both to allow users to observe changes in their mood across the treatment period and as a means of risk monitoring.

Monitoring feelings was favoured for inclusion in the new programme by most healthcare professionals having found this a useful tool when delivering face-to-face therapy. Specifically, it allowed them to track how young people were feeling, both within and between treatment sessions, and monitor both progresses and deteriorations given the variability in feelings inherent to low mood. Similar views were expressed by several adolescent participants who had previously monitored their feelings and found it useful in allowing them to see improvements even if they had not noticed positive changes.

Although important to include this component, its implementation needed to consider the concerns expressed by some participants relative to discussing feelings. In general, adolescents disliked talking to others face-to-face about their feelings and, although they felt that an online treatment approach alleviated their concerns, it was important to ensure that this component was minimal. Therefore, at each log on programme users are simply asked to complete the Short Mood and Feelings Questionnaire (SMFQ: Angold et al., 1995) with the addition of two questions from the longer, 33-item MFQ (Angold et al., 1987) relating to risk. This approach to risk monitoring, has been used in previous research (Abeles et al., 2009; see 5.2.4.3). Responses are graphically presented and accessible from the homepage so users can monitor their feelings over time. The lead researcher also has continued access to SMFQ responses and is alerted via an automated email if any user responds to a risk question in the affirmative. In these instances, users are contacted to ascertain whether additional support is required.

4.2.4.6 Practicing new skills

Practicing new skills was included as a component in activity one of the qualitative study (Chapter Three) with the only discussion dedicated to this being a suggestion by a service-user that information about exercise could be provided. Aligning to Kanter's description of skills training (i.e. techniques delivered to help individuals engage in effective behaviour), many of the components incorporated in the new programme including activity scheduling, problem-solving and monitoring activities and mood can be regarded as practicing new skills. Owing to this, and as not to overwhelm programme users with too much information, a standalone therapy component with any additional skills other than those described earlier is not included in the new programme.

4.2.5 Selecting the programme content: Summary

A review of its delivery with both young people and adults demonstrates that BA can encompass different components in varied combinations. Whilst Kanter et al. (2010) identified eight BA intervention types, only activity monitoring and activity scheduling were consistently identified across the BA approaches identified both in their review and the systematic review (Chapter Two). Some have suggested that simpler BA models may be as efficacious as those that are more complex (Spates et al., 2016; Kanter et al., 2010). In the narrative synthesis presented within Chapter Two, all included studies reported reductions in depressive symptoms following BA despite variations in the number of intervention types employed (See Table 14). Furthermore, Spates et al. (2016) highlighted that just because elements of a treatment package can be successfully implemented does not necessarily provide evidence of their efficacy. Whilst Kanter et al. (2010) speculated that activity scheduling is likely to play a primary role in the delivery of BA, a lack of component analyses of the BA packages available (Hoyer, Hoefler & Wuellhorst, 2020; Kanter et al., 2010) mean it is not clear what mechanisms are responsible for the changes reported following its use.

Given the uncertainty about the mechanisms responsible for change in the delivery of BA, and that the new programme under development was the first known online version for adolescents, caution was required when selecting its content. Aligning to previous BA deliveries, both activity scheduling and monitoring were considered important for inclusion at the outset, with further endorsement received from most participants of the qualitative study albeit alongside some stipulations. However, more careful consideration was required in selecting additional content as not to omit anything that could be important whilst also not including things that may be deemed superfluous. A balance was therefore sought between including therapy components that had been delivered and empirically supported in previous deliveries whilst also acknowledging the views of adolescents and healthcare professionals and selecting content that could be delivered in an online format. The final content selected for inclusion, relative to the intervention types outlined by Kanter et al. (2010), is presented in Table 15. Overall, seven of the intervention types are represented in the new programme with only relaxation omitted. Where possible additional components of therapy proposed during the qualitative study (Chapter Three) have been included. To minimise user burden and ensure the programme can be sufficiently tailored to individual needs, some content has been made optional.

The next part of this chapter examines how the selected content was structured, delivered and presented within the new programme. This information is also presented in Table 15.

Table 15: The final structure, content and delivery of information in the new BA programme relative to the BA intervention categories as described by Kanter et al. (2010)

Session(s)	Kanter et al (2010) Intervention categories										BA programme core content	Delivery
	AS	AM	AG/V	ST	CM	PTVB	PTA	R	A	O		
1: Programme Introduction									X		Psychoeducation (introduction to depression, statistics, symptom checker)	Text/activity
						X	X		X		Treatment rationale (vicious cycles of depression, short/long-term impact of behaviour)	Text
										X	Programme aims/using the programme	Text
		X							X		Current activity assessment	'Homework'/ diary sheets
2: Goal Setting			X								Values assessment (relationships, education, hobbies/interests, health)	Activity
	X		X								Goals assessment (short/long-term goals, mood-directed vs goal-directed behaviour)	Text/activity
							X				Avoidance (coping skills, TRAP/TRAC)	Text/activity
					X						Making changes to the environment (getting help from others)	Text
									X		Considering activities to reach goals	'Homework'/ searching the internet

Session(s)	AS	AM	AG/V	ST	CM	PTVB	PTA	R	A	O	BA programme core content	Delivery	
3: Selecting activities to try	X										Introduction to activity scheduling, tips for selecting activities	Text	
	X										Selecting 12 activities	Text	
	X										Introduction to activity hierarchies and completion	Activity	
	X										Activity scheduling	Diary sheets	
	X	X							X		Activity engagement	'Homework'	
4-8: Activation		X									Activity review	Text/activity	
		X									Activity engagement support	Text	
	X										Activity scheduling	Diary sheets	
	X	X							X		Activity engagement	'Homework'	
9: Relapse								X	X	Relapse (what is a relapse, identifying a relapse, managing a relapse using techniques learned in the programme)	Text		
10: Follow-up		X									Progress review and guidance (symptoms, mood, activity levels)	Text/activity	
										X	Programme recap	Text	
			X						X	X	Next steps and the future	Text/activity	
Supplementary content										X	Monitoring feelings (SMFQ completion)	Activity	
										X	Links to additional support	Text	
										X	Aids to understanding (glossary)	Text	
				X								Information for parents/guardians and friends	Text
				X								Communication and conflict resolution	Text
				X								Problem-solving	Activity

Notes. AS: Activity Scheduling, AM: Activity monitoring, AG/V: Assessment of goals and values, ST: Skills Training, CM: Contingency Management, PTVB: Procedures Targeting Verbal Behaviours, PTA: Procedures Targeting Avoidance, R: Relaxation, A: Ancillary Components, O: Other

4.3 Stage two: Selecting the programme structure

4.3.1 Organising session content

After ascertaining the new programme's content, how this would be structured was considered. Kanter et al. (2010) organised their review of BA components in the order they would expect to see them delivered in treatment. Therefore, assessment techniques including activity monitoring and goals and values assessment were discussed first followed by techniques for activation including activity scheduling and procedures to target avoidance. The review concluded with an examination of the BA components involved in increasing the likelihood of activation. This was consistent with the structure discussed in earlier work by Kanter et al. (2009) which highlighted how standard assessment types like activity monitoring and values assessments could be used to plan activity scheduling, an approach also taken in BATD/BATD-R (Lejuez et al., 2011; 2001) and *BA* (Martell et al., 2001).

Regardless of the BA model applied, all studies within the systematic review outlined a similar treatment course in their BA deliveries. Initial sessions started with the treatment rationale, psychoeducation about depression and the impact of activation and monitoring current activity and mood. Generally, therapy sessions then progressed to increasing engagement in positive behaviours with strategies to help with identifying barriers, overcoming avoidance and problem-solving applied alongside. Young people were encouraged to set goals/sub-goals and practice skills, often between sessions. Treatments concluded with progress reviews, maintaining treatment gains and relapse prevention. Regardless of treatment session number and frequency this general structure was followed across all included studies relative to the BA components employed. In most included studies, maintaining treatment gains and relapse prevention were covered across one or two sessions.

Although this typical session structure was reported in the included studies, several authors highlighted how flexibility could be exercised in therapy delivery. Particularly, therapists could tailor the session order relative to individual client needs (e.g. McCauley et al., 2015; Jacob et al., 2013; Ritschel et al., 2011; Weersing et al., 2008). Consequently, components could be repeated if necessary or components scheduled for future sessions could be brought forward if required at an earlier treatment stage.

Given the logical sequence of therapy outlined by Kanter et al. (2010) and reported in the studies within the systematic review, the new programme adopts a similar

structure. The initial sessions include psychoeducation about low mood and/or depression and provide information about BA and the treatment rationale. These sessions are preparatory, demonstrating the connections between activity and mood and encouraging users to assess their current activity levels, set goals and plans for scheduling activities. Later sessions are practical and encourage individuals to engage in pre-selected activities, with support and guidance provided to maximise success. The programme concludes with focus upon maintaining treatment gains and relapse prevention. However, given the online delivery of the new programme some adjustments were required.

Unlike face-to-face deliveries, the order of information presented had to remain static and could not be adjusted relative to individual needs. Therefore, although programme users can decide what to view and can repeat sessions or re-access content, having no clinician present to amend the structure of sessions requires them to be completed in linear succession. Therapy components involving increasing activation are also more 'practical' in the new programme than in those described in face-to-face therapies. In most of the studies within the systematic review, young people were encouraged to engage in activities between sessions and attend face-to-face sessions alongside where strategies to increase success were discussed. Given the online nature of the new programme, it was not possible to determine when an activity would have been completed. Consequently, strategies to increase success (i.e. reducing avoidance, incorporating others in activation, goal setting) are presented prior to activation. Users therefore engage in activities, relative to pre-specified goals, and review their progress on a session-by-session basis, revisiting information about strategies to support them if and when required.

4.3.2 Establishing session number, length and frequency

In the studies within the systematic review treatment was designed to be delivered across four to 18 sessions over six to 24-weeks. Like the structure of content, treatment sessions were sometimes flexible with some allowing an extra four (McCauley et al., 2015; Ritschel et al., 2011) or five (Chu et al., 2016) to be delivered if required. Although many included studies did not specify session lengths, those that did reported them to last between 30 minutes and one hour. Generally, sessions were weekly or delivered with just over a week lapsing between. Only one study (McCauley et al., 2015) reported a slightly higher session frequency with 14 sessions delivered over 12-weeks.

The qualitative study findings showed that generally around 30 to 45 minutes per programme session was regarded as optimal across the participant groups. Covering topics over multiple sessions or increasing session frequency were favoured over lengthening sessions. Six sessions were regarded as the minimum and 12 the maximum with the participants of the qualitative study wanting no longer than a week to lapse between sessions. Despite these suggestions several participants discussed the possibility of structuring the new programme relative to user needs rather than session number and length being prescriptive. Examples included allowing the programme structure to be guided by individual choice (e.g. users deciding the frequency and length of log ins), depression severity (e.g. session access guided by the support required) or developmental level. Whilst basing the new programme on individual needs was important for some, its online format made this difficult to operationalise and a prescriptive number of sessions was required.

When treatments are considered too long users may not want to continue and withdraw early (Ritterband et al., 2009). Therefore, enabling all content to be covered whilst adhering to the qualitative findings was important. Consequently, the selected content of the new programme was carefully grouped and placed in sessions designed to last no longer than 45 minutes as per the qualitative study findings. This resulted in the development of ten sessions of varying length with more practical sessions taking less time to complete and introductory sessions, with more content to view taking longer.

Despite the need for a clear session structure, to address the views gathered in the qualitative study, flexibility in session completion has been incorporated where possible. Users can decide when they log onto the programme and for how long, moving through sessions at their own pace. Where sessions cannot be completed in one sitting, users can return to the same point at a later date. Furthermore, whilst it is advised that between three days and one week are left between completing one session and starting the next to allow activities to be completed, this is flexible, with programme access available at all times.

4.3.3 Including follow-up sessions

The participants of the qualitative study felt some form of follow-up in the new programme was important to allow users to review their progress and ensure that therapy did not simply stop. Suggestions ranged from incorporating a single follow-up session one month after therapy completion to multiple sessions for six months. A single session, one month after programme completion, in line with what several

participants of the qualitative study suggested was deemed sufficient. This follow-up session reviews user progress during their time on the programme, repeats important programme content and determines the next steps (i.e. setting future goals). This aims to encourage users to continue using the skills they have been taught to manage symptoms of their low mood and/or depression.

4.3.4 Selecting the programme structure: Summary

Information from previous research and the views collected during the qualitative work guided the new programme's structure (see Table 15). Adopting a similar structure to previous BA deliveries all programme content is presented in a logical sequence starting with an introduction to treatment focusing upon the interactions between mood and activity, followed by an activation section where individuals engage in pre-selected activities and concluding with a focus upon relapse prevention and a progress review. The programme's online format requires a clear session structure with content needing to remain static and completed in linear succession. Whilst the session structure cannot be amended as in face-to-face therapy, through the requirement of completing preparatory sessions first users will have reviewed information to support activation prior to activity engagement, thus hopefully increasing the likelihood of success.

Through incorporating the qualitative study findings, it is hoped that the new programme's structure, session length and frequency are regarded as optimal by users. Furthermore, the additional flexibility in allowing users to choose when and for how long they log on to sessions aims to ensure that the programme is adaptable to individual needs.

4.4 Stage three: Selecting the programme presentation and delivery-specific considerations

The final process in developing the new programme ahead of computerisation was establishing how its content would be presented and delivered. The findings from the qualitative work, given its focus upon therapy delivered in an online format, predominantly guided this, particularly about issues surrounding presentation. Information about the programme's physical presentation is discussed first before focus is placed upon the delivery components selected and additional logistical factors.

4.4.1 The programme's physical presentation

4.4.1.1 Appearance

Ritterband et al. (2009) contended that how an online programme looks and feels (e.g. colour, layout) may impact upon both initial and continued use and engagement. Within the qualitative study time was dedicated to discussing the programme's appearance, albeit minimally. The programme's colourfulness featured in the list of factors rated by the adolescent-participants in order of importance to make it attractive. Whilst the community sample rated this as the most important factor, the service-users rated it as one of the least. In one of the studies included in the systematic review (Ritschel et al., 2011), to make BA more developmentally appropriate, several handouts were presented in different themes with clinicians choosing which to use with individual clients. It was found that most young people found a nonthematic approach acceptable. This was considered in the development of the new programme which was displayed fairly neutrally with minimal colour added. This approach aimed to ensure that the programme would not be seen as 'too mature' nor 'too childish' and would reduce the chance that the programme would be too colourful and potentially dissuade some individuals from using it. Furthermore, based on the findings by Ritschel et al. (2011), by adopting a nonthematic programme presentation, the risk that some users would not engage simply because they did not like the theme selected, would hopefully be reduced.

The qualitative study highlighted how some adolescent participants wanted the programme to be sensitive and relaxed whilst providing adequate information – not too much that it could be overwhelming nor too simple that content would not be taken seriously. This was considered during the programme's development with all information provided as succinctly as possible to avoid being too attentionally demanding.

4.4.1.2 Tailoring to individual needs and personalisation

Research with adolescents about online therapies has highlighted the importance of tailoring therapies to users. Cheek et al. (2014) conducted focus groups with 16 adolescents following their use of a CCBT programme for depression (SPARX) to examine its acceptability. 'Personalisation' emerged as a key theme and included both issues surrounding how individuals used the programme and the physical personalisation of the intervention. In the former, adolescents wanted to choose how

and when they accessed the programme and whether they shared their experiences with others. These findings were similar to those in the qualitative study and therefore incorporated, with the new programme developed to be flexible, allowing users to choose what to view and when (see 4.3.2). Given the stressors already experienced by adolescents, users are not set 'deadlines' nor receive any sanctions for failing to participate in scheduled activities. It is also hoped that users feel able to tailor the programme to themselves in other ways such as through being able to select activities for engagement and set individual goals. Where possible the programme is also designed to process certain responses. For example, when reviewing activation, if a user has been unable to complete planned activities information to support future engagement is presented.

The programme's physical personalisation was more difficult to achieve within time and financial constraints. Whilst it was not possible to provide more than one programme presentation to suit the developmental level of individual users, where possible, and as described in more detail later (see 4.4.2) information is presented in varied formats (e.g. text, pictures, activities) to meet the learning preferences of as many users as possible. However, with only one programme presentation possible, the complexity of the information presented required consideration.

As previously discussed, (see 4.2.1.4) the adolescent period sees a move from concrete to more abstract thinking (Taddeo et al., 2008) where individuals develop the ability to think more logically and are able to both formulate and test hypotheses (Arnett & Hughes, 2012). This was referred to as the formal operations stage according to Piaget's theory of cognitive development. According to this theory, individuals move through stages of thinking as a result of maturation which Piaget contended often occurs across individuals at similar ages and suggests that once a person has reached formal operation thinking they will always use it (Arnett & Hughes, 2012). More recent research suggests that instead individuals might select when to use this type of thinking with some using it often and others not at all (Arnett & Hughes, 2012). In addition, at times adolescents may regress back to more concrete thinking for example when experiencing stressful situations and overwhelming emotions (Stang and Story, 2005). Thus, cognitive development might be considered to be less stage-like than Piaget suggested (Gardner, 2006).

Despite critique, Piaget's theory of cognitive development is one of the most influential (Arnett and Hughes, 2012) and requires consideration in the development of new young-person therapies but with acknowledgement of individual differences. According

to the theory, the transition from concrete to more abstract thinking occurs in parallel to the target age range for whom the new programme was being designed. As the move from concrete to abstract thinking is transitional, occurring over time and can involve regression during stressful and emotional periods, therapies designed for adolescents need to be written in such a way that they accommodate the capacity for the abstract thinking of all users. Ideally, having different versions of therapy could address this with information presented in varied ways to accommodate both concrete and abstract thinking types or be determined by personal preference. When only one version of the new programme was possible, presenting content aligning to a more concrete-thinking approach was considered most suitable. It was felt that if a more abstract presentation was adopted, users who are more concrete thinkers, or those experiencing a particularly stressful or emotional period, might not understand programme content and feel overwhelmed. When developing a new treatment for low mood and/or depression this needed to be avoided. Furthermore, it has been suggested that not all adolescents will have the ability required to understand constructs often used in therapies that are abstract and hypothetical (Garber et al., 2016). It was however acknowledged that this may result in more abstract thinkers deeming programme content to be too simplistic. To adopt a more concrete-thinking approach information is required to be both simple and straightforward (Sturdevant & Spear, 2002) and presented in a more black and white manner where information is devoid of abstract terms with concrete examples provided (Oetzel & Scherer, 2003). This approach was taken in the presentation of information in the new programme.

A similar approach was taken when selecting the language used within the new programme to ensure it could be easily understood. Like other BA deliveries with young people (e.g. Wallis et al., 2012) all language is jargon-free and based upon a lower adolescent literacy level. Again, whilst this may have resulted in those with higher literacy levels deeming the programme to be too simplistic, this approach aimed to enable more programme users to understand its content. Several researchers have suggested ways to make therapeutic concepts more 'adolescent friendly' including employing the client's own vocabulary, using clear, simplified language and providing specific, task-orientated instructions (Kingery et al., 2006; Wilson & Sysko 2006; Ginsburg & Drake 2002). Furthermore, Stallard (2000^b) proposed that clinicians working with adolescents should use terminologies with dimensionality rather than dichotomy (e.g. 'better/worse' instead of 'good/bad'). Although, due to the programme's online format, it was not possible to deliver the therapy in each user's vocabulary, the remaining suggestions were all adhered to.

When examining adolescent psychosocial development relative to counselling, Sturdevant and Spear (2002) stipulated that more abstract thinkers will require additional time to complete treatment through needing to examine all possible solutions to a problem. Owing to the nature of BA and the requirement of treatment to consider alternative ways of coping and make plans for activation, for example, the timing to complete treatment also needed consideration. As previously discussed, the programme was designed to be flexible with users able to work through it at their own pace and without time constraints. This flexibility is especially important in the context of low mood and/or depression where particularly low periods can have significant impacts upon both energy levels and concentration.

4.4.2 Selecting delivery components

The methods employed by clinicians when delivering face-to-face BA appear similar with both adults and young people. Generally, therapy comprises a combination of client-therapist discussion, practical activities and the use of visual resources including handouts, graphs and diary sheets. Although variation across treatments, Kanter et al's (2010) review demonstrated how these methods have been implemented. Whilst client-therapist discussions occur throughout therapy (e.g. to discuss experiences, treatment processes and progress), visual resources are generally used for assessment strategies and practical techniques for activation. Therefore, relative to the interventions described by Kanter et al. (2010) visual resources are used both within and between sessions during discussions about activity monitoring, assessment of goals and values and activity scheduling and more practical activities adopted for skills training (e.g. during modelling, role-play and therapeutic feedback), relaxation and procedures targeting verbal behaviour (e.g. thought monitoring and positive self-talk).

Given the new programme's online format, adaptations to the delivery components seen in face-to-face therapies were required. Whilst visual resources and activities associated with activation could be retained, practical techniques (e.g. role-play, clinician modelling) and client-therapist discussion had to be replaced with alternative processes that were technologically deliverable. In an evidence review of behavioural interventions, Mohr et al. (2013) contended that the common components of most web-based interventions include a combination of text-based didactic information and interactive tools to support learning with feedback tools to demonstrate progress. Audio, video and animation were described as additional components to supplement any text-based information provided. Determining the delivery components for the new

programme required establishing a balance between; i) those that are the most effective in BA delivery, ii) those deliverable in an online format and iii) those that would support engagement and usability, whilst adhering to financial and temporal constraints.

Like previous face-to-face BA deliveries, visual resources are implemented for the therapy components regarding general assessment strategies with diary sheets used to support activation (see 4.2.1.1 and 4.2.1.3) and graphs assisting with monitoring mood/feelings. For activation, engagement in pre-specified activities or behaviours is encouraged. Client-therapist discussions and engagement in practical activities (e.g. role-play) have been replaced with text-based information and interactive tools as described by Mohr et al. (2013). For example, psychoeducation is presented in written text with embedded diagrams, illustrations and graphics and any skills training components presented as text-based information and interactive exercises. It has been suggested that the use of graphics, audio and interactivity are preferred components of internet interventions (Ritterband et al., 2009) with the latter of these specifically endorsed by those in the qualitative study also. Therefore, graphics and interactive activities feature throughout the new programme whilst an audio option is embedded to allow all content to be read aloud. It was hoped that employing varied deliveries would accommodate the needs of different users and enhance engagement.

Alongside audio, Mohr et al. (2013) described how videos and animation commonly feature in web-based interventions to supplement text-based information. As previously discussed, (see 4.2.3.2), the qualitative study revealed mixed views about videos with them endorsed by healthcare professionals but regarded less favourably by adolescent participants. Interestingly, some were explicit that if included, videos should not include animation. Given these different opinions, alongside both temporal and financial constraints, videos and animation were omitted from the new programme.

As part of the text-based information often incorporated in web-based interventions, printed self-help sheets are often included (Mohr et al., 2013). Whilst some adolescent participants of the qualitative study did not regard the inclusion of handouts as important, some wanted programme content to be printable. Thus, all information presented in the new programme is provided in a printable format with the printing of content optional.

4.4.3 Logistical considerations

4.4.3.1 Navigation

Although programme content is displayed linearly, the qualitative study demonstrated that several individuals wanted to be able to move both forwards and backwards through the programme (i.e. to revisit or skip content) and able to save and delete inputs. These elements were considered important in enhancing the programme's usability and enabling users to exercise control over how they completed sessions. Therefore, forward and back buttons are displayed throughout sessions to allow easy navigation and if a user exits the programme they will return to the same point at next log in as not to have to repeat content. As sessions need to be completed linearly, a new session will not become available until the former has been completed. However, all completed sessions appear in a repository that can be revisited from the homepage if required. Users can also both save and delete content. To allow additional flexibility, parts of the programme are editable and can be changed in response to circumstances. For example, the activity hierarchy order can be amended if users find that activities initially regarded as easier to complete are in fact harder.

4.4.3.2 Security

Good security was important to many of the participants of the qualitative study with some expressing concerns about others accessing programme data. Similar findings have been reported elsewhere. Ring (2014), following a survey of 1,200 16 to 24-year-olds, reported that 90% were concerned about what happens to the data they share with 67% stating security as their main priority when considering an internet-based product. Owing to this and the suggestions made during the qualitative study, good security was embedded in the new programme. All users are given an individual username that contains no personal information. This is connected to their email address and, via a link sent to them, users set their own password which is known only to them. This was deemed more secure than issuing users with passwords and requesting these to be changed at first log in. In response to the qualitative study findings, the programme also includes an automatic log-off after ten minutes of inactivity.

4.4.3.3 Privacy and anonymity

Alongside good security, many participants of the qualitative study highlighted the need for both privacy and anonymity in the new programme. Similar findings have been reported elsewhere with Farrer et al. (2015) finding that university students discussed the importance of anonymity in maintaining trust and privacy of access in focus groups about the development of an online mental health clinic. Although some participants of the qualitative study felt that delivering therapy in an online format would increase anonymity, further consideration for this and privacy were required. All programme responses are anonymised and no requests for personal information disclosure are made. Access to responses entered in the programme are also only accessible by the user to whom they belong and the lead researcher with users made aware of this on programme entry. Although as part of risk monitoring, the lead researcher may be required to discuss a user with their primary care provider, no specific responses are disclosed as part of this.

4.4.3.4 Availability and access

Several participants of the qualitative study wanted the programme to be available at all times, accessible when most convenient and most needed. However, some healthcare professionals worried that this would make risk monitoring difficult. To ensure the programme was available when most needed, it was made accessible to users at all times. However, acknowledging the healthcare professionals' concerns, and as previously mentioned, risk monitoring was added to the programme (see 4.2.4.5). As risk cannot be monitored on a 24/7 basis, a requisite of programme use included users having to consent to seek additional support if required.

4.4.4 Selecting the programme's name

All participants of the qualitative study were asked what the new programme could be called and reasons for this. Although few suggestions were received, the consensus was that the programme's name needed to be discreet and not indicative of what it was being used for. Whilst suggestions including 'what do I do next?' and 'control' were made, several individuals proposed an acronym. After discussion of alternatives the new programme was named 'BALM' (Behavioural Activation for Low Mood).

4.4.5 Selecting the programme presentation: Summary

Careful consideration was given to the new programme's presentation and treatment delivery components with both predominantly guided by the qualitative study findings. Although, the programme's online format restricted the use of some delivery methods such as therapist-client discussion, varied delivery methods were included where possible. Whilst programme personalisation was limited by the availability of only one presentation, it was hoped that adopting a nonthematic theme and presenting content relative to a more concrete-thinking style would ensure the needs of all users were met.

4.5 Online programme development

The final part in the production of BALM was creating an online version of the programme. In 2019 a successful bid to a local NHS Trust research fund secured an award of £8000 towards BALM's development. This money funded a web development company (PCM), with experience of working in health research, to produce BALM in an online format. The web developers were given a document containing all content to be included in BALM alongside diagrams depicting how users would work through the programme to ensure it was accurately structured. Over several months the lead researcher worked closely with PCM to develop the programme.

In the adoption of a participatory design as applied within this thesis, web developers are crucially important (Scholten & Granic, 2019). Whilst the participants of the qualitative study were important in informing the development of the new programme, the web developers were essential in ensuring a workable, online delivery was operationalised. Scholten and Granic (2019) outlined the extensive ways in which web developers can contribute to the development of digital technologies. This includes not only the programme development but ensuring its compatibility with varied platforms (e.g. mobile phones) and its continued use with the emergence of new technologies. Furthermore, and as with BALM, well-designed digital technologies can provide additional information about programme use such as user access, interaction and engagement. This provides researchers with essential information about the fidelity of a technology that can be considered alongside participant feedback. In the context of BA, it may even be possible to gather important information about the mechanisms of change through the employment of online deliveries for example in allowing activation to be measured in real-time (Spates et al., 2016). Despite this, engagement with web developers is often ignored (Scholten & Granic, 2019). Engaging the web developers

early enabled the collaborative development of BALM to ensure it was designed to both meet the needs of the user and also provide important information to inform its future refinement and development.

4.5.1 Changes to BALM following computerisation

BALM was scheduled for first use with adolescents as part of a feasibility study (Chapter Five) in early 2020. This coincided with the COVID-19 pandemic and subsequent government restrictions which limited social contact. In response, BALM was amended to ensure its use would be suitable whilst restrictions were in place with several areas of text updated to ensure that any examples of engagement adhered to government guidelines. For example, in the activity scheduling section of the programme activity examples under restriction (e.g. swimming) were replaced with activities that adhered to national guidelines (e.g. walking/running). A disclaimer, reiterating the need for programme users to adhere to government guidelines when completing activities during the pandemic was also added to the programme's homepage. Coinciding with these changes it was decided that the words 'depression/depressed' would be replaced in the programme with the terms 'low mood/low'. It was felt that this terminology would be more suitable for adolescent use.

4.6 Discussion

This chapter has described the development of a new online BA programme (BALM) for adolescents with mild to moderate low mood and/or depression. Whilst the benefits of providing therapy in an online format (Chapter One) warranted the development of BALM, evidence suggests that digital technologies can be subject to challenges including low uptake, adherence and engagement (Jones et al., 2020). Adopting a participatory or empathy-based approach (Scholten & Granic, 2019) in the development of interventions has been suggested to ensure the needs and preferences of target users are met (Jones et al., 2020). Through this collaboration it is hoped that interventions will be considered more engaging, satisfying and useful by users (Thabrew et al., 2018). Indeed, the development of BALM adopted a participatory approach with stakeholders, including adolescents, healthcare professionals and web-developers, involved in its design and development. Synthesising their views with the findings of previous research in the area as well as considering the developmental challenges inherent to the adolescent period, it was

hoped that BALM would address the needs of target users thus increasing the chances of uptake, satisfaction and adherence.

Whilst careful consideration was given to ensuring that BALM was suitable for its target users, several limitations about its development were evident. As demonstrated in Chapter Three, within discussions about some programme components, differences were evident in the opinions of each of the three qualitative study participant groups. At times compromises could be reached within BALM's design, however this was not possible in all instances. Although a balance was sought between including important content and ameliorating any concerns expressed by participants this unavoidably led to the inclusion or omission of components, decisions not necessarily favoured by all.

To ensure BALM was designed with consideration for important developmental factors occurring during the adolescent period a number of biopsychosocial changes were addressed within this chapter. The area of adolescent development is considerably large and therefore addressing all of the changes occurring during this life stage was far beyond the scope of this chapter as was addressing the included areas in anything more than superficial detail. Therefore, whilst the chapter provides some information about how developmental changes influenced BALM's development, only a small proportion have been included with many additional challenges not having been addressed. In addition, for ease of reporting, the areas that have been addressed have been presented as independent constructs yet the biopsychosocial changes occurring during this time are significantly inter-related. For instance, it has been reported that difficulties with one developmental domain may contribute to problems in another (Garber et al., 2016).

Biopsychosocial development is also subject to both inter and intra-personal variability. For example, the onset of puberty, which has been seen to influence both the structural and functional development of the brain (e.g. Blakemore et al., 2010; Forbes & Dahl, 2010; Schulz et al., 2009), and thus has the potential to influence cognition, mood and behaviour (Walker, 2002), varies across individuals. According to Blakemore et al. (2010) the process of puberty normally occurs anywhere between the ages of eight and 14 years for females and between nine and 15 years for males. Furthermore, unlike chronological age, development is not necessarily linear with regressions evident in some developmental abilities (e.g. Stang & Story, 2005) with differences in some skills reported to be context-dependent (Garber et al., 2016).

Several of these limitations may have been ameliorated if multiple versions of BALM had been possible. Here, versions could have been developed that were sensitive to the specific changes and challenges of the user whilst also accommodating personal preferences. This however was not possible within temporal and financial constraints. As described earlier, therapists can incorrectly regard individuals within a particular age range as homogenous thus adopting a 'one-size-fits-all' approach with negative effects on treatment outcome (e.g. Garber et al., 2016; Holmbeck et al., 2006). Through undertaking a review of the biopsychosocial development of adolescents in the design of BALM, it was hoped that simply making inferences based upon chronological age would be avoided with more focus placed upon developmental attributes of the target user. Although chronologically the target user age range, 11 to 16 years, appears narrow, the variability in development that this range can include is broad. With only one version of BALM available it was not possible to accommodate the specific needs of all.

4.7 Chapter summary and next steps

This chapter has described the development of a new online BA programme (BALM) for use with adolescents aged 11 to 16 with mild to moderate low mood and/or depression. This aligns with phase four of co-design as described by Eyles et al. (2016). The next chapter presents the findings from a non-randomised feasibility study to assess the acceptability of BALM with an adolescent sample.

Chapter Five: Online Behavioural Activation programme for the treatment of low mood and/or depression in adolescents: Findings from a non-randomised feasibility study

This chapter describes a non-randomised feasibility study conducted as the first test of the BALM online BA programme with adolescents experiencing low mood and/or depression. In line with the phases of co-design followed throughout this thesis, this chapter presents work conducted within the remit of phase five: pre-testing of intervention prototypes. The results of this work will be used to inform the design of future pilot testing of the intervention in line with phase six of co-design: 'intervention pilot testing in the 'real world'', described in further detail in Chapter Six.

5.1 Introduction

5.1.1 Background and rationale

As discussed throughout this thesis, depression is one of the main causes of illness and disability in young people globally (WHO, 2019) with an estimated prevalence of 2% in UK adolescents (Sadler et al., 2018). Whilst it is imperative that adolescents receive effective treatments to mitigate the impact of depression, approximately 65% do not seek help (Rickwood et al., 2005) often due to both individual and service-related barriers (Chapter One). To overcome some of these barriers, recent years have seen an increased focus placed upon the delivery of therapy, in particular CBT, in an online/computerised format (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009). However, BA which has similar effectiveness, is simpler and can be delivered by a wide variety of clinicians (Ekers et al., 2011), has received less attention within this context. Indeed, in the systematic review (Chapter Two), no online BA deliveries for use with young people experiencing low mood and/or depression were identified. This prompted the development of BALM, the first known UK-based online BA programme for adolescents with low mood and/or depression.

As presented in Chapter Four, whilst BALM is based upon previous BA models, several pieces of work including a systematic review and meta-analysis specific to BA deliveries with young people (Chapter Two), a qualitative study (Chapter Three) and an examination of the biopsychosocial development of the user group (Chapter Four) were conducted to inform its design and ensure it meets the needs of the target user. The completion of this work aligned to phases one to three of co-design (Eyles et al., 2016)

which encompass an assessment of (i) background knowledge and evidence, (ii) user needs to inform intervention focus, and (iii) user needs to inform technology type. The consolidation of this information into a workable online therapy package corresponded to phase four – development of the intervention including content and framing. According to the phases of co-design (Eyles et al., 2016, see 1.4.2), phase five involves the pre-testing of intervention prototypes to inform the subsequent sixth phase: intervention pilot testing in the real world.

Feasibility studies are normally conducted as preparatory work for definitive RCTs and used to decide whether a future, larger study can and should be done whilst informing the approach to be taken (Eldridge et al., 2016). In addition, they can provide key information to establish design parameters for larger trials (Teare et al., 2014). Through conducting feasibility work, the likelihood of a subsequent larger and more cost-intensive study succeeding may be established allowing researchers and funders to invest in studies that are more worthwhile and less likely to result in significant waste (Morgan et al., 2018). Feasibility studies, alongside pilot studies, are now recommended as part of the guidance on designing and evaluating complex interventions published by the UK Medical Research Council (MRC) (Craig et al., 2008). Therefore, as this was the first test of BALM, a non-randomised feasibility study was conducted.

5.1.2 Aims and objectives

The primary aim was to 1) assess the feasibility of undertaking a pilot RCT of BALM and 2) examine the acceptability of the intervention in treating adolescents experiencing low mood and/or depression. The study aimed to provide key information including:

- The research methods to be employed in a pilot RCT
- Where in the care pathway BALM may be best placed
- Any components of BALM for modification or removal to inform the development of future versions.
- Whether adopting an unguided approach in the delivery of BALM was acceptable

5.2 Methodology

5.2.1 Study design

A non-randomised feasibility study design was adopted. This study was essential developmental work needed to inform a pilot RCT of the clinical effectiveness of BALM. This preparatory work adopted a mixed methods approach and sought to further the understanding of the new intervention's delivery. A pre-written and ethically approved protocol (Appendix C) was adhered to throughout.

5.2.2 Sample size

Limited guidance is available about the sample size requirements for both feasibility and pilot studies (Billingham, Whitehead & Julious, 2013). In an audit of pilot and feasibility studies from the UK Clinical Research Network (UKCRN) database, Billingham et al. (2013) found feasibility trial samples to range from 10 to 300 (median: 36). According to Julious (2005), as a rule of thumb, a sample size of 12 participants per group is recommended. As this was a non-randomised feasibility study, no sample size calculation was undertaken. However, following statistical advice (York Trials Unit), a sample of ten to 15 participants was deemed sufficient to meet the feasibility objectives. This was also deemed suitable to provide sufficient data for a larger pilot study to allow a power calculation in a subsequent full-scale RCT.

5.2.3 Participants

5.2.3.1 Inclusion criteria:

To be considered eligible, participants had to be:

- Aged between 11 and 16 years at the date of consent
- Experiencing low mood and/or depression symptoms (defined by a score of ≥ 20 on the MFQ)
- In agreement that their primary care provider and parent/guardian could be informed of any concerns the lead researcher had about their wellbeing during participation

5.2.3.2 Exclusion criteria:

Participants were not considered eligible if they were:

- Within the normal range on the measure of depressive symptoms (i.e. attaining ≤ 19 on the MFQ).
- Experiencing severe low mood and/or depression symptoms (a cut-off score on the MFQ was not applied here instead this was decided by the individual referrer).
- Diagnosed with Bipolar Disorder or Psychosis.
- Non-English speaking (due to the study's small scope and limited resources, providing translated versions of the BA programme and outcome measures was not feasible).
- Deemed to be actively at risk of self-harm or suicide.
- Without access to the internet and therefore no programme access.

5.2.4 Study measures

Several outcome measures (Appendix C) were completed by participants at baseline, on a session-by-session basis and on completion or withdrawal from BALM. Optional administrative calls with participants at fortnightly intervals during their programme use provided additional information about adherence. The study measures and the time points they were completed are presented in Table 16.

5.2.4.1 Demographic information

At baseline all participants completed a demographic questionnaire, specifically developed for the research, that gathered further information about themselves (e.g. age, gender, etc.) and their experience of low mood and/or depression (duration, treatments received).

5.2.4.2 Acceptability and feasibility

Evaluation Questionnaires

To assess BALM's acceptability all users completed a short evaluation questionnaire at the end of each treatment session. This comprised a combination of open and closed questions to identify what participants thought of each session including the time spent

on sessions, the work completed and how useful they had deemed the session to be. Further satisfaction with programme content was also collected on a session-by-session basis where participants selected how satisfied they were with each section of information in BALM by awarding it a star rating out of five.

A further, longer evaluation questionnaire was available at the point of programme completion or withdrawal. Again, this comprised a series of open and closed questions asking participants about how they had found BALM overall. Questions included the number of sessions attended, what they had found the most and least useful components and whether they felt the programme had affected their mood.

The evaluation questionnaires were specifically designed for the research with the help of a qualitative expert (PT). All evaluation questionnaires were embedded within BALM and completed online.

Feasibility was measured by establishing the percentage of those eligible for study inclusion and consented, adherence to the intervention and frequency of session attendance. The number and reasons for withdrawal were also assessed as was the acceptability of the programme through an examination of the evaluation questionnaire responses.

5.2.4.3 Other outcomes

The Mood and Feelings Questionnaire (MFQ: Angold et al., 1987)

The MFQ is a 33-item screening measure of depression which can be used with young people aged six to 18 years. The measure comprises descriptive statements about how a young person has been feeling or acting in the preceding two weeks. Individuals select whether each statement has applied to them using the responses 'true', 'sometimes' or 'not true'. A score of ≥ 20 indicates the presence of any depressive disorder (Daviss et al., 2006). The MFQ has demonstrated good reliability and validity (Daviss et al., 2006; Wood et al., 1995) with a Cronbach's alpha of .95 being reported and suggesting the measure's high internal consistency. The 33-item MFQ was used to assess eligibility for study entry.

The Short Mood and Feelings Questionnaire (SMFQ; Angold et al. (1995)

The SMFQ is a 13-item, self-report, measure of depression derived from the longer (33-item) measure (Angold et al., 1987). The SMFQ comprises 13-items, which are used to assess the depressive symptoms of young people aged eight to 18 years and has demonstrated good internal reliability (Cronbach's alpha = 0.85) (Angold et al., 1995).

In a study by Abeles et al. (2009), the SMFQ was used with the addition of two items from the 33-item MFQ ('I thought about death and dying' and 'I thought about killing myself') to monitor suicidality. This approach was taken within this study also. As with the MFQ, individuals select a response ('true', 'sometimes' or 'not true') in relation to 15 descriptive statements. Participants completed this measure each time they entered BALM to monitor their mood throughout programme use and assess risk. Although in the 33-item MFQ individuals are asked to consider their responses based on the preceding two weeks, here responses related to the period since last programme access. According to Angold et al. (1995) a score of eight or more on the 13-item SMFQ is considered to be clinically significant. The scoring of the SMFQ did not include the two additional questions.

Knowledge

All participants were asked ten questions about their knowledge of low mood and/or depression and BA at baseline and following treatment (completion or withdrawal). This measure, designed by the research team, comprised multiple choice and true/false based questions. All correct responses were assigned one point. This aimed to determine whether any knowledge about low mood and/or depression and BA had been gained during programme use irrespective of whether it had helped with mood.

Participant follow-up calls

As research suggests that including human contact in digital interventions may benefit adherence and effectiveness (Hollis et al., 2017), at baseline all participants were asked whether they would be happy to be contacted by the lead researcher at fortnightly intervals by telephone. These administrative calls reminded participants about programme use and asked about any barriers and facilitators to programme adherence. No therapeutic support was given during these calls, nor any additional

personal information collected. Follow-up calls were not a requisite of study entry and could be discontinued at any time.

Table 16: Feasibility study outcome measures

Measure	Time-point completed	Delivery method
Mood and Feelings Questionnaire	Screening	Self-completion
Demographic questionnaire	Baseline	Face-to-Face/telephone or video call administered
Knowledge Questions	Baseline	Face-to-face/telephone or video call administered
	BALM completion or withdrawal	Online
Short (15-item) Mood and Feelings Questionnaire	Each session log in	Online
Programme evaluation questionnaires	Short version: Following each session	Online
	Long version: Study completion or withdrawal	Online
Follow-up calls (optional)	Fortnightly intervals post-baseline	Telephone administered

5.2.5 Recruitment

Initially study recruitment was due to occur via two channels; by healthcare professionals working within two local CAMHS and wellbeing workers based within local schools. Both can be accessed through the single point of access (SPA) which was outlined in the government Green Paper about the organisation of UK CAMH services (DHSC & DfE, 2017). However, prior to starting recruitment, the school-based service became unable to support the study as, in response to internal service changes they did not feel they would be able to identify eligible adolescents for participation nor have instances of risk reported to them. All study recruitment therefore took place within CAMHS.

Adolescents were purposively sampled to ensure those recruited represented a variety of ages, sexes and levels of depression severity. Individuals could be included from a variety of positions within the CAMHS care pathway including those presenting with symptoms of low mood and/or depression to the SPA, those awaiting treatment for low mood and/or depression and those who had received therapy for symptoms of low

mood and/or depression but had not responded to it (here BALM was offered as an alternative to medication).

Healthcare professionals based within CAMHS were informed of the study and asked to discuss it with anyone whom they felt may be eligible and interested in participating. Anyone expressing interest was given two participant information leaflets – one for themselves and one for their parent/guardian. Different versions of this information were available based upon the adolescent's age; leaflets for those aged 11 to 13 years and their parent/guardian and leaflets for those aged 14 to 16 years and their parent/guardian. The healthcare professionals ensured the correct information was distributed accordingly. Alongside the information leaflets individuals were given a copy of the MFQ to complete in their own time.

After reviewing the study information, those interested in participating completed an expression of interest form (containing their contact details). This, alongside the completed MFQ was passed to the lead researcher (LT) either directly by the participant and their parent/guardian or by the recruiting healthcare professional. The lead researcher's details were included on the information leaflets who could be contacted directly if any individual and/or their parent guardian had specific questions.

5.2.6 Consent process

Following receipt of an expression of interest form and completed MFQ the lead researcher ascertained whether an individual was eligible for study inclusion with those attaining a score of ≥ 20 considered. Anyone obtaining a score lower than this was informed that they did not meet the threshold for the study and were not entered. If an MFQ score was particularly high and the lead researcher had any concerns that this may be indicative of severe depression, this was discussed with the referring healthcare professional. This individual then made a clinical decision as to whether they felt the adolescent was suitable for study entry. Whether they entered the study or not, all adolescents could access alternative services as usual.

The lead researcher allowed at least 24 hours to elapse before seeking to obtain consent. This allowed sufficient time for the adolescent and their parent/guardian to review the study information and make an informed decision about participation. The information leaflets outlined the research aims, described what participating entailed, provided information about data storage and GDPR and informed all individuals of their right to withdraw and the withdrawal process. The different versions of the information

leaflets ensured that the research was explained in language deemed appropriate for each participant based upon their age in line with ethical advice.

Originally, those interested in participating were to be contacted by the lead researcher and invited to attend a meeting to discuss the research in more detail. However, as recruitment coincided with the COVID-19 pandemic when government restrictions were in place (see 5.2.9.3) this meeting was replaced with a telephone or video call (determined by resources and participant preference). During this meeting, the researcher answered any questions, reiterated what study involvement entailed and asked interested individuals to complete a consent/assent form which had been emailed to the participant and their parent/guardian beforehand. The consent process differed depending on the age of the adolescent:

Participants aged 11 to 13 years

Those wishing to participate and aged 11 to 13 years completed an assent form with consent for them to take part obtained from a parent/guardian. During the consent process the parent/guardian was required to agree to support their son/daughter when using BALM, have any instances of risk reported to them and agreed to seek additional help for their son/daughter if necessary.

Participants aged 14 to 16 years

Those wishing to take part and aged 14 to 16 years signed a consent form confirming this. Although individuals aged 14 to 16 years could consent themselves, given the nature of the study it was important that they had support during their time using BALM. Therefore, to enter the study a parent/guardian had to consent to support them during their time using BALM and agree to be notified of any instances of risk.

Permission to inform their GP of participation was obtained from prospective participants and their parent/guardian as part of the consent process.

5.2.7 Procedure

All eligible and consenting adolescents completed two baseline measures - the demographic questionnaire and knowledge questions - at their initial telephone/video call with the lead researcher. Both measures (see 5.2.4) were brief, collectively taking approximately five minutes to complete, to ensure little burden was placed upon the

participant. The participant was then given a unique username and sent a link to be able to access BALM. On first entering the programme, users were required to set up a password to ensure their access was secure. Alongside this, the lead researcher talked to participants about how to navigate through BALM. Whilst programme access was only given to the participant, they could decide whether they invited others (e.g. parent/guardians or friends) to complete sessions with them.

Participants were asked whether they would like to receive reminders from the study team about completing sessions and, if so, specified how (email or text message) and provided the relevant contact details. Individuals were also asked whether they would be happy to receive fortnightly telephone follow-up calls (see 5.2.4.3) during their time using BALM.

5.2.7.1 The intervention: BALM

As described in further detail in Chapter Four, BALM is an online treatment programme comprising ten sessions each designed to last 30 to 45 minutes. A detailed outline of BALM sessions and their content can be seen in Appendix C with an overview of the programme structure presented in Table 15 (Chapter Four). Users could access the programme when they wished although were advised to allow between three days and one week to elapse between sessions to allow activities to be completed sufficiently.

On completion or withdrawal from BALM, participants were asked to repeat the knowledge questions that they completed at baseline and the long evaluation questionnaire, online. The individual who referred them to the research and their parent/guardian was informed of their completion or withdrawal.

5.2.7.2 Healthcare professional survey

To gather additional information about the barriers and facilitators to recruitment, adherence and the potential impact of the COVID-19 pandemic (see 5.2.9.3) healthcare professionals recruiting to the study were invited to complete a short survey (Appendix C) about their experiences of offering the research to adolescents. Individuals were identified by the professional networks of the lead researcher, established when the study was set up, and reminded about the survey at weekly team meetings attended by the lead researcher. To supplement recruitment, secretaries based within the CAMH centres involved in the feasibility study were asked to forward the survey to their teams. All healthcare professionals were asked to circulate the

survey to other colleagues who they felt would be in a position to participate. The survey was hosted on the Qualtrics Platform and could be completed online or telephone-administered by the lead researcher (depending upon preference and availability). A consent statement at the start of the survey outlined its aims and provided information about confidentiality, data storage and processing and GDPR. All healthcare professionals willing to participate were required to agree to the consent statement. This was either agreed to verbally where surveys were telephone-administered or by clicking a link to the survey if completed online. The survey took approximately ten minutes to complete and comprised a series of short open and closed questions with Likert scales embedded. No personal information was collected.

5.2.8 Data analysis

As this was a non-randomised feasibility study, and not statistically powered, no analyses of effectiveness were undertaken. Instead, information is provided as descriptive summaries with means and standard deviations used where data were continuous and frequencies and percentages where data were categorical. Responses to the open-ended questions presented in the evaluation questionnaires, the optional follow-up call questions and the healthcare professional survey are presented as a narrative. Information is provided relating to:

- The percentage of those eligible who consented to the study
- Demographic information
- Session attendance
- Session adherence
- Overall questionnaire response rates
- Number and reasons for withdrawal
- Responses on all measures completed (including baseline, session-by-session, end of treatment – either completion or withdrawal).
- Barriers and facilitators to adherence – (adolescent participants)
- Barriers and facilitators to recruitment and adherence – (healthcare professionals)

5.2.9 Ethics

5.2.9.1 Ethical considerations

Risk Monitoring

Although BA is not known to have any serious adverse effects, inherent to low mood and/or depression was the risk that an adolescent might have become distressed during participation or experienced a worsening in symptoms. The research was therefore developed with measures in place in either of these situations.

Firstly, only individuals experiencing mild to moderate low mood and/or depression were eligible to use BALM. No one with severe depression or anyone where concerns had been raised about thoughts of self-harm or suicide were entered into the study. Although mood can change significantly in a short period of time and symptoms can worsen it was hoped that the healthcare professionals who referred participants to the research were confident that they would be able to receive online therapy and access it independently relative to the severity of their low mood and/or depression. If an individual's score on the MFQ used to assess eligibility was particularly high, the lead researcher discussed this with their primary care provider who made a clinical decision as to whether they felt the individual should enter the research.

Within BALM information was provided to participants about what to do if they experienced a worsening of symptoms or felt they needed to talk to someone. A help section within BALM contains several links to external providers of support – including websites with further information about low mood and/or depression and telephone helplines. As part of this there is the number linking users to their local CAMHS including their 24-hour crisis helpline. During the demonstration of BALM all users were shown this section. Throughout the programme participants were also reminded of what to do if they had any concerns and were directed to this information.

As BALM is delivered online, participants could access it at any time of day, and it was not possible to monitor the responses entered 24/7. However, the lead researcher ensured that SMFQ responses, completed at each session log in, were monitored daily. If a participant had responded 'true' to the questions 'I thought about killing myself or 'I thought about death or dying' BALM was programmed to send an automated email to the research team. This enacted a risk protocol (Appendix C) that was closely adhered to in all situations of this type. In these instances, an email was

sent to the participant asking them to seek additional support if they deemed it necessary, with information about sources of support provided. In addition, the lead researcher contacted the user's primary care provider and parent/guardian as soon as possible and asked them to speak to the participant about this as a matter of urgency. If a primary care provider was unavailable, the participant (and their parent/guardian) were advised to contact their local CAMHS, GP, or in serious events present to A&E or call 999. This process was outlined to all participants and their parent/guardians during the consent process and was a requisite of study entry. Furthermore, all individuals entering the study agreed to access additional support if they felt they may be at risk, or their mood significantly declined.

The SMFQ was the only information monitored regularly by the research team. This was outlined in the participant information leaflets to inform participants and their parent/guardian that other information entered in BALM would not be reviewed until the end of the research.

Confidentiality and anonymity

Confidentiality was maintained for all participants throughout the study. Full information about the purpose and uses of participant contributions was given in the participant information leaflet and clarified during the consent process. All information collected from participants was kept confidentially as described elsewhere (see 5.2.10).

To access BALM all participants were given a username which was individual to them. Usernames were based upon a participant ID number and did not contain any information that could personally identify them. When given access to BALM, participants received an automated email which allowed them to set up a password ensuring that only they had access to their individual account. During completion of the programme each user could only access their individual data and were never asked to enter any identifiable information. Any reminders sent to users were based upon pre-specified preferences provided by the participant at baseline. No communication provided any information about what the programme was being used for.

Study withdrawal

Participants could withdraw from the study at any time, without having to give a reason, however any information provided up until the point of withdrawal was retained, as agreed during the consent process. All participants were also informed that withdrawal

from the research would have no impact upon any current or future treatments. If a participant chose to withdraw, their primary care provider and parent/guardian was notified.

Burdens and benefits to participants

Those who consented were expected to spend time using BALM and completing all associated outcome measures. This was made clear during the consent process and outlined in the participant information leaflets. Whilst it could not be certain that BALM would be an effective treatment, it was hoped that study participants would find it beneficial in helping with the symptoms of their low mood and/or depression and provide them with techniques to practice in the future. The risk protocol also ensured that, during their participation, all consenting individuals were closely monitored for any worsening of their symptoms or any deemed self-harm or suicide risks and directed to appropriate care immediately.

As a thank you for taking part, and with consent, participants completing all BALM sessions and the associated outcome measures were entered into a prize draw. A £50 “Love to Shop” voucher was awarded to the winner and a £20 “Love to Shop” voucher awarded to one runner up.

5.2.9.2 Ethical approval

The study was initially considered by the HSRGC at the University of York in October 2019. Written feedback from the board requested several changes to some of the study documentation. Once these changes had been implemented, approval from the HSRGC was granted on 24.10.2019. The study was then submitted for NHS REC approval and considered by the Yorkshire and Humber - Leeds West Research Ethics Committee in December 2019. The committee, requesting no further changes, awarded the study a favourable ethical opinion on 02.01.2020 [Reference: 19/YH/0426] (see Appendix C for HSRGC and REC approval letters). Following the study’s ethical approval, and in line with the REC conditions of approval, the study was registered on clinicaltrials.gov [Identifier: NCT04291547].

5.2.9.3 Ethics amendments

During the course of the study four non-substantial amendments were submitted for HRA approval, all of which were in response to the COVID-19 pandemic.

Study recruitment commenced in January 2020 with sites approached and local agreements in place for recruitment to proceed. However, this had to be paused in March 2020 in response to the COVID-19 pandemic when England entered a national lockdown and many restrictions were placed upon social interactions. At this time no one had been identified for participation. The pandemic posed two particular challenges to the feasibility study. Firstly, all recruiting CAMH services had to postpone face-to-face appointments and were only able to deliver therapies remotely and to those most at risk. At this point one of the recruiting CAMH services postponed involvement in the study. Secondly, there was concern about continued recruitment given the nature of BA in increasing activity engagement, some of which will be social in nature. In response to this, non-substantial amendment one was submitted which sought permission to complete all study related measures remotely (via telephone or video) with data collection documents distributed, completed and returned electronically. Alongside this, sections of BALM were re-written to ensure the programme was suitable for delivery during the COVID-19 pandemic (see 4.5.1). In response to this amendment, changes were made to several study documents including the participant information leaflets, consent forms, expression of interest form and protocol. Approval to operationalise this amendment was received in April 2020.

When restrictions began to be lifted and services started to resume usual practice, additional challenges further affected recruitment. Several individuals who had been involved in initial discussions about study recruitment were no longer based within the recruiting services having been redeployed elsewhere. The process of re-embedding the study back into services therefore had to be achieved. This was more difficult than previously as healthcare professionals' availability to discuss the study and dedicate time to identifying potential participants was significantly reduced. Therefore, the number of individuals recruited was lower than anticipated. Owing to these further recruitment delays non-substantial amendment two was submitted which sought to extend the study recruitment end from late August 2020 to late December 2020. During this time discussions were also had with some of the study healthcare professionals about recruitment barriers with several citing the exclusion criteria as making it difficult to identify and refer to the study. Two of original exclusion criteria stated that individuals would not be eligible for the study if 'experiencing *any* comorbid mental health diagnosis' or 'deemed to be at risk of self-harm or suicide'. The healthcare professionals felt that the comorbidity criterion excluded several adolescents who may have benefitted from participation and requested more clarity. These two criteria were therefore amended, in line with clinical advice, to state that individuals would be excluded if they 'had a comorbid mental health diagnosis of

Bipolar Disorder or Psychosis’ or were ‘deemed to be actively at risk of self-harm or suicide’. The study principal investigator (PI) for one of the recruiting CAMH services also left during this time and was replaced, permission for which was also sought as part of non-substantial amendment two. Approval for this amendment was received in August 2020.

Study recruitment continued to be lower than anticipated and those who were recruited demonstrated low adherence with BALM. Therefore, and aligning to the feasibility aims, collecting additional information from healthcare professionals and participants to explore recruitment and adherence barriers and the potential impact of COVID-19 on the study was deemed important. In October 2020, a third non-substantial amendment was submitted to enable this. This amendment included the addition of fortnightly follow-up telephone calls with participants to ask about their participation experience and a short survey with healthcare professionals exploring their experience of recruiting (see 5.2.4.3 and 5.2.7.2 respectively). Whilst the study had not sought to collect this information *a priori* it was hoped that the inclusion of these two data collection methods would help the feasibility aims to be met. Approval to operationalise this amendment was received in October 2020.

Following continued low recruitment, a fourth non-substantial amendment was submitted to extend recruitment to late March 2021. Approval was received in December 2020.

5.2.10 Data storage and quality assurance

All study data were pseudonymised using a unique identifier for each participant. All study data were completed and stored electronically. This was stored on secure servers at the University of York, password protected with access limited to members of the research team. Datasets were transferred from software platforms to a restricted-access shared University drive via secure encrypted, GDPR-complaint methods.

The University of York’s data protection policy was adhered to at all times with all personal data collected as part of the study treated in accordance with GDPR and the Data Protection Act (2018). Information was provided in the participant information leaflets about the safe and secure storage of personal data. In addition, as per HRA advice, a link to further information about the requirements of GDPR was included. All

research data generated from the study will be archived for ten years as required by the National Institute for Health Research (NIHR).

5.3 Results

5.3.1 Recruitment

Recruitment took place between January 2020 and January 2021, pausing briefly between March and April 2020 in response to the COVID-19 pandemic. Two CAMHS (encompassing three sites and based in two local NHS Trusts) agreed to support recruitment however one of these postponed recruitment, again due to the COVID-19 pandemic, between March and July 2020 and then did not identify any eligible participants. All recruitment was therefore conducted within one NHS Trust CAMH service based across two sites. All recruited participants were identified in only one of these sites.

Owing to the significant delays in recruitment a data collection cut-off for inclusion in the analysis was implemented. This was set at 31st March 2021, at which point recruitment had been open for 13 months.

Overall, 35 individuals were identified as potential participants and provided with study information by healthcare professionals. Of these 12 (34%) were deemed eligible and consented to the study whilst the remaining 23 (66%) did not. Reasons for non-recruitment included individuals not being interested ($n=12$), becoming non-contactable following initial interest ($n=9$), not meeting the eligibility criteria ($n=1$) or not considering themselves to have low mood and/or depression ($n=1$).

5.3.2 Participant characteristics

As presented in Table 17, 12 adolescents ranging in age from 13 to 16 years ($M= 14.8$, $SD= 1.11$) were recruited. The majority were female (75%) and White British (92%). Most (83%) had experienced low mood and/or depression for over a year with 92% having received previous support including CBT, counselling (CAMH-based and/or school-based), medication and psychotherapy. Overall, 42% were receiving support including medication, psychotherapy or seeing a clinical psychologist, 25% were awaiting CBT, psychotherapy or a referral for private support and the remaining 33%

were receiving no help. At baseline, scores on the MFQ ranged from 22 to 56 ($M= 40$, $SD= 10.38$).

Table 17: Participant demographics and outcome measures at baseline, session-by-session and follow-up

ID	Sex	Ethnicity	Low mood duration	Age (years)	Sessions completed	Duration in study* (days)	Baseline MFQ	SMFQ scores by session										Knowledge	
								1	2	3	4	5	6	7	8	9	10	Pre	Post
001	M	WB	≥1 year	16	2	260	47	23	17	-	-	-	-	-	-	-	-	9	-
002	M	WB	≥1 year	14	5	215	22	10	6	8	7	7	-	-	-	-	-	5	-
003	F	WB	≥1 year	16	3	38	56	14	13	15	-	-	-	-	-	-	-	9	9
004	F	WB	≥1 year	15	3	188	42	18	19	16	-	-	-	-	-	-	-	10	-
005	F	WB	≥1 year	15	1	60	36	18	-	-	-	-	-	-	-	-	-	10	-
006	F	WB	≥1 year	16	3	83	34	14	13									9	-
007	F	WB	6-12 months	15	9	79	52	18	21	24	24	7	25	21	24	24	-	8	-
008	F	WB	1-6 months	13	0	71	45	-	-	-	-	-	-	-	-	-	-	7	-
009	F	WB	≥1 year	13	0	64	44	12	-	-	-	-	-	-	-	-	-	8	-
010	F	WA	≥1 year	15	5	64	23	11	9	14	11	12	-	-	-	-	-	9	-
011	F	WB	≥1 year	16	2	63	36	9	5	-	-	-	-	-	-	-	-	7	-
012	M	WB	≥1 year	14	5	61	43	12	8	10	13	11	-	-	-	-	-	8	-
<i>M</i>	14.8	3.2	104	40	14.5	12.3	14.3	13.8	9.3	25	21	24	24	-	8.5	9
<i>SD</i>	1.11	2.55	73.17	10.38	4.29	5.77	5.12	7.27	2.63	-	1.42	...

Notes. WB: White British, WA: White and Asian, *The number of days between being given programme access and withdrawal point/data-cut off point, - missing information, ... not applicable

5.3.3 Feasibility outcomes

5.3.3.1 Session attendance

As displayed in Table 17, at the data cut-off point, the mean number of study sessions completed by participants was 3.2 ($SD=2.55$). Only one participant (8%) completed the nine programme sessions with the remainder completing between four and six ($n=3$, 25%), one and three ($n=6$, 50%) or zero ($n=2$, 17%) sessions. Time to complete sessions (from the point of programme access to withdrawal or data cut-off) ranged from 38 to 260 days ($M=104$, $SD=73.17$). The mean time left between completing one session and starting the next was 11.2 days (range 0-113 days). No participants completed the final follow-up session.

5.3.3.2 Session adherence

Where participants attended sessions, adherence to the included activities was generally good. As presented in Table 18, completion rates were 100% for the symptom selection activity in session one as well as the activity reviews completed in sessions four to eight. Adherence however was lower for sessions two and three with the activities in these sessions being completed by 67% and 57% of the participants who accessed them, respectively.

Table 18: Session activity completion rates

Session number	Activities for completion	Number accessing (n)	Completion rates (n (%))
1	Symptom selection	10	10 (100%)
2	Short/long terms goal selection	9	6 (67%)
	TRAP/TRAC	9	6 (67%)
3	Activity hierarchy	7	4 (57%)
4	Activity review	4	4 (100%)
5	Activity review	4	4 (100%)
6	Activity review	1	1 (100%)
7	Activity review	1	1 (100%)
8	Activity review	1	1 (100%)

5.3.3.3 Questionnaire response rates

Questionnaire response rates reduced throughout the course of the study (Table 19). Only one participant completed the second set of knowledge questions and no participants accessed the long evaluation questionnaire. Both of these measures became available for completion when participants completed or withdrew from BALM.

Table 19: Questionnaire response rates

Time point	Measure (n=12)	Completed by (n, %)
<i>Baseline</i>	Demographic questionnaire	12 (100%)
	Knowledge questions (1)	12 (100%)
<i>Session-by session</i>	Short evaluation (1)	10 (83%)
	Short evaluation (2)	9 (75%)
	Short evaluation (3)	7 (58%)
	Short evaluation (4)	4 (33%)
	Short evaluation (5)	4 (33%)
	Short evaluation (6)	1 (8%)
	Short evaluation (7)	1 (8%)
	Short evaluation (8)	1 (8%)
	Short evaluation (9)	1 (8%)
<i>Follow-up/withdrawal</i>	Knowledge questions (2)	1 (8%)
	Long evaluation	0 (0%)

5.3.3.4 Study withdrawals

From recruitment start to the data cut off-point in March 2021 two participants had withdrawn from the study, one following completion of session three and the other following session one. Both withdrew as they did not consider the programme to be beneficial to them.

5.3.4 Acceptability outcomes

Data about the perceived acceptability and satisfaction with BALM were collected via the short evaluation questionnaires completed on a session-by-session basis and the five-star ratings displayed throughout BALM. Whilst no participants completed the long evaluation questionnaire at study completion or withdrawal, additional information about the acceptability of BALM was collected during participant follow-up calls (5.3.5.3).

5.3.4.1. Short evaluation responses

At the end of BALM sessions one to nine all participants were asked to complete the short evaluation questionnaire about how they had found the session they had completed. The perceived usefulness of sessions was measured using a scale from one (not useful at all) to ten (very useful). Responses for each session are presented below.

Session one (n=10)

Most participants reported to have spent 10 to 20 minutes on session one (n= 8, 80%) with the remainder reporting either ≤10 minutes (n=1, 10%) or 20 to 30 minutes (n=1, 10%). All stated to have looked at additional information presented in BALM during session one but only two participants provided information about this; one had looked at information about problem solving and the other about communication and conflict resolution. The mean session usefulness score was 5.8 (range: 1-8).

Five participants provided some additional comments about their experience of using session one. The general consensus was that the session was *'too wordy'* and could be improved if information were presented more visually. Whilst one participant said that the amount of text had made using BALM difficult with them struggling to focus another said that this had not been a problem as they had expected this of session one. One individual stated how they already knew about much of the information presented and therefore did not find this helpful. However, they acknowledged that others who had never been to CAMHS or received therapy before may find the information *'helpful or interesting.'*

Session two (n=9)

Nine participants completed evaluation questions about session two. Time spent on the session was reported to be ≤10 minutes (n=3, 33%), 10 to 20 minutes (n=3, 33%), 20 to 30 minutes (n=2, 17%) or over an hour (n=1, 8%). All participants stated that they had looked at extra programme information when completing session two but only one provided additional information about this, reporting to have looked at information for parents/guardians as well as information for friends. The mean session usefulness score was 5.5 (range: 1-8).

Four participants provided additional information about their experience of using session two. Like session one, the consensus was that the session contained too much text, described by one participant as *'info dumping'*. Therefore, one participant reported to have found it hard to read through the text without getting bored whilst another stated that they did not understand most of the content. However, one participant described how they had found BALM's inbuilt glossary very helpful and liked that key words were highlighted with their definition appearing if selected. One participant made several suggestions of how BALM's presentation could be adapted to help users maintain focus when using the programme:

“As someone who struggles with a short attention span and staying engaged, what really helps me keep focus on the subject is making key words and phrases a bigger, bold font. It helps my eye go directly to the word and keeps me wanting to read on. This would really help others who, like me, may have had to come back to this session a few times to really take in the material and benefit from it fully! I think also spacing paragraphs as well helps me read a lot easier, and often helps my brain process and understand long strings of text faster” [01/011, female, 16 years old]

Session three (n=7)

Most participants who provided feedback about session three had spent ≤ 10 minutes completing it (n=5, 71%) with the remainder spending 20 to 30 minutes (n=2, 29%). All reported to have looked at extra information in the programme during session three with two having looked at information about more help and one of these also viewing information about problem solving. The mean session usefulness score was 5.2 (range: 1-10).

Only one participant provided additional feedback relating to session three. As part of this session young people were asked to select 12 activities to engage in. The participant who provided feedback felt that to improve the session, help in selecting activities to engage in should be provided as they had found this difficult. Therefore, they felt the programme had made them feel worse:

“I didn't pick any activities as I don't enjoy anything and haven't for a while, this session didn't help with this and simply made me feel worse” [01/007, female, 15 years old]

Session four (n=4)

Most participants reported to have spent ≤ 10 minutes on session four (n=3, 75%) with the remaining individual spending 20 to 30 minutes (n=1, 25%). All reported to have looked at extra programme information during the session; one had looked at information about communication and conflict resolution and another at problem solving information. The mean session usefulness score was 6.3 (range: 1-9).

Only one individual provided any additional information about session four, stating that to make the programme better, pictures could be added to make the information presented clearer for younger users.

Session five (n=4)

Four participants provided evaluation information for session five. Two individuals stated that they had spent ≤ 10 minutes on the session whilst the remaining two had spent 10 to 20 minutes. All reported to have looked at other information during the session but only two provided further information. Both had looked at information about problem solving, whilst one had also looked at information about communication and conflict resolution and the other, information for friends. The mean session usefulness score was 6.5 (range 3-10).

Only one individual provided any additional information about session five, simply stating that they had found this session '*really helpful*'.

Sessions six to nine (n=1)

Only one participant provided any feedback on BALM sessions six to nine. The participant reported to have spent ≤ 10 minutes on each session and, although stated that they had looked at extra information did not specify what. The usefulness score for each session given was 2. No additional qualitative information was provided.

5.3.4.2 Five-star rating results

Completion of the five-star rating during BALM use was poor; ratings were only completed for the first three sessions with the number of participants providing ratings reducing as sessions progressed (Table 20). Where provided, ratings awarded for individual programme sections were generally good with multiple sections receiving ≥ 4 out of 5 stars. Whilst only rated by one participant, all supplementary information provided within BALM was awarded the maximum five stars as was the programme's homepage and mood graphs. As depicted in Table 20 the programme sessions rated the least favourably were help with engagement (session two) and the recap of session two presented at the beginning of session three. Unfortunately, as no star ratings were provided past session three, comparisons could not be made between satisfaction with earlier and later sessions.

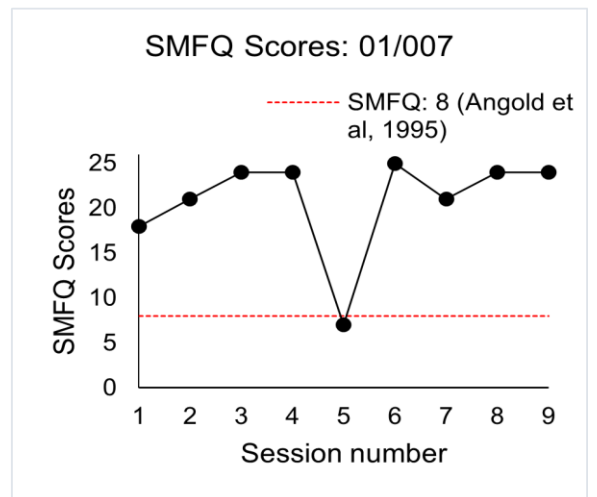
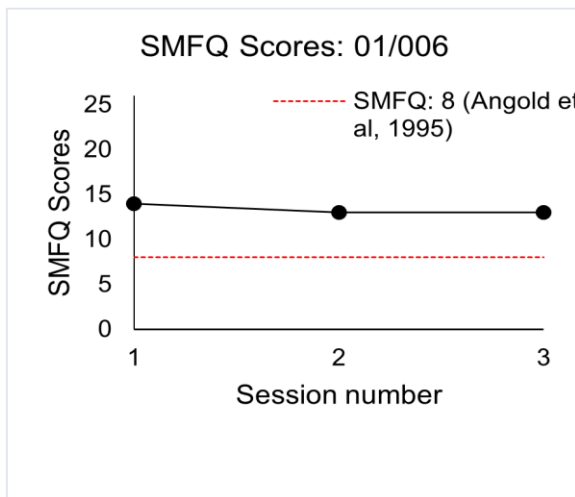
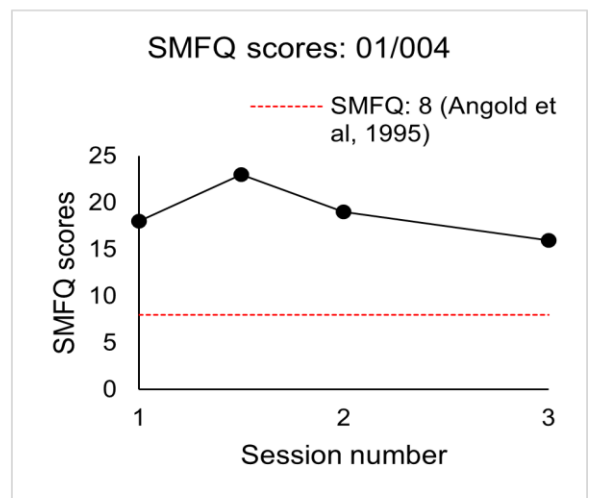
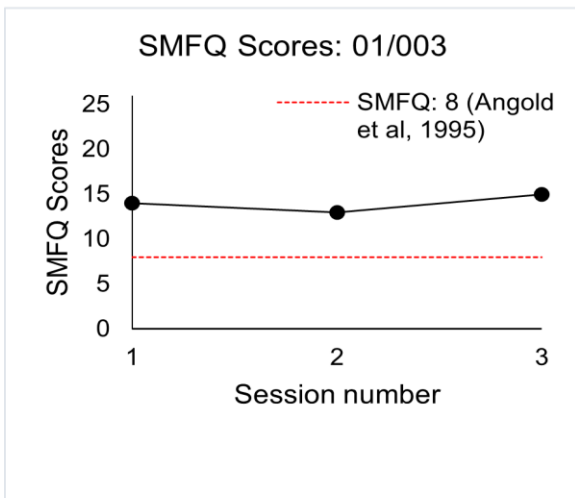
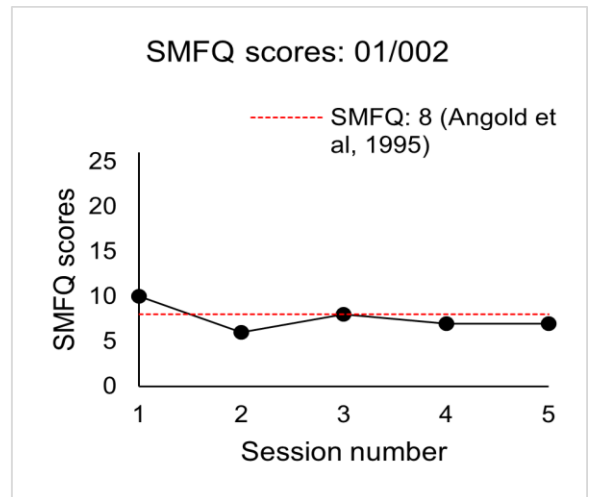
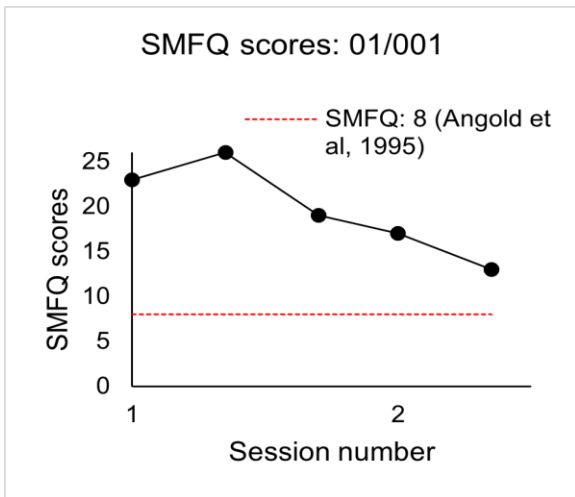
Table 20: BALM programme 5-star rating responses

Session number	Content rated	Times rated	Mean rating
Session 1	Welcome and introduction	5	4.20
	Low mood	4	4.75
	Low mood: Feelings	4	4.75
	Your feelings	4	4.25
	Introducing BALM 1	4	4.50
	Introducing BALM 2	4	4.50
	Introducing BALM 3	4	4.25
	Goals before next session	3	4.33
Session 2	Introduction and 'homework' review	1	4.00
	Re-cap of session 1	2	3.50
	Helping with engagement	2	2.50
	Helping with avoidance	2	3.50
	Helping to use the environment	3	4.00
	Short/Long-term goals	2	4.50
	TRAP/TRAC	4	4.25
	Goals before next session	1	3.00
Session 3	Introduction and 'homework' review	3	3.33
	Recap of session 2	2	2.50
	Planning activities	2	3.00
	Selecting 12 activities	1	5.00
	Tips for selecting activities	2	3.00
	Goals before next session	2	4.00
Supplementary information	Guide to low mod for parents/guardians	1	5.00
	Guide to low mood for friends	1	5.00
	Communication and conflict resolution	1	5.00
	More help	1	5.00
	Problem solving	1	5.00
	Programme recap	1	5.00
Other	BALM Homepage	1	5.00
	Mood graph	1	5.00

5.3.5 Additional measures

5.3.5.1 SMFQ scores

Although most participants only completed the SMFQ when they completed a session on BALM some accessed the measure more regularly (n=5), completing this at a higher frequency than BALM sessions. Over the course of the study, one participant did not complete the SMFQ at all and two only completed this once when programme access was given. All SMFQ scores, relative to session completion, for the remaining nine participants are presented in Figure 7. A score of eight or more on the SMFQ is considered to be clinically significant (Angold et al., 1995), this is depicted as a red dotted line.



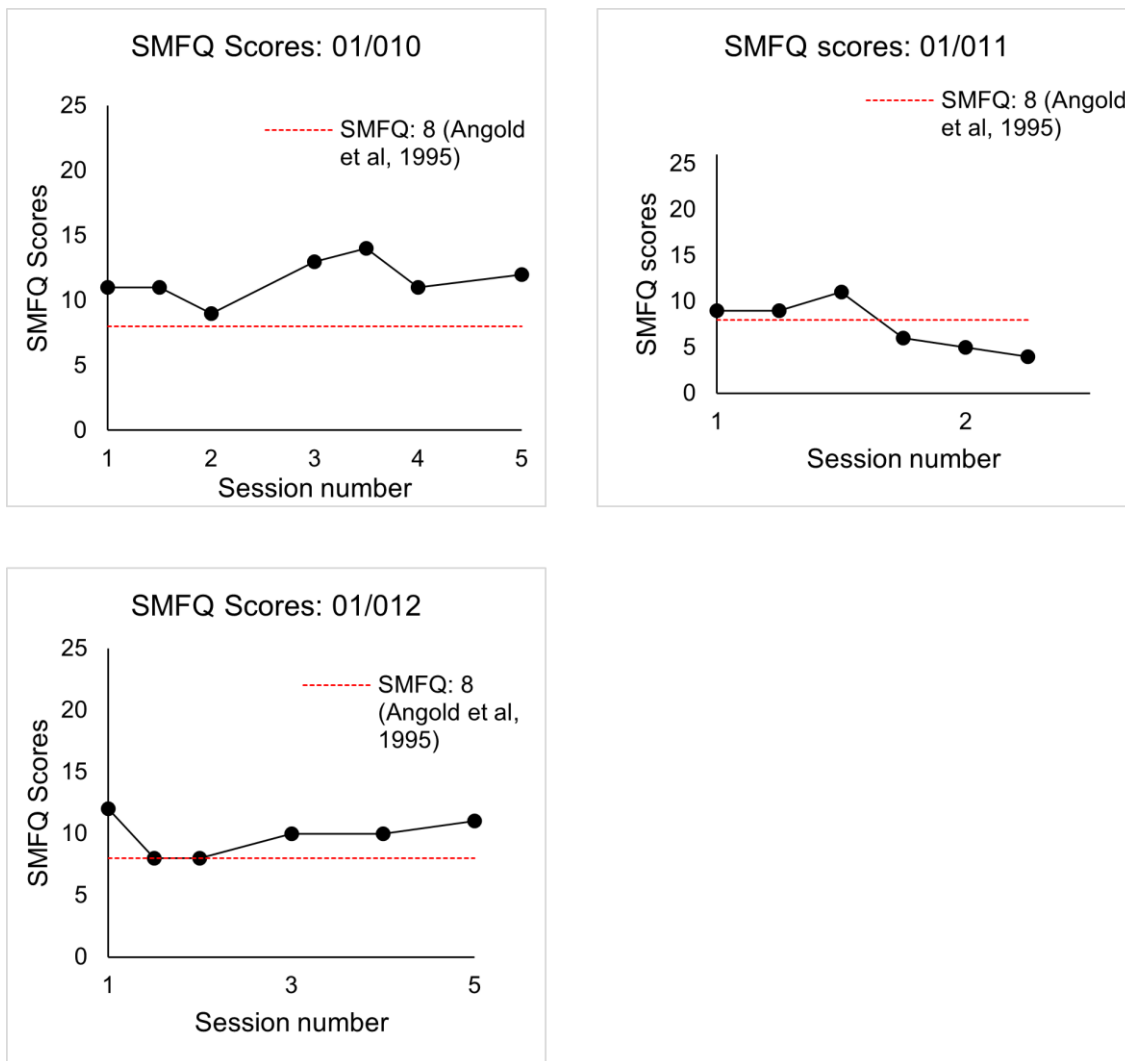


Figure 7: SMFQ scores relative to session completion

As demonstrated in Figure 7, SMFQ scores were variable across participants with most seeing both declines (suggesting improved mood) and increases (suggesting reduced mood) throughout their time using BALM. Three individuals demonstrated reductions in SMFQ scores from their first to last completion of this measure, with scores reducing from 23 to 13 (01/001), 10 to 7 (01/002) and from 9 to 4 (01/011). According to Angold et al. (1995) a score of eight or more on the SMFQ can be considered to be clinically significant. Therefore, as presented in Figure 7, two of these participants (01/002 and 01/011) attained scores that were ≤ 8 at the end of BALM use and therefore not considered to be clinically significant. For two participants (01/003 and 01/006) SMFQ scores remained stable across the three sessions that they completed, changing by only one point across sessions. For three participants (01/004, 01/010, 01/012), despite seeing increases or decreases in SMFQ scores during participation, scores were similar (changing by only 1-2 points) between the first and last SMFQ completed. The remaining participant (01/007) had a score of 18 at study entry which gradually

increased across initial sessions before decreasing to a score of 7 (considered not clinically significant; Angold et al., 1995) at session five. Scores increased again following this session with an SMFQ score of 24 attained at programme end.

5.3.5.2 Knowledge questions

At baseline, scores on the knowledge questions ranged from 5 to 10 ($M= 8.5$, $SD=1.42$). Only one participant repeated the questionnaire, attaining the same score (9/10) on both completions of the measure. This was completed at the point of withdrawal.

5.3.5.3 Participant follow-up calls

All participants agreed to receive follow-up calls with the lead researcher during their time using BALM with 35 calls ($M: 2.9$, range 2-7) completed over the course of the study. Although scheduled to take place fortnightly, owing to participants being non-contactable or unavailable, this was not always possible with some only completing calls once per month. The calls were conducted irrespective of programme progress and therefore at times, no further sessions had been completed between one follow-up call and the next.

In 74% of follow-up calls ($n=26$), participants reported to be successfully working through BALM. When asked about their experiences, several were positive about the programme describing it as '*good*' or '*very good*' and reporting to have found it easy to navigate and straightforward to use. The programme's diary sheets and mood monitoring were particularly valued with participants finding these helpful in encouraging them to plan activities and observe changes in their mood over time. One individual had noticed a decline in mood on their mood monitoring graph so described how they had actively looked at what they had been doing on that day to establish why this may have happened. The embedded audio option was also regarded positively, with some participants describing how this had enabled them to obtain information without having to read text. Having different voices available throughout the programme had allowed sections of text to be broken down thus enhancing understanding. One young person particularly valued having definitions of words presented throughout BALM which they had found a useful function in enabling them to gain a better understanding of programme content.

A frequently discussed negative feature of BALM, and aligning to the short evaluation questionnaire responses, related to the amount of text presented. Consequently, several participants had struggled to engage with the programme, finding sessions took too long to complete and therefore found themselves '*switching off*'. This also meant that some lacked the motivation to complete sessions, something identified as particularly problematic for those with low mood and/or depression. One young person described how they had struggled to understand some of the information presented including the TRAP/TRAC section and the embedded diagrams demonstrating the vicious cycle of depression. This individual reported to have spent approximately 25 minutes trying to find examples to complete the TRAP/TRAP activity before giving up and skipping to the end of the session. Another participant had found selecting activities to complete particularly difficult.

Several participants provided suggestions of how to make BALM more engaging. These included embedding videos to accommodate more visual learners and making key sections of text stand out (i.e. being presented in bold) enabling those preferring to skim read to review key points easily. One young person also suggested adding an optional dark setting to the programme to avoid eye strains. They explained how this could be particularly useful for young people with low mood and/or depression who may have problems viewing things for a long time.

As part of the follow-up calls, all participants were asked whether they were managing to access the programme as much as they would like, with most saying yes. Some reported how their frequency of accessing the programme had reduced as they had progressed through it. This was to allow them extra time to think of information to input and to engage in planned activities.

Where participants stated not to have used the programme, either at all or between follow-up calls, they were asked about the barriers to accessing it. Most reported a lack of time owing to the competing demands of school or college work or through simply forgetting to log on. Several participants also stated that they had experienced difficulties in accessing BALM either through forgetting their log in details or being unable to locate the programme's webpage. One young person described how, after spending a significant amount of time locating BALM, when they accessed it, they no longer wanted to complete a session. Another based programme access on their mood, describing how, if they were feeling particularly low, they avoided it otherwise they tended to look at the information and feel like they were being '*lectured*'. Others also described how their low mood had affected their programme use, with one young

person stating that through feeling particularly low they had not had the motivation to use BALM. Those who had not accessed the programme were asked whether they were planning on completing sessions. Only one participant said that they were unsure if they would stating: *'I will see how I feel'*. The remainder all highlighted that they intended to complete sessions. When asked whether there were any changes the research team could make to increase the likelihood of them accessing sessions, all participants said no.

Regardless of whether participants logged into BALM, all described how the programme was accessible to them at all times. On two occasions participants reported computer problems but said that they were simply accessing BALM through their mobile phones instead.

Ten of the participants were enrolled in school or college during their time using BALM. Owing to government restrictions in response to the COVID-19 pandemic most were being home schooled or engaging in a mixture of home and school-based learning for the majority of their study participation. All also experienced periods where educational establishments were reopened, but frequently only for short intervals or for particular year groups. Whilst several participants felt that their educational circumstances had had no impact on their programme use, others reported both positive and negative experiences. For some home schooling had provided them with more availability to access BALM or increased the likelihood of them remembering to complete sessions. Conversely, some felt that home schooling had a negative impact as, after completing lessons online, accessing the programme was regarded as *'too much screen time'*. Therefore, one young person felt that returning to classroom-based learning would make completing the programme easier. However, when participants did start to return to educational settings, the additional work provided to enable them to catch up with school/college work was reported to be an additional barrier to programme use. One young person described how returning to school had been *'chaotic'* and therefore they had not had time to dedicate to BALM.

When asked about whether they felt COVID-19 had affected them using BALM, participant responses were again mixed. Several reported that the pandemic had had no impact upon their programme use, with one individual saying that COVID-19 had resulted in them having more free time and were therefore more likely use BALM. Two individuals highlighted how, as the pandemic had been around for the duration of them using BALM, they did not feel it had had an impact as they did not know what their experience would have been like without it. Where an impact was reported, this

was in relation to two key areas – the pandemic’s impact on schooling, as previously discussed, and on activity engagement with several participants describing how they had found it difficult to think of ideas for activity scheduling that conformed to government regulations.

5.3.5.4 Healthcare professional survey

The healthcare professional survey was available for completion between October 2020 and January 2021. The survey link was distributed to 89 individuals based within two CAMH services either by the lead researcher or team secretaries. Through adopting the latter of these approaches, it was expected that 23 individuals who received the survey would not be able to participate (e.g. those in administration roles). It is not known whether any individuals forwarded the survey onto other colleagues however as whole teams received it this is unlikely. Of the 66 healthcare professionals who received the survey and able to provide information, 15 (23%) accessed it overall. Of these, ten completed it entirely with the remainder providing partial (n=1) or no (n=4) responses. The partial response contained only demographic information and therefore only the ten complete survey responses are reported.

Healthcare professional characteristics

The ten healthcare professionals represented a variety of roles within CAMHS including three psychiatrists, three nurses, one clinical psychologist, one children’s wellbeing practitioner, one healthcare assistant and one psychotherapist. Length of service ranged from one month to 25 years. Across the sample the number of young people they saw with low mood and/or depression per month ranged from one to 30. Two respondents were unable to provide a figure here, responding ‘unknown’ or ‘many’.

Healthcare professionals’ recruitment experiences

Four healthcare professionals had approached service-users about the study, discussing it with 19 individuals and providing additional information to 11 of these (of whom six were recruited). All individuals had been identified from current caseloads or therapy waiting lists. Despite this, three of the four healthcare professionals did not feel they had been able to dedicate sufficient time to discussing the study with individuals. Those who had identified adolescents for the research felt that the main factors that influenced participation were adolescents’ (i) motivation to receive

additional support for low mood and/or depression, (ii) interest in learning about an alternative therapy type and (iii) preference to have therapy delivered in an online format rather than face-to-face. It was felt that those who had chosen not to participate had done so through lacking motivation and/or interest or having alternative pressures (e.g. school/college work). One healthcare professional stated that by the time individuals had reached them within their service they were too unwell to receive therapy in an online format.

The healthcare professionals felt that a lack of motivation and/or interest, a lack of therapist presence, concerns about additional screen time and other pressures (e.g. school/college work) would be the main barriers to adherence. Conversely, being motivated to get help with low mood and/or depression or wanting to please a parent or clinician were considered the main facilitators here.

The remaining six healthcare professionals had not discussed the study with any adolescents. The majority (n=4) cited not deeming any adolescents that they had seen as suitable for participation as their main reason. One healthcare professional had been too busy to discuss the study and described how the COVID-19 pandemic had created huge clinical challenges for them resulting in them seeing fewer adolescents face-to-face. The remaining healthcare professional said they did not know anything about the study.

COVID-19 impact on the feasibility study

When asked about the extent to which the healthcare professionals felt recruitment to the feasibility study had been affected by COVID-19, 50% selected scores indicative of high to extremely high impact, conversely 30% reported low to no impact at all.

Where responses were indicative of COVID-19 having a significant impact on recruitment, the reasons were mixed. For some, this related to them being able to recruit fewer adolescents to the study through finding it difficult to explain the research remotely, having increased workloads and less time to dedicate to research recruitment and reports of reduced referrals of those with mild to moderate low mood and/or depression. Interestingly, whilst some healthcare professionals reported that the pandemic had resulted in them seeing more individuals with severe low mood and/or depression who were unsuitable for participation, one healthcare professional felt that young people appeared happier during government restrictions through reduced school pressures and were less likely to contact services. Where clinicians reported COVID-

19 to have had a significant impact on recruitment this was not always through experiencing difficulties. One healthcare professional stated that, whilst they had previously not supported internet-based therapies, they had been overwhelmed with referrals due to the pandemic and therefore more likely to recruit than previously.

The impact of COVID-19 on study adherence generated more of a consensus with 70% of healthcare professionals believing this would be moderately to highly affected. Most commonly it was felt that the pandemic had resulted in many activities requiring completion online (e.g. schoolwork, meeting friends, etc.) and therefore providing therapy in this format could be too overwhelming. In addition, some highlighted that with less routine in place adolescents may become more apathetic about completing a structured online therapy or less motivated. One healthcare professional felt that with reduced face-to-face contact with clinicians and potentially less familial support due to additional pressures created by the pandemic (e.g. unemployment etc.) young people would not have sufficient support to help them to engage in therapy. Conversely, some suggested that the pandemic may enhance study adherence through providing adolescents with more time to complete the therapy and being more adept to working online.

Increasing recruitment and adherence

To increase recruitment healthcare professionals suggested wider study advertising via the distribution of leaflets in suitable locations like GP practices, embedding the study more in SPA teams and having designated clinicians to support recruitment with time protected for this. Several also proposed embedding the study in school-based services and providing recruitment slots for any adolescent experiencing low mood and/or depression to attend and discuss the study.

Suggestions for increasing adherence included providing incentives, setting appointment times for session log ins and completing regular check ins with young people. One healthcare professional also suggested exploring whether protected time and space could be provided during the school day for programme completion.

Overall, 30% of healthcare professionals felt that study recruitment was well-placed within CAMHS. The remainder either felt that recruitment needed to be expanded to other locations alongside CAMHS (40%) or wholly placed elsewhere (30%). Suggested alternative recruitment sites included schools, GP practices and community-based mental health services.

5.4 Discussion

5.4.1 Summary of the results

This chapter presents the findings of a non-randomised feasibility study of the newly developed BALM programme. The completion of this work aligned to phase five of co-design: pre-testing of intervention prototypes. As previously discussed, feasibility studies are often useful preparatory work for definitive RCTs in determining whether a larger study should be conducted and if so the approach to be taken (Eldridge et al., 2016). Specifically, this study aimed to assess the feasibility of undertaking a pilot RCT of BALM and examine its acceptability in treating adolescents experiencing low mood and/or depression.

5.4.1.1 *The feasibility of undertaking a pilot RCT of the intervention*

Study recruitment

Overall, 12 adolescents consented and used BALM to help with their low mood and/or depression. Whilst the successful attainment of the recruitment target demonstrated it possible to recruit to research of this type, only one participant (8%) completed the first nine treatment sessions by the data collection cut-off in March 2021, with none accessing the follow-up session. Furthermore, although only two participants withdrew from the research and most had programme access for a long period of time ($M= 104$ days), the majority did not progress past session three despite expressing their intentions to complete sessions during follow-up calls.

BALM adherence and dropout

Adherence often represents the proportion of a treatment that is completed (e.g. Karyotaki et al., 2015), with 'dropout' used to describe non-completion and frequently defined relative to the time spent on treatment or the number of sessions completed (de Haan et al., 2013). In their review of predictors of dropout relative to unguided web-based interventions, Karyotaki et al. (2015) considered dropout to be those who completed <75% of an intervention based on the assumption that most fundamental treatment components would have been presented at this point in therapy. Whilst dropout in the current feasibility study was not established *a priori*, if adopting a similar approach to Karyotaki et al. (2015) it could be suggested that those who completed <50% of BALM sessions would represent dropout in this context. At this stage in

BALM, all treatment categories of BA as suggested by Kanter et al. (2010) (minus relaxation – see 4.2.5) had been presented, with specific focus upon both activity scheduling and monitoring – the two intervention types consistently delivered in BA (Kanter et al., 2010). Aligning to this definition, 67% (n=8) of participants could be regarded to represent dropout in the current feasibility study. This finding corresponds to a meta-analytic review by de Haan et al. (2013) who reported that between 28% and 75% of children and young people drop out of psychotherapy treatments.

Again, although not established *a priori*, if based upon the number of sessions completed relative to the overall number of BALM sessions available, adherence in this feasibility study ranged from 0 to 90% ($M= 32\%$). Where sessions were accessed, adherence to individual session activities was generally good. However, declines in activity completion were evident across sessions two and three – the points in the programme where most participants were seen to dropout.

These results suggest higher dropout and lower adherence rates than reported in previous reviews within this context. For example, in a systematic review of the delivery of CCBT for young people (aged ≤ 18 years) with depression and anxiety, Richardson, et al. (2010) reported therapy completion rates to range between 33.3% and 69.9% in ten included studies. More recently, in a systematic review and meta-analysis of technologically delivered interventions for young people (aged 6 to 18 years) with anxiety and depression, Grist et al. (2019) reported mean intervention completion rates to be 64% (range 0-100%) across 34 RCTs. Similar findings have also been reported in reviews with older participant samples. Rasing et al. (2020), in their review of online interventions with young people (aged 12 to 23 years) experiencing depression, reported adherence rates between 62-94% and dropout rates of 0 to 21% when an unguided therapy approach was adopted.

When looking at the results of studies examining unguided treatment approaches specifically for depression, the feasibility results are more comparable. In a large RCT comparing two unguided CCBT programmes (Beating the Blues[®] and MoodGYM) with usual care for the treatment of depression in adults, Littlewood et al. (2015) reported low adherence in the use of both CCBT programmes. Here, the most frequent number of sessions completed was one across both groups with only 18% of individuals completing the eight-session Beating the Blues programme and 16% completing the six-session MoodGYM programme. This RCT, like the current feasibility study also incorporated regular administrative phone calls to provide technical support. Several studies have examined the delivery of MoodGYM with adolescents also. In a cluster

RCT of MoodGYM with 12 to 17 years (Calear et al., 2013; 2009) 62% of the sample were reported to have completed three or more of the five sessions. Two earlier studies however reported adherence rates to be more concordant with those reported in this feasibility study. In a study by O’Kearney et al. (2006) 40% of males aged 15 to 16 years completed three or more sessions of MoodGYM (out of a total of five). In a later study with females aged 15 to 16 years (O’Kearney et al., 2009) only 29.8% of the sample completed three or more sessions. The dropout rates reported in these studies were however much lower than those reported with BALM with 15% reported by O’Kearney et al. (2006) and 14.6% reported by O’Kearney et al. (2009).

Possible explanations for the low adherence and high dropout in the current feasibility study are explored in further detail elsewhere (see 5.4.3).

5.4.1.2 The acceptability of BALM in treating adolescents with low mood and/or depression

The acceptability of BALM was examined at various points, during completion of short evaluation questionnaires and star ratings on a session-by session basis and the completion of follow-up calls. As most participants did not proceed past session three, ≤50% of the sample completed evaluation questionnaires beyond this point (reducing to only 8% (n=1) for sessions six to nine). Therefore, reliable conclusions about the acceptability of the whole programme cannot be drawn. However, where feedback was provided, information about the acceptability of several components of the therapy was obtained.

Several participants particularly valued the mood monitoring component, evidenced in the feedback received during follow-up calls but also by the frequency in which this tool was used throughout programme use. Nearly half of the sample (n=5, 42%) completed the mood measure more frequently than programme sessions, with several stating during follow-up calls that they valued being able to see changes in their mood over time. This finding was similar to those reported in the qualitative study (Chapter Three) where several service-users discussed the value of mood monitoring. In addition, during follow-up calls the diary sheets used for activity scheduling were identified by some as useful for assisting them in planning engagement. Whilst only 57% of the sample selected 12 activities to engage in and created an activity hierarchy during session three (see Table 18), 100% of these individuals then completed activity reviews in the remainder of sessions that they completed. These findings suggest that the scheduling and monitoring of engagement was regarded as acceptable by some.

Despite several programme components being regarded favourably, one area which was frequently discussed negatively was the amount of text presented in BALM. Many participants regarded the programme as being *'too wordy'*, with several highlighting that this had made them *'switch off'* and had affected their motivation to complete sessions. Whilst some participants valued the embedded tools to assist with processing the information presented (e.g. audio, glossary, definitions of words) others did not deem these to be sufficient, instead highlighting the requirement of more visual information. In line with the feedback received, it is likely that the amount of text presented in the programme contributed to why 2/3 participants did not proceed past the first three sessions – those that contained the most text to read.

Whilst the effectiveness of BALM on treating low mood and/or depression was not investigated in this study, scores on the SMFQ suggested that some saw improved mood across programme use.

5.4.2 Evaluation of the non-randomised feasibility study

5.4.2.1 Strengths of the study

This study provided important information about the acceptability and feasibility of the first known online version of a BA programme for adolescents with low mood and/or depression in the UK. Specifically, regarding the methods to be employed in a pilot RCT, the modifications needed for further development of BALM and the delivery approach to be adopted. This is important in informing future development of the programme and in providing useful information to inform a larger pilot RCT. As previously discussed, (see 5.1.1) feasibility work can help to establish whether further, larger and more cost-intensive research is likely to succeed thus enabling researchers and funders to invest in research less likely to result in significant waste (Morgan et al., 2018). By using the feasibility findings to inform future work, issues such as high drop-out, low adherence and slow recruitment, as reported here, may be successfully addressed in subsequent, similar studies within this area therefore enhancing their chance of succeeding and reducing the chance of research waste. The study also provided an additional therapy option to participants with feedback suggesting that several therapy components had been deemed useful. The inclusion of a robust risk protocol ensured the safe delivery of the research with continued monitoring of participants allowing the identification of any worsening symptoms or deemed self-harm or suicide risks. Furthermore, as all outcomes were pre-specified, no selective reporting took place enabling reliable conclusions to be drawn. Despite these identified

strengths, caution with the interpretation of the results is required owing to several limitations of the study.

5.4.2.2 Limitations of the study

Although only minimal changes were made to the feasibility study for it to proceed during the COVID-19 pandemic, significant delays in recruitment occurred. These were as a result of the time taken to implement study changes, the pausing of recruitment to accommodate COVID-related service delivery changes and the subsequent re-embedding of the study when services resumed. Consequently, recruitment did not start until much later than anticipated which, due to temporal constraints, resulted in the data collection period being much shorter than originally planned. As many of the participants left significantly long periods of time between sessions, much more data may have been available for analysis had there been more time available between recruitment end and the end of the data collection period.

The pandemic also placed great pressures on the recruiting healthcare professionals. In particular through having to adjust to new ways of working and dealing with increased caseloads that had resulted from them having to postpone face-to-face appointments and, initially, only see those considered high risk. Given the low programme adherence, investigating whether the unguided treatment approach was a moderating factor would have been favoured. For instance, examining whether adopting a more guided approach would have affected adherence through sampling a cohort of participants to complete the programme alongside healthcare professional support. However, the significantly reduced availability of healthcare professionals meant that this could not be explored. Furthermore, as the pandemic lasted for the duration of the study it is difficult to know the extent to which COVID-19 affected the study findings nor generalise them to time periods where restrictions are not in place.

Recruiting participants from CAMHS alone was another limitation. Recruitment was initially due to take place in a school-based service as well as CAMHS (see 5.2.5) thus enabling adolescents to be recruited from different positions in the care pathway. Through only recruiting in CAMHS, identifying adolescents with mild to moderate low mood and/or depression was more difficult as those entering services generally had more severe presentations and were therefore not eligible for study inclusion. In addition, during personal communication with two of the recruiting clinicians (24.09.2020) it was highlighted that referrals of those with mild to moderate low mood and/or depression were generally retained as cases for their trainee children's

wellbeing practitioners as part of their training model. Consequently, several adolescents who may have been eligible for the study would not have been identified. It is therefore unsurprising that 70% of those who completed the healthcare professional survey felt that recruitment needed to be expanded alongside CAMHS or based in a completely different setting. Although the study demonstrated that adolescents could be recruited from CAMHS comparisons could not be made about the feasibility of recruiting more broadly including within community and school-based settings. As a result, conclusions could not be made about the aim established *a priori* regarding establishing the best position of BALM in the care pathway. As school-based services are increasingly involved in mental health provision, in response to the government's 2017 Green Paper, (DHSC & and DfE, 2017) recruiting to the study from such a service would have provided important information about whether BALM could be successfully embedded within alternative settings also. Furthermore, with increasing pressures on CAMHS, and yearly increases in entry thresholds (Fairchild, 2019) identifying adolescents with mild to moderate low mood and/or depression is likely to become more difficult within CAMHS. Therefore, exploring whether low-intensity therapies such as BALM can be successfully delivered in services other than CAMHS is essential.

Recruiting only from CAMHS also affected the generalisability of the findings. One of the rationales for developing an online approach was to circumvent barriers to accessing services (e.g. reluctance to engage with therapists face-to-face, concerns about stigma). Therefore, as all participants had already accessed CAMHS at the point of identification for the study they are unlikely to be representative of those who experience significant barriers to service access. For example, although speculative, it could be inferred that through accessing CAMHS those recruited were more amenable to receiving a face-to-face treatment approach. This may also explain why 12 of the 23 individuals who were identified for the study but declined, chose not to participate through not being interested.

Although study recruitment was originally due to take place within two CAMH services encompassing three different sites all participants were identified in only one of these locations. This further affected the generalisability of the findings as the overall sample of participants were recruited from only one geographical area and not culturally or ethnically diverse. This was a similar difficulty reported in the qualitative study (Chapter Three).

Several methodological limitations may also have affected the results found. Minimal information was collected from participants post session-three of BALM owing to high dropout, specifically no participants completed the long evaluation questionnaire. This was designed to provide evaluation about the BALM programme overall and became available to participants on completion or withdrawal from the programme. None of the participants completed the programme and only two withdrew, which suggests that this questionnaire may be better positioned at an alternative time-point to enhance completion rates and thus the collection of additional information about programme satisfaction and acceptability. This may have been better completed as part of the follow-up telephone calls where those who had not accessed BALM for some time could have been asked to provide additional information about their experiences. Alternatively, questions about the programme overall, as opposed to just about individual sessions could have been added to the short evaluation questionnaires available at the end of each session. As no objective measures were employed during the feasibility study, all collected data were self-report and may have been subject to bias. Future research in this context may therefore seek to collect information utilising varied outcome assessment approaches. The lack of a control group meant that an examination into whether the changes in SMFQ scores (Figure 7) could be attributed to BALM use or were the result of other factors could not be conducted. Finally, an error in the short evaluation questionnaire was noted after completion of the feasibility study. When asked to record how long they had spent on programme sessions, participants were presented with responses that overlapped (i.e. 10 to 20 minutes, 20 to 30 minutes, 30 to 40 minutes, etc.). Therefore, the results reported in section 5.4.3.1 are not a truly accurate reflection of the time spent upon sessions.

5.4.3 Implications of the findings

Several conclusions can be drawn from the study's findings. As introduced in Chapter One and revisited throughout this thesis, an empathy-based approach, adopting a participatory design, was employed in the development of BALM. This approach, which incorporated stakeholders including adolescents, healthcare professionals and web-developers sought to ensure that BALM met the needs and preferences of target users. This aimed to address several weaknesses often associated with digital technologies including low uptake, low adherence, and high attrition (Scholten & Granic, 2019; Jones et al., 2020) and result in an intervention more likely to be seen by users as engaging, satisfying and useful (Thabrew, et al., 2018). Despite this approach, this feasibility study found high dropout and low adherence with BALM. According to Scholten and Granic (2019) both attrition and low adherence are higher

amongst young people. Considering this, and as research suggests that higher intervention adherence may be associated with better treatment outcomes (Donkin et al., 2011), identifying the factors that may have contributed to this may have important implications for future work in this area.

Firstly, several factors relating to BALM itself may have affected the findings. The lack of available component analyses of BA packages available (Hoyer et al., 2020; Kanter et al., 2010: see 4.2.5) and thus uncertainty about the mechanisms for change in their delivery, resulted in caution when selecting the content for inclusion in BALM. Whilst this was guided by an extensive examination of previous BA deliveries with young people and adults, as well as the qualitative study findings (Chapter Four), the findings of this feasibility study suggest that less content may have been favourable. Whilst the value of activity scheduling and both mood/activity monitoring were highlighted, little data were provided by participants about other components potentially as a result of them not proceeding sufficiently far enough through the programme to be able to do so. Aligning to the feedback received this is likely to be, at least in part, due to adolescents disengaging early in response to the amount of information presented. Most critique about the 'wordiness' of the programme was received following session one, where an introduction to low mood and/or depression and BA was provided. Whilst several elements of this introductory session set the basis for future sessions (i.e. establishing the treatment rationale) the majority was in the form of psychoeducation (e.g. providing information about depression, statistics, etc.), deemed 'ancillary' by Kanter et al. (2010). As initial programme sessions contained greater proportions of information than later, more practical sessions it is likely to explain why many participants disengaged from the programme early. Furthermore, and as reported during follow-up calls, many participants, especially those with previous experience of accessing CAMHS appeared knowledgeable about this information already. In a qualitative study by Garrido, Cheers, et al. (2019) examining young people's experiences of several mental health apps, the authors reported that the simplicity of an intervention was deemed important, particularly the presentation of minimal text-based information. In a systematic review of digital mental health interventions in the same year (Garrido, Millington, et al., 2019), educational content was identified as one of the main features of digital interventions disliked by young people. This could suggest that more active therapy components such as activity scheduling and monitoring are required at the outset of programme use with additional information (e.g. psychoeducation, treatment rationale) either removed entirely or added as supplementary content for those wishing to view this.

Support for consolidating the information presented in BALM was also found when observing the time spent on sessions with the programme length also a potential contributor to early disengagement. Whilst sessions were designed to last between 30 and 45 minutes to enable programme content to be covered in ten sessions (Chapter Four), the short evaluation questionnaires highlighted that of the 38 sessions completed, 33 (87%) were reported by participants to have taken less than ten minutes (n=18) or between ten to 20 minutes (n=15) to complete. Furthermore, whilst leaving between three days and one week between sessions was recommended, the mean time left was 11.2 days with a range that extended from zero to 113 days. During follow-up calls many participants attributed their limited programme use to a lack of time resulting from conflicting demands. Several also suggested the amount of screen time required for the programme was too much, especially during periods of home-schooling comprising remote learning. Taking these findings together, both low adherence and high dropout may have been influenced by the quantity of information presented, and time taken to work through it, within the programme. Some have suggested that simpler BA models may be as efficacious as those that are more complex (Spates et al., 2016; Kanter et al., 2010). Therefore, providing adolescents with a tool that is quick-to-use and encompassing only active treatment components may be a more successful approach.

Another contributing factor to both the low adherence and high dropout of BALM may have related to elements of the programme's delivery and presentation. In response to the programme's perceived 'wordiness', as previously discussed, several participants highlighted the requirement of more visual information. In a previous RCT (Titov et al. 2015) treatment completion rates were similar between guided and unguided CCBT deliveries with the finding attributed to the quality of the unguided intervention, particularly its use of high-quality materials. Whilst the empathy-based approach and participatory design adopted in the development of BALM sought to address the needs of target users, not all needs could be addressed, mainly in response to temporal and financial constraints (Chapter Four). As a result, the majority of BALM had to be presented in a text-based format with interactive activities and graphics embedded where possible. Whilst tools, (e.g. audio, glossary, definition of terms) were added to assist with processing textual information, the feedback from several participants suggested that this approach was not sufficient for enhanced understanding and sustained programme engagement. In addition, whilst more than one version of BALM would have been preferable owing to the significant variability in development during the adolescent period (Chapter Four), this was not possible.

Scholten and Granic (2019) stated that one potential flaw of digital interventions is the tendency for developers to simply reproduce the content of a treatment to an online delivery and assume that this will be more engaging for young people. Therefore, many digital tools may comprise uploaded manuals which have received little modification from their original paper-format and may in fact be even less engaging (Scholten & Granic, 2019). Specifically, Scholten and Granic (2019) emphasised several limitations of digital interventions for young people including their reduced flexibility, personalisation, and responsiveness to user needs. Through limited resources, the incorporation of more high-quality materials, interactive content, and personalisation (Scholten & Granic, 2019; Titov et al., 2015) was not possible in BALM. The lack of these tools may have significantly affected user satisfaction and engagement through not accommodating individual needs sufficiently.

Adopting an unguided treatment approach in the delivery of BALM may have also been a contributing factor to the low adherence and high dropout rates reported. As discussed in Chapter One, research has suggested that adopting an unguided approach when delivering online therapies may produce clinical outcomes comparable to those adopting a guided approach (e.g. Karyotaki et al., 2021; Rasing et al., 2020; Titov et al., 2016; 2015). Furthermore, additional benefits of an unguided approach including their increased cost-effectiveness, extensive dissemination (Karyotaki et al., 2021), and both increased privacy and perceptions of self-control (Rasing et al., 2020) have been highlighted. Whilst the rationale for adopting an unguided approach was predominantly based upon the results of previous research in the area (e.g. Karyotaki et al., 2021; Rasing et al., 2020), allowing adolescents the opportunity to exercise autonomy was also a driver here. The requirement for adolescents to take responsibility for issues surrounding their own health was evidenced both from the qualitative work findings and the review of adolescent biopsychosocial development presented in Chapters Three and Four. Particularly in the qualitative work, adolescent participants discussed the importance of anonymity and privacy as well as how they wanted opportunities to exercise autonomy. Autonomy was regarded as important relative to both using a therapy (e.g. choosing what content to view, selecting activities to engage in, etc.) and in deciding whether to involve others in treatment.

In the development of BALM, accommodating both of these opportunities for autonomy was sought with users able to control how they navigated through the programme (e.g. selecting what and how much content they viewed) and choosing whether to complete therapy independently or with others present. Adopting an unguided delivery approach supported this with programme use not influenced in any way by additional face-to-face

support which may have affected session timings, activity completion requirements, etc. However, the low adherence and high dropout of BALM suggests that this approach was not successful.

Attributing low adherence early in the feasibility study to the unguided delivery approach adopted, follow-up telephone calls were introduced. These calls did not attempt to move the programme to a guided delivery, rather mitigate low adherence by reminding participants to complete programme sessions and offer practical support if required. This approach was favoured over moving to a guided approach (i.e. introducing the presence of a therapist) which was felt may re-introduce some of the barriers to treatment access (e.g. reduced treatment flexibility and anonymity). Furthermore, with limited clinician availability, moving to a guided approach was not practical and was deemed counter-productive to the aim of BALM in providing an accessible treatment option. Adding more administrative support in this way has been reported elsewhere and demonstrated increased adherence. For example, in a systematic review and meta-analysis examining online psychological interventions for adults with depression, Richards and Richardson (2012) found that dropout rates were much higher (74%) in studies where no support was provided compared to studies where administrative (38%) or therapist support (24%) was given. Whilst this finding favours therapist support over administrative support, it still suggests that dropout rates may be considerably reduced when some support is adopted. Furthermore, in a review of unguided therapies for anxiety and depression, Talbot (2012) concluded that including non-guidance contacts (i.e. those that do not involve providing therapy assistance) in treatments can elicit similar benefits to those where a therapist is present. Despite these previous findings suggesting the benefits of including administrative support, this was not found in the current feasibility study. Whilst the follow-up calls reminded participants about the programme, the low adherence and high dropout from BALM suggest that their implementation did not increase programme access. Furthermore, whilst scheduled to take place at fortnightly intervals, these calls rarely adhered to this owing to participants being unavailable or non-contactable. As the calls were completed to simply check on progress they may have been regarded as less important by participants than if delivered by therapists.

Whilst BALM sought to allow adolescents control over the therapy they were receiving, adopting an unguided approach, and supporting programme completion through reminders and administrative follow-up calls, this may not be sufficient. When providing feedback, several participants discussed their lack of motivation in accessing BALM sessions especially at times when their mood was particularly low. This was

reiterated in the healthcare professional survey with reduced motivation as well as reduced additional support (from both clinicians and within the family) being identified as barriers to adherence. As reduced motivation has been associated with depression (Loonen & Ivanova, 2016), in future, similar work providing increased therapeutic support to help adolescents work through the programme might be required. Although adopting a guided approach may negate some of the benefits of online deliveries (e.g. autonomy, flexibility of use, etc.) and might be difficult owing to limited clinician resources, a blended approach might be one solution. The unguided treatment approach may also have impacted upon the number of young people referred to the programme. Whilst the recruitment target (n=12) was attained, this took 13 months to achieve. Like reported by Rasing et al. (2020) (See section 1.3.2) clinicians may have been concerned about BALM, given its online format and unguided approach, being able to adequately monitor risk. This may have deterred some from referring to the study.

Besides the programme itself, the characteristics of the participant sample may also have affected both adherence and dropout rates with BALM. As all participants were recruited from CAMHS, which maintain a threshold for service entry, it is likely that participants had more severe presentations of low mood and/or depression than if recruitment had occurred within community settings. In the context of online therapy deliveries, some have suggested that lower completion rates may be associated with higher depression scores at baseline (e.g. Clarke, Kuosmanen & Barry, 2015; Gerrits et al., 2007). However, whilst the baseline MFQ scores presented in Table 17 do not suggest this was the case, the study's small sample size and inclusion of only one baseline depression measure (the MFQ) make drawing reliable conclusions here difficult.

Finally, the study was conducted during a period of unique challenges and changing situations as a result of the COVID-19 pandemic. Although during the participant follow-up calls COVID-19 itself was not necessarily identified as a barrier to programme completion, its impact upon educational situations and the restrictions it imposed created barriers and challenges to both accessing BALM and completing some activities, particularly activity scheduling. This was supported by the findings from the healthcare professional survey which demonstrated that most felt that programme adherence would be negatively affected during this period. The key findings from the feasibility study are presented in Box 1.

Box 1: Summary of key findings

Summary of Findings

Feasibility outcomes

- 12 participants aged 13-16 years ($M= 14.8$) recruited
- Mean sessions completed: 3.2; Adherence: 0 to 90%
- Dropout (completing ≤ 5 sessions): 67%
- Programme access ranged from 38 to 260 days ($M=104$).
- 87% of sessions completed were done so in less than 10 minutes or between 10 and 20 minutes

Acceptability and satisfaction outcomes

- BALM considered straightforward and easy to navigate
- Liked components: activity scheduling and monitoring, mood monitoring, mechanisms to support understanding (e.g. definitions of terms, audio)
- Dissatisfaction with the level of text included, BALM considered 'too wordy'

Possible contributors to low adherence and high dropout

- Too much content
- Adolescent competing demands
- Limited use of high-quality materials, interactive content, personalisation
- Unguided treatment approach
- CAMHS-only recruitment
- COVID-19 restrictions

5.4.4 Future considerations

The completion of this non-randomised feasibility study has both presented methodological considerations for future studies of BALM and provided important information to inform the programme's future development.

5.4.4.1 Methodological considerations for a larger study of BALM

Whilst important information to inform future research has been obtained from the feasibility study, it is difficult to make firm conclusions or generalise the results due to the uncertainty of the impact of the COVID-19 pandemic. Therefore, an additional examination of the feasibility and acceptability of BALM when social restrictions are not in place or significantly minimised is required. Of particular importance would be establishing whether recruitment and adherence are different if the programme is delivered in more 'normal' circumstances. As part of this, as all data collection was completed remotely owing to the pandemic, future research could examine whether the original aim of completing baseline measures and the demonstration of the programme face-to-face is acceptable and whether it impacts upon programme use. Whilst this

feasibility study demonstrated that it was possible to recruit adolescent participants from CAMHS, no information was obtained about BALM in the wider care pathway. Future research should seek to examine the feasibility and acceptability of delivering BALM within additional services including those that are community-based and school-based. Furthermore, obtaining additional information about why study uptake varied across services, could provide useful information to inform its positioning in the future. In particular why recruitment was successful in one site but not another in the same CAMH service.

Whether in the context of an additional acceptability and feasibility study of BALM or a larger pilot study, future research should seek to administer evaluation questionnaires at additional time points and in varied ways. The inclusion of a control group would allow comparisons across groups to be made with examinations of cause-effect on outcomes as well as mechanisms for change possible. As RCTs are considered the 'gold standard' in effectiveness research (Hewitt et al., 2010) and regarded as the most robust approach to prevent selection bias (Craig et al., 2008), larger studies of BALM should consider adopting an RCT design.

5.4.4.2 Future development of BALM

This study has also highlighted several areas in which the BALM programme may be refined to make it more acceptable to adolescents with low mood and/or depression. As previously discussed, this should include the consolidation of information to ensure users are presented with more active therapy components at the outset and not overwhelmed by large quantities of additional information. This is especially important in ensuring that the programme can be successfully completed alongside the competing demands faced by the target group. To further accommodate the needs of the user group more high-quality materials allowing for increased personalisation and interactivity need to be embedded whilst also providing multiple versions of the programme to suit different developmental capabilities.

As one contributor to low adherence may have been BALM's unguided delivery approach future research should seek to examine whether adherence is affected if additional therapeutic facilitation is available. Whilst adopting a guided approach may negate some of the benefits of an online therapy delivery, and acknowledging the significant demands on clinicians, a more blended treatment approach could be considered. This may include users working through BALM independently whilst also receiving some face-to-face therapist guidance alongside (Rasing et al., 2020).

Alternatively, increasing the frequency of researcher-led calls and embedding more therapeutic support could be explored.

5.4.5 Conclusions

This feasibility study has provided important information to inform future research within this context. Whilst the study has demonstrated it possible to recruit some adolescents from CAMHS to research of this type and identified components of BALM deemed acceptable by some, important changes required for future research have been recognised. Methodological changes include examining the programme's use when social restrictions have been reduced and embedding feasibility and acceptability research of BALM in broader service settings. Consolidating the programme content, embedding more high-quality materials, and adopting a more blended treatment approach have been identified as key areas for programme refinement. Whilst three of the four aims made *a priori* have been addressed, recruiting only from CAMHS limited the conclusions that could be made about the fourth aim: establishing where in the care pathway BALM may be best placed.

5.5 Chapter summary and next steps

This chapter has reported the findings from a non-randomised feasibility study to assess the acceptability of BALM with an adolescent sample. Areas for refining the programme have been identified and methodological considerations for future research presented. This aligns to phase five of co-design as described by Eyles et al. (2016). The next chapter provides a conclusion for the overall findings of this thesis. As part of this the implications of the findings are explored with recommendations for future directions made.

Chapter Six: Conclusions, implications, and future directions

This chapter integrates the key findings from the thesis and discusses their implications for policy and practice. Whilst methodological strengths and limitations have been discussed throughout, here implications of the thesis in its entirety are presented. Recommendations for future research are discussed and conclusions drawn about phase six of co-design: 'intervention pilot testing in the 'real world'.

6.1 Summary of thesis findings and contribution to knowledge

This thesis has presented research focused on the development and initial evaluation of a new online BA programme (BALM) for adolescents with low mood and/or depression. Adopting an empathy-based approach, with a participatory design, and aligning the work to important phases of co-design in intervention development as described by Eyles et al. (2016), the thesis has made original contributions to knowledge in three respects: assessment, development, and evaluation.

6.1.1 Assessment

The assessment work completed addressed aims one and two of the thesis, which were to:

- Explore the current use of BA with young people experiencing low mood and/or depression via a systematic review and meta-analysis.
- Examine the views and preferences of adolescents and healthcare professionals regarding the development of a new online BA therapy through adopting an exploratory qualitative design.

Elements of assessment have been discussed throughout the thesis and predominantly presented in Chapters One to Three. Phase one of co-design encompasses an assessment of background knowledge and evidence within a given area (see Table 2; Eyles et al., 2016). The initial rationale for considering BA as an alternative to current recommended treatment approaches, in particular CBT, and exploring whether it could be effectively delivered in an online format was introduced in the opening chapter. Chapter One presented the high prevalence of depressive

disorders in young people and identified and discussed the multifaceted barriers to this group accessing effective treatments in a timely manner. It also presented a review of the theoretical underpinnings of BA and the behavioural techniques frequently adopted in its delivery (e.g. Kanter et al., 2010; Lejuez et al., 2011; 2001; Martell et al., 2001). Although not currently a NICE recommended treatment option for young people with depression, BA's demonstrated effectiveness in treating depression in adults (e.g. Richards et al., 2016; Ekers et al., 2014; 2008) warranted further exploration for its delivery with this group also. An examination of emerging literature in this area (e.g. Kitchen et al., 2020; Pass, Hodgson et al., 2018; Pass, Sancho et al., 2018; Pass et al., 2017; 2016; 2015; McCauley et al., 2015) as well as the completion of the systematic review and meta-analysis (Chapter Two) provided preliminary support for BA's application with young people. Although only ten studies were included in the systematic review, all reported reductions in depression for young people following a behavioural intervention. These reductions were evident across a range of measures including the CDRS-R (Poznanski & Mokros, 1996) the most widely used measure of child and adolescent depression in research trials internationally (Kim et al., 2014; Plener et al., 2012). Results of the meta-analysis including three RCTs provided further support demonstrating a statistically significant difference on CDRS-R scores favouring BA. However, some caution in the interpretation of these results is needed owing to the presence of clinical heterogeneity across the studies (i.e. different settings, inclusion criteria, etc.).

Although BA has been included within NICE recommended treatment guidelines for adult depression since 2009 (NICE, 2009), the assessment phases of this thesis highlighted the reduced focus on its application with young people by comparison. This is particularly surprising given that one of the ten studies included in the systematic review and meta-analysis demonstrated that consideration was given to BA as a treatment for young people several decades ago (Stark, 1985). However, whilst more research into BA's application with young people is emerging, it had previously not been examined to the same extent as with adult populations. This is likely to be explained by more emphasis being placed upon CBT which has been the most studied treatment of adolescent depression (Hussain et al., 2018; Weisz et al., 2006). More recently, acknowledging that BA places specific focus on common symptoms of depression in young people (e.g. withdrawal, inactivity, avoidance), NICE (2019) has made recommendations for research to investigate the effectiveness of BA for this group also. The assessment work within this thesis has contributed to this, demonstrating the initial promise of BA for young people, and highlighting the need for future work.

To ameliorate the barriers associated with young people accessing low-intensity treatments, an extensive amount of research findings has supported an online delivery approach, again with a significant focus placed upon evaluating CBT in this format (e.g. Smith et al., 2015; Wright et al., 2014; Abeles et al., 2009). Although online versions of BA have started to emerge for adult populations (e.g. Spates et al., 2016), none specifically developed for adolescent low mood and/or depression was identified in the systematic review. This demonstrated a gap in the knowledge base surrounding online therapy delivery for young people and provided support for both developing and evaluating an online BA programme for this population. Owing to significant demands on current CAMH services (CQC, 2018), addressing this gap was both timely and relevant.

The completion of qualitative research with adolescents and healthcare professionals (Chapter Three) further strengthened the rationale of the thesis. This work aligned to phases two (assessment of user needs to inform intervention focus) and three (assessment of user needs to inform technology type) of co-design (Eyles et al., 2016). Findings from the qualitative work demonstrated that both adolescents and healthcare professionals endorsed an online therapy delivery, with advantages of the approach including enhanced anonymity and treatment accessibility identified. In addition, helpful information was provided about potential barriers and challenges in using this approach. Through both focus group and interview discussions as well as the associated activities completed, the contention that BA may be an acceptable treatment for delivery in this context was supported and important suggestions made to inform the design of any such treatment. As no known UK-based versions of BA exist in an online format, this work provided an initial insight into an under-researched area. Of particular importance here was obtaining the views of participants about their perceptions of BA components and how they could be successfully adapted for an online delivery. Through obtaining the views of multiple stakeholders, the perceptions and opinions from a variety of perspectives were obtained, information that can be used to inform future work in this area.

During the assessment phases, the decision to develop a new treatment adopting an unguided approach was made. This was in response to the findings of several systematic reviews (e.g. Karyotaki et al., 2021; Rasing et al., 2020) and RCTs (e.g. Dear et al., 2018; Titov et al., 2016; 2015) (Chapter One) that suggested comparable clinical outcomes to guided deliveries and identified benefits including increased cost-effectiveness, extensive dissemination (Karyotaki et al., 2021), and both increased

privacy and perceptions of self-control (Rasing et al., 2020). Several findings from the qualitative work further supported the adoption of an unguided treatment approach, with adolescent participants highlighting their need for anonymity, privacy and opportunities for autonomy.

6.1.2 Development

The development work completed addressed the third aim of this thesis which was to:

- Consolidate the findings from the previous phases of research alongside considering the biopsychosocial development associated with the adolescent period to develop an online BA programme for adolescents with low mood and/or depression.

Phase four of co-design (Eyles et al., 2016) relates to the development of an intervention including content and framing. As the systematic review and meta-analysis demonstrated that no known online versions of BA were available for adolescents with low mood and/or depression and the endorsement for such an approach provided in the qualitative work, the online programme 'BALM' was produced. The programme's development was based on synthesising and consolidating the findings from Chapters One to Three whilst considering the specific developmental changes inherent to the adolescent period. This information was used to inform BALM's content, structure, and presentation/delivery. Adopting this approach was essential in ensuring that BALM was an adolescent-specific intervention rather than, as can be the case, a downward or upward extension of a treatment for adults or children, respectively (Weisz & Hawley, 2002). The final version of the programme comprised ten treatment sessions delivered in a combination of text-based information with embedded interactive activities. Seven of the eight BA intervention types outlined by Kanter et al. (2010) were included in BALM, with only relaxation omitted.

Through this development work, which demonstrated it possible to design and produce BA in an online format, an original contribution to the field of online therapy development has been made. Furthermore, through adopting a creative and innovative approach to the development of BALM in synthesising and consolidating information from multiple sources, increased insights into the needs of the target user were obtained. Specifically, this work demonstrated the need to consider the adolescent population as less homogenous owing to the significant inter and intra-personal variability evident across this life stage. This is a particularly important finding to inform

the design of new therapies for adolescents, ensuring user needs are addressed more effectively.

6.1.3 Evaluation

The evaluation work completed addressed aims four and five of the thesis which were to:

- Examine the acceptability of the newly developed BA programme and assess the feasibility of undertaking a pilot RCT of the intervention.
- Examine whether the newly developed BA programme can be successfully delivered using an unguided treatment approach.

The final phases of co-design encompass the testing of new interventions with phase five regarding the pre-testing of intervention prototypes and phase six about intervention testing in the real-world (Eyles et al., 2016). Chapter Five presented the findings of a non-randomised feasibility study which provided important information about the first test of BALM and demonstrated it feasible to recruit adolescents to a treatment of this type. Furthermore, with several therapy components deemed acceptable by participants and regarded as helpful, initial promise for delivering BA in an online format with adolescents was shown. However, low adherence and high dropout highlighted the modifications required both to BALM and in the delivery of future, similar research. Of particular importance was the need to further consolidate the information presented, developing a simpler, quick-to-use therapy incorporating high-quality materials with increased focus upon active treatment components and less emphasis on educational content. In addition, and contrasting to the assumption made *a priori*, BALM was not successful when delivered as an unguided treatment approach suggesting increased clinician facilitation in future deliveries. As BALM is the first known UK-based online BA programme, its initial testing in this study has made a valuable contribution to the area of online therapy provision for adolescents. Specifically, in demonstrating it possible to deliver BA in an online format to this group and in highlighting the improvements required, both to BALM and the research methods employed, to benefit future development of this area. Through this work existing knowledge about online therapy deliveries with adolescents has been built upon whilst new knowledge has been generated about alternative deliveries of BA.

Although phase six of co-design (i.e. pilot testing within the real-world) could not be conducted within the remit of this thesis, important information to inform a larger RCT of BALM has been obtained (see 6.4.2).

6.2 Thesis strengths and limitations

The studies conducted as part of this thesis had several strengths and limitations, with some common limitations evident in those including participant recruitment. Most notably, both the qualitative study and feasibility study experienced recruitment delays and reported findings with limited generalisability owing to their completion within few recruitment locations and incorporating participant samples that were not culturally nor ethnically diverse. Whilst the strengths and limitations of individual studies have been identified and discussed in detail within their corresponding chapter (e.g. sections 2.5.2, 3.4.2, 5.4.2), several evaluative points relating to the thesis in its entirety must be examined.

6.2.1 Thesis strengths

The 2019 NICE guidelines about the identification and management of depression in young people made recommendations for research examining the use of BA with young people. Early in the completion of this work, most notably highlighted in the systematic review findings (Chapter Two), the paucity of research within this area became apparent with the majority of studies examining BA completed with adults. Whilst this is changing as more research emerges (e.g. Kitchen et al., 2020; Pass, Hodgson et al., 2018; Pass, Sancho et al., 2018; Pass et al., 2017; 2016; 2015), this thesis has provided important information within an under-researched area. Although the feasibility study completed was non-randomised and included a small sample, its findings provided preliminary support for the use of online BA with adolescents as well as important information to inform future work.

The mixed methods approach adopted within this thesis allowed the development and evaluation of BALM to be based upon the adoption of several different methodologies and data collection techniques. This allowed an increased insight to be gained about the subject area and is especially important in the field of adolescent mental health where a deeper understanding about the challenges faced by adolescents as well as the impact of contextual factors can be obtained (Tilzey et al., 2019). The adoption of an empathy-based approach, with a participatory design which aligned to important

phases of co-design was an additional strength and considered very important by the author. This ensured the vital phases of intervention development were completed with consideration for the needs of different stakeholders including adolescents, healthcare professionals and web-developers. This work also collected information from multiple sources, which was a further benefit of adopting a mixed methods approach (Tilzey et al., 2019). The qualitative work (Chapter Three) particularly demonstrated this. Through incorporating the views of adolescents (both with and without experience of accessing mental health support) as well as those from healthcare professionals, the development of BALM considered, and aimed to address, the perspectives of multiple stakeholders. Through this, the likelihood of designing and developing an intervention suitable for the needs of the target user was maximised.

Finally, the work presented has been adaptable to changing situations and additional challenges encountered during its completion, most notably the COVID-19 pandemic. Whilst much of the work presented in this thesis had been conducted prior to the pandemic, government restrictions were in place for the duration of the feasibility study with implications for its completion. Through adaptations including making BALM programme changes (see 4.5.1) and introducing remote data collection (see 5.2.6), it was possible to proceed with recruitment and allow adolescents access to BALM during the pandemic. Whilst the impact of the pandemic on the study's findings remain unknown, continuing the study at this time ensured that adolescents with low mood and/or depression had access to an alternative treatment approach. This was particularly important during a period where many face-to-face treatments were paused or reserved for individuals with needs considered to be greater.

6.2.2 Thesis limitations

Although the thesis was adaptable to unforeseen challenges during its completion, and whilst the COVID-19 pandemic enabled some strengths of the study to be realised (see above), the pandemic also presented one of the most notable limitations of this work. Whilst important information has been presented about the delivery of an online BA programme, the findings are caveated due to their limited generalisability to non-COVID situations and uncertainty as to how much they were affected by the pandemic. Consequently, whilst several conclusions can be drawn to inform future research in the area these are tentative and additional feasibility work may be required when restrictions are not in place.

Another limitation of this thesis was the minimal embedding of work in non-CAMH locations. Although recruitment of the community sample in the qualitative study (Chapter Three) was conducted within school settings, this was the only alternative recruitment from CAMHS across the PhD. In 2017 the Government green paper outlined the inclusion of the single point of access (SPA) within the organisation of CAMHS in the UK (DHSC & DfE (2017)). Principally, the role of the SPA is to clarify the process of seeking help and includes providing a single point of contact to access a variety of services, allowing the identification of the most suitable source of support for young people to be identified promptly (Rocks et al., 2020). In the feasibility study it was envisaged that some recruitment would be embedded within the SPA, enabling the identification of adolescents from a variety of positions within the care pathway including those who were then referred into CAMHS as well as those signposted to alternative services (e.g. school-based, community services). However, as the school-based service identified to support the feasibility study became unable to do so (see 5.2.5) this was not possible with all feasibility study participants being those who had been accepted to receive support within CAMHS. This was a major limitation as, with entry thresholds increasing on a yearly basis (Fairchild, 2019) to have been accepted into CAMHS, these individuals may have had more severe presentations of low mood and/or depression or more complex needs. Furthermore, owing to these increased thresholds it is likely that low-intensity therapies including BALM will be better placed in school-based services which are increasingly involved in mental health provision in response to the 2017 government Green Paper (DHSC & DfE, 2017). As early intervention may reduce deteriorations and the requirement for more costly treatments (Crenna-Jennings & Hutchinson, 2020) examining whether BALM can be delivered as a more preventative approach to those with less severe presentations of low mood and/or depression may have been possible through broader recruitment.

Although BALM's development was based upon the consolidation of multiple data obtained through the assessment phases of this research, the limited number of studies included in the systematic review meant that few examples of BA deliveries with young people were available. Specifically, no online versions of BA existed in this context. Owing to this, BALM's development had to be flexible with the initial content for consideration based upon an adult model and further refined from the ten studies included in the systematic review as well as the findings of the qualitative work.

A final limitation of this thesis was its completion over a six-year period. Whilst the emergence of new research within this field is significantly important to the subject area, it was not possible to include recent contributions in several areas of the work

presented. For example, the systematic review and meta-analysis were conducted in the first year of this work and therefore preceded several important contributions made to the area (e.g. work by Kitchen et al., 2020; Pass, Hodgson et al., 2018; Pass, Sancho et al., 2018; Pass et al., 2017). Although these have been acknowledged and discussed throughout this thesis including within the systematic review chapter retrospectively (see 2.4.4), they were not included in the systematic review nor meta-analysis, the findings of which substantially contributed to later chapters. Whilst it is unlikely that the results of the thesis would have been significantly affected by this, the overall findings do not completely reflect the current situation.

6.3 Implications for policy and practice

Despite limitations, the findings of this thesis have several important implications for policy and practice. Firstly, this work has added support to considering BA as an alternative low-intensity treatment option for adolescents experiencing low mood and/or depression (Chapter Two, Tindall et al., 2017). Despite depression being a major health concern and experienced by approximately 2% of UK adolescents (Sadler et al., 2018) those presenting with an emotional disorder are the least likely to receive specialist help (Ford et al., 2003). Whilst the barriers to accessing support are multifaceted, this evident gap between treatment provision and need (Crenna-Jennings & Hutchinson, 2020) is likely to be explained, in part, by the pressure on CAMH services to address increased demand with limited capacity to do so (CQC, 2018). The challenges faced by such services include limited numbers of clinicians and resources (Roberts, 2013; Saxena et al., 2007; Crenna-Jennings & Hutchinson, 2020), long waiting times (Sadler et al., 2018) and concerns about reductions in funding (CQC, 2018). These challenges are likely to be further affected by limitations associated with current recommended treatments such as CBT which has limited availability and accessibility (Thapar et al., 2012) and can be both expensive and time consuming. Through BA's simple delivery (Ekers et al., 2011) and cost-effectiveness (Richards et al., 2016), considering this as an alternative approach may relieve some of the pressures experienced by CAMHS and help bridge the gap between provision and need. Furthermore, with service entry thresholds for CAMHS increasing each year (Fairchild, 2019), the ability for BA to be delivered by individuals not formally trained (Richards et al., 2016) may also allow it to be embedded more so in additional positions within the care pathway. According to Crenna-Jennings and Hutchinson (2020), through early intervention, deteriorations in conditions requiring more costly treatment approaches may be avoided. Therefore, by seeking to deliver low-intensity therapies such as BA in alternative locations including within school-based services,

pressures on current CAMH services may be reduced. However, more research in this area is required.

The thesis findings have also demonstrated that BA can be developed and delivered in an online format for adolescents. Despite temporal and financial factors constraining several elements of BALM's development, the intervention types identified by Kanter et al. (2010) as frequently delivered within BA were reproducible into a workable treatment package. Through synthesising the findings from previous chapters, in particular considering the needs of young people and healthcare professionals as ascertained in the qualitative work, these intervention types could be modified as appropriate to accommodate user needs. Although areas for the future refinement of BALM have been recognised (Chapter Five), the initial findings highlighted that certain treatment components delivered in an online format were helpful and acceptable. This provides preliminary support for considering further development of online BA for adolescents. This has the potential to address service-related barriers to treatment provision, as well as those associated with individuals such as concerns about stigma, expense and transportation issues and young people's reluctance to engage one-to-one with a therapist (Gulliver, Griffiths & Christensen, 2010; Cohen et al., 2009; Rickwood et al., 2005).

Whilst initial support for delivering BA in an online format has been presented, the need to address the challenges associated with digital technologies including low uptake, adherence, and engagement (Jones et al., 2020) has been highlighted. As presented in Chapter Five, several factors may have contributed to the low adherence and high dropout of BALM which require consideration in future work in this area. This is particularly important given that higher intervention adherence may be associated with better treatment outcomes (Donkin et al., 2011). Of particular importance is establishing the optimal amount of therapist facilitation with online therapies. One of the main findings of the qualitative study (Chapter Three, Tindall et al., 2021) was the requirement of young people to exercise autonomy. This finding supports previous research (e.g. Christie & Viner, 2005) which has emphasised the desire of young people to assume increased responsibility for aspects of their own lives including their health. Through BALM's online delivery and unguided treatment approach, opportunities for exercising autonomy were enabled throughout programme use. However, the low adherence and high dropout evident in the feasibility study suggested that increased therapist facilitation may be required to support adolescents in exercising autonomy successfully. Seeking the correct balance between therapist facilitation and allowing opportunities for autonomy is therefore required. This may

include allowing adolescents to exercise autonomy in certain elements of therapy such as choosing what content to view and selecting activities to engage in yet also having therapist assistance to encourage and support engagement. Whilst online therapy deliveries have a place in the treatment of adolescents with low mood and/or depression (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009), consideration should be given to adopting a more blended approach in their delivery to enhance effectiveness.

Finally, the importance of tailoring interventions to individual needs and refraining from assuming a 'one-size-fits-all' approach has been demonstrated, particularly within the qualitative study (Chapter Three) and the review of adolescent development (Chapter Four). The development of BALM was based upon those aged 11 to 16 years which, as from a similar educational cohort, were considered to provide a more homogenous sample than if extended to include those in primary or further education. However, several findings from this thesis have highlighted the significant variability evident in this age range. Whilst the review of adolescent development (Chapter Four) highlighted the many biopsychosocial changes occurring during this life-stage, the qualitative study (Chapter Three) demonstrated the variations in perceptions, needs and preferences across this group. This adds further support to adopting an empathy-based approach with a participatory design in the undertaking of future work in this area to ensure the needs and preferences of target users are met (Jones et al., 2020). As demonstrated in the qualitative study (Chapter Three), this needs to incorporate the opinions of a range of stakeholders and should be a consideration for all therapy development whether delivered face-to-face or in an online format.

6.4 Implications for future research

6.4.1 General recommendations for future research

The findings presented within the preceding chapters have highlighted several areas for future research. Firstly, a common theme throughout this work has been consideration for the unique changes and challenges of the adolescent period. As introduced in Chapter One and revisited in Chapter Four, more biological, psychological, and social changes occur during this period than any other life stage except infancy (Lerner et al., 2018; Viner et al., 2012). However, the trajectory of these changes does not follow a continuum, instead being subject to regressions and significant inter and intra-variability. Owing to this, whilst the thesis aimed to examine the development and evaluation of an online BA intervention with a more homogenous

group (i.e. those aged 11 to 16 years), a review of the biopsychosocial development of this age range highlighted the significant variability in adolescent development and the limited ability of chronological age to map this. Although BALM was developed with consideration of the developmental level of the users, providing more than one version would have strengthened this and allowed a more individualised programme delivery. This is particularly important in the delivery of online therapies if no therapist is present to identify level of understanding for example. Future research should therefore seek to develop varied presentations of online therapies such as BALM to suit different developmental abilities. As part of this, research is required to further understand adolescent developmental trajectories, and differences within them, and consider how these may be effectively incorporated into future CAMH intervention research.

As well as accommodating different development requirements, the importance of providing therapies individualised to other user needs has also become apparent. For example, during the qualitative work, differences in perceptions and opinions about the development of BALM (e.g. the content to include) were found across participant groups. As all could not be accommodated in only one programme, a balance was sought between incorporating important content whilst considering any concerns expressed by participants. This unavoidably led to the inclusion or omission of certain components; decisions which would not have addressed the needs of all. The impact of this was evidenced in the feasibility study where a participant highlighted that, having previous experience of CAMHS they did not find the presentation of educational content useful but acknowledged that others, with less or no experience of support, might. Whilst varied presentations of BALM may accommodate different developmental requirements, increased opportunities for personalisation during programme use may address varied needs and preferences. Future research should seek to enable this through the use of more high-quality materials.

Additional research is also required to examine the mechanisms of change in BA deliveries. As discussed in Chapter Four (see 4.2.5), the limited component analyses of available BA packages (Hoyer, Hoefler & Wuellhorst, 2020; Kanter et al., 2010) meant that caution was required when selecting the content for BALM as not to omit anything important. However, one explanation for the low adherence and high dropout in the feasibility study (Chapter Five) may have been the inclusion of too much content. As conclusions have been drawn about providing a quick-to-use therapy in further BALM iterations, future research should explore the mechanisms responsible for change to allow the optimal content to be selected for inclusion. To accommodate

individual needs, exploring how programme users may be given more control over the content they view, is required alongside this.

6.4.2 Informing phase six of co-design in intervention development

As part of the UK MRC guidance for complex interventions, before a full-scale evaluation several studies may be required for refining a study design with both feasibility and pilot work recommended for this purpose (Craig et al., 2008). Whilst this thesis has presented feasibility work and assessed the acceptability of BALM, the completion of RCT pilot testing in the real-world which aligns to phase six of co-design was not possible. An examination of BALM's initial clinical effectiveness is particularly required. According to Craig et al. (2008), a pilot study does not need to be a smaller version of a full-scale trial, rather it should examine any problems identified during development that might occur in future work. The findings presented in the preceding chapters, most notably through the feasibility study, have provided important information to inform a pilot study of BALM.

Firstly, and discussed in more detail in Chapter Five (see 5.4.4.2), the feasibility work highlighted several areas of refinement for the BALM programme itself ahead of pilot testing. These changes include incorporating more high-quality materials to allow increased personalisation and interactivity and reducing the amount of information presented with increased focus upon active treatment components. Acknowledging that the initial acceptability of content was obtained from a small sample, pilot work could retain all content but ensure that only active therapy components are presented within sessions with additional, more educational content, presented as supplementary and optional to view. As the feasibility work did not obtain evaluative feedback on several components of therapy due to early disengagement, future pilot work should seek to gather more information about programme content. This may include administering evaluation questions at additional time points (i.e. earlier in programme completion) and collecting data in varied ways. Short qualitative interviews with participants specifically focusing on the content they have viewed may be successful here. In addition, through embedding interviews, information about the best way to present information using more high-quality materials and how content could be adapted to ensure it is more developmentally appropriate could be obtained.

According to Eldridge et al. (2016) pilot work may include testing alternative methods to inform the design of future studies. Two specific areas where additional testing is required ahead of a full-scale evaluation of BALM have been highlighted. Firstly, pilot work should compare the most suitable methods of data collection. As the feasibility

study was conducted during the COVID-19 pandemic all data were collected remotely and future work should establish whether a face-to-face approach is regarded as more acceptable and increases outcome measure completion. Secondly, as one contributor to BALM's low adherence may have been its unguided delivery, pilot work should examine its delivery with varied additional support. This may include randomising participants to receive the programme alongside face-to-face therapist guidance or through a higher frequency of researcher contact incorporating therapeutic support.

As pilot work may allow an examination of an intervention's initial effectiveness or efficacy (Eldridge et al., 2016) several additional components, not incorporated in the feasibility study should be considered. A control group should be recruited to allow examinations of cause-effect on outcomes and randomisation included to prevent selection bias (Craig et al., 2008). To assess the initial clinical effectiveness of BALM, additional measures of low mood and/or depression at varied time points (i.e. baseline, end of treatment and follow-up) are required. This may include adopting measures such as the CDRS-R (Poznanski & Mokros, 1996), a semi-structured interview and the most widely used measure of child and adolescent depression severity in research trials internationally (Kim et al., 2014; Plener et al., 2012). As the systematic review identified little information about the cost-effectiveness of BA and its impact on QoL, both should be measured in future pilot work. Furthermore, aligning to previous research of BA (e.g. McCauley et al., 2015), changes in both activation and avoidance resulting from programme use may be assessed through incorporating a measure such as the Behavioral Activation for Depression Scale (BADSD; Kanter et al., 2007). As the feasibility study sample was recruited from only one area, to ensure a more representative sample and increase the generalisability of findings, future pilot work should be multi-centre, both delivered in more geographical locations and across varied services within the care pathway.

The work presented throughout this thesis, particularly during the feasibility study, has been essential developmental work needed to inform a pilot RCT of the clinical effectiveness of BALM. Through a pilot study it is hoped that the design of a full-scale RCT will be further refined and sufficient data to allow a power calculation obtained. However, owing to the COVID-19 pandemic, additional feasibility and acceptability work may be necessary beforehand.

6.5 Final conclusions and future directions

This thesis has presented the development and initial evaluation of an online BA programme for use with adolescents experiencing low mood and/or depression. Through stages of assessment, development, and evaluation this work has provided preliminary support for delivering BA in an online format. This has both furthered existing knowledge relating to online therapy delivery and generated new knowledge about the delivery of BA in this context. This work encompassed the first five stages of co-design in intervention development and has provided useful information to inform both further refinement of BALM as well as testing in a larger, pilot study. As no known UK versions of online BA for adolescent depression were previously available this provides a significant contribution to a previous gap in the knowledge base.

Appendices

Appendix A: Additional information relating to the systematic review and meta-analysis (Chapter Two)

ORIGINAL SYSTEMATIC REVIEW PROTOCOL

Is Behavioural Activation effective in the treatment of depression in young people? A Systematic Review Protocol

Background

Approximately 20% of adolescents will have had at least one depressive episode by the time they reach the age of 18 years, an experience that may have negative impacts on many aspects of their lives, including their educational attainment, interpersonal relationships, and health behaviours (Curry et al, 2006; National Institute for Healthcare Management, 2010; Saluja et al, 2004). It is therefore important that young people experiencing depressive episodes are identified early and receive effective treatment to deal with the impact of their depression (i.e. on their family, social and academic functioning) and reduce the likelihood or impact of future episodes (Birmaher & Brent, 2007).

However, despite such high rates of depressive disorders in young people, only 35%, seek help (Gladstone et al, 2015). This limited help-seeking behaviour may be influenced by various factors associated with treatments including stigma, transportation issues and young people's reluctance to engage one-to-one with a therapist. For those who do seek help few actually receive it from specialist mental health services (Richardson et al, 2010) often as a result of limited clinician capacity and the availability of therapies within such services (Roberts, 2013).

Increasing activity may be an important component in reducing depressive thoughts and feelings (Lejuez et al, 2001) and thus interventions incorporating this are important. One such treatment, Behavioural Activation (BA) can be defined as 'A structured, brief psychotherapeutic approach that aims to (a) increase engagement in adaptive activities (which often are those associated with the experience of pleasure or mastery), (b) decrease engagement in activities that maintain depression or increase risk for depression, and (c) solve problems that limit access to reward or that maintain or increase aversive control' (Dimidjian et al., 2011, p. 4).

Multiple studies have demonstrated the effectiveness of face-to-face-delivered BA in the treatment of depression in adults. In a systematic review, Chartier and Provencher (2013) found BA to be as effective for symptoms of depression as other psychotherapies including CBT, whilst in a meta-analysis of 17 studies Ekers et al. (2008) found BA was significantly superior to controls, brief psychotherapy, and

supportive therapy and equal to CBT in its effectiveness for ameliorating symptoms of depression. Meta-analyses by Cuijpers et al (2007) and Mazzucchelli et al (2009) have further supported the effectiveness of BA in the treatment of adult depression with the former finding BA to be as effective as cognitive therapy and the latter finding a large effect size in favour of BA over controls. In a later review examining depression symptom levels, Ekers et al. (2014) found BA to be clinically effective in comparison to a control group and a group using anti-depressant medication. There is also evidence that BA shows promise regarding relapse prevention (Gortner et al., 1998; Dobson et al., 2008). Consequently, BA has been included within the National Institute for Health and Clinical Excellence (NICE) (2009) guidelines as an evidence-based treatment for depression.

Although BA is a NICE recommended treatment in adults with depression with extensive research supporting its use in this context, less research focuses on BA use with young people. Research in young people has generally been in the form of case series and case reviews with small sample sizes e.g. Chu et al. (2009) (n=5); Wallis et al. (2012) (n=2). Both provided support for BA use in the treatment of young people with depression and/or anxiety, finding treatment satisfaction and clinical benefits including symptom reductions. Similar results were obtained in a pilot, uncontrolled study of the use of BA workbooks for treating depressed young people in rural Australia (Jacob et al, 2013) with all participants (n=5) showing reduced levels of depressive symptoms between baseline and program completion.

Given the paucity of research in this area and the serious consequences untreated depression has for the future life of the affected young people (Weissman et al, 1999), an examination of BA for use with children and adolescents is required and timely (Chartier and Provencher, 2013).

It has been suggested that young people experiencing depression may be treated more effectively using computer-administered therapies than traditional face-to-face therapies, which can increase their availability and accessibility (Stallard et al., 2010) without stigma and in a format (IT) attractive to many young people. Thus far much research has focused on the delivery of Cognitive Behavioural Therapy (CBT) in this form (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009), with computerised CBT (CCBT) representing an alternative form of therapy delivery with the potential to enhance access to CBT at various stages of illness. Furthermore, CCBT can be administered at a much lower cost than traditional treatments (Merry et al, 2012). This review will therefore also seek to establish whether BA in a computer-

based format has been used with young people experiencing depression and, if so, whether it is an effective treatment.

Review question and inclusion criteria

Review Objectives

This review will seek to investigate:

Whether BA is effective in the treatment of depression in young people

Whether BA delivered in a computerised format is effective in the treatment of depression in young people.

Inclusion Criteria:

Population

Young people (≤ 18 years of age). If the age range crosses 18 years, then the study will be included if 90% of the sample are ≤ 18 years of age).

Experiencing depression or depressive symptoms established by a validated screening measure or a diagnosis based on a structured clinical interview conducted to internationally recognised standards (e.g., ICD, DSM).

Interventions

Behavioural treatments for depression (for studies to be included such treatments must be either based upon operant conditioning / learning theory principles or comprise techniques fundamental to behavioural treatments of depression including activity scheduling, self-monitoring, goal setting). Interventions based on third-wave CBT principles (e.g., ACT) will be excluded.

Interventions of any duration

Settings of interventions can be community, healthcare and educational

Any delivery mode (e.g. computerised, internet based, face-to-face)

Comparators

Any comparators (e.g. wait-list control, treatment as usual, pharmacological)

Outcomes

Primary Outcome measure:

Levels of depression/ depressive symptoms measured by validated assessments (e.g. measurement scales, clinician or researcher administered ratings)

Secondary outcome measures:

- Cost-effectiveness
- Levels of anxiety symptoms measured by validated assessments (e.g. measurement scales, clinician ratings)
- Quality of life
- School attendance

No restrictions will be placed on the timings of outcomes

Study Design

Randomised trials (both controlled and uncontrolled)

No exclusions will be placed on sample sizes or sampling methodology

Language

No language restrictions will be placed upon papers for inclusion in the review.

Publication type/ status

All studies, published and unpublished, will be included within the review.

Identifying research evidence

The electronic databases to be searched will include:

Cochrane library

EMBASE

Medline

CINAHL Plus (EBSCO)

PsychINFO

Scopus

ISCRTN registry

Grey literature resources will also be searched, including websites, conference abstracts, interim reports, dissertations and theses. Databases for such searches will include the health management information consortium (HMIC), NHS evidence and Open Grey. The search strategy used for searching grey literature will be simplified accordingly. The reference lists of all included studies will also be searched and reverse citation searching carried out on included studies. Experts in the field will be contacted to identify additional references. Authors will be contacted for further information as required. This will also provide an opportunity to enquire about any further research that has been undertaken/ is ongoing since the reviewed papers were produced.

The key words used in the search will be:

Behavioural Interventions (including behavioural activation, behavioural therapy, behavioural interventions, self-monitoring, activity scheduling)

Depression (including depressive disorder, depressive, depression, depressed)

Young people (including adolescents, children, teen, youth, juvenile, youth, pre-pubescent, student)

Study selection

Titles and abstracts will be screened by the lead researcher alongside a second reviewer. Both will then screen full papers deemed to be suitable from the initial search. If any disagreements occur between the two researchers, the two will meet to discuss these. If a decision cannot be reached between the two, a third researcher will be asked to screen the disagreed papers and make an overall decision regarding selection.

Data extraction

Information relevant to the inclusion criteria will be extracted within this review. The authors of primary studies will be contacted and asked to provide any additional or missing data. All extracted data will be managed within EndNote to assist with the management of the review and allow the author to identify duplicate citations.

A pre-piloted extraction form will be used to extract the following information from each included study:

- Study characteristics (study name, author(s), year of publication, study location and setting)
- Study design
- Study populations (including basic demographics of participants, methods of depression diagnosis)
- Intervention details and comparators (intervention type, comparator, duration of the intervention, number of sessions)
- Relevant outcome data for effect size calculations (depression severity, unit of measurement)

Quality Assessment

The methodological quality of studies examined as part of this review will be formally assessed using the Cochrane risk of bias tool (Higgins et al, 2011) and the quality rating scale as proposed by Moncrieff et al (2001). The Moncrieff scale was specifically designed to assess the quality of controlled studies examining interventions for depressive and non-psychotic symptoms. The inclusion of this scale will allow comparisons to be made between general quality assessment tools and one specifically designed for use within the proposed field. Both scales can be found in appendix 2.

Data synthesis

Overview of Analysis Strategy

A narrative synthesis of the findings of included studies will be provided which will include a summary of outcome measures for each and the quality appraisal. A meta-analysis is planned following the completion of the data searching although this will be dependent on the number of studies included and the level of clinical heterogeneity found between them.

Calculation of effect sizes

For continuous measures, standardised mean differences (SMD) using Hedge's adjusted g (Hedges, 1981) and the associated 95% confidence interval will be calculated. For dichotomous outcomes, odds ratios and their associated 95% confidence intervals will be calculated.

Pre-planned comparisons

For each outcome, studies will be grouped on the basis of the design (RCTs vs. controlled but non-randomised designs) and comparator (control condition vs active comparator).

Details of Meta-Analysis

If there are a sufficient number of comparable studies available a random effects meta-analysis will be conducted to examine whether there were overall effects of BA interventions on depression diagnosis and severity. The meta-analysis will be based upon a random effects model as it is assumed that included studies will differ in terms of study characteristics and therefore true effect sizes will vary between studies.

Assessing and managing heterogeneity

If a meta-analysis is conducted, statistical heterogeneity will be assessed using the I² statistic. For the I² statistic, a value of 25% will be regarded as low, 50% as moderate and 75% as high (Higgins et al, 2003). If moderate to high statistical heterogeneity is present (I² ≥ 50%) the analysis will be re-run with any outliers excluded. Potential reasons for heterogeneity will be explored using meta-regressions of main variables and quality assessment criteria.

Analysis of Publication Bias

If there are a sufficient number of studies included, publication bias will be examined using funnel plots.

Additional analyses

Three pre-planned subgroup analyses will be conducted if there are enough included studies to do so. Such sub-group analyses will involve examining studies grouped by setting (e.g. primary care, secondary care, educational settings), publication language and intervention delivery mode (face-to-face, web-based).

Dissemination

The completed review will be published within a relevant peer-reviewed journal.

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FINAL SEARCH STRATEGY (MEDLINE)

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present> 28/05/15

Search Strategy:

-
- 1 Behavio* activation.ti,ab.
 - 2 (behavio* adj2 (intervention* or therap* or treatment* or psychotherap* or psychotherap*)).ti,ab.
 - 3 Behavior Therapy/
 - 4 Cognitive Therapy/
 - 5 self monitor*.ti,ab.
 - 6 (Activit* adj3 (schedul* or plan* or arrang* or organis* or organiz*)).ti,ab.
 - 7 1 or 2 or 3 or 4 or 5 or 6
 - 8 Depression/
 - 9 exp Depressive Disorder/
 - 10 Depression.ti,ab.
 - 11 Depressive.ti,ab.
 - 12 Depressed.ti,ab.
 - 13 ((low or negative or decreas*) adj2 (mood* or affect)).ti,ab.
 - 14 8 or 9 or 10 or 11 or 12 or 13
 - 15 7 and 14
 - 16 young people.ti,ab.
 - 17 young person*.ti,ab.
 - 18 (child* or schoolchild*).ti,ab.
 - 19 teen*.ti,ab.
 - 20 adoles*.ti,ab.
 - 21 youth*.ti,ab.
 - 22 student*.ti,ab.
 - 23 juvenile*.ti,ab.
 - 24 pre-pubert*.ti,ab.
 - 25 (pre-pubert* or prepubert*).ti,ab.
 - 26 (pre-pubescen* or prepubescen*).ti,ab.
 - 27 (pre-teen* or preteen*).ti,ab.
 - 28 (puberty or pubertal).ti,ab.
 - 29 Child/
 - 30 Adolescent/
 - 31 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
 - 32 7 and 14 and 31
 - 33 exp animals/ not humans.sh.
 - 34 32 not 33

RELEVANCE CHECKING PROFORMA

Study Number	
90% of sample 18 or under	Yes No
Behavioural treatments for depression (based upon operant conditioning / learning theory principles or comprise techniques fundamental to behavioural treatments of depression including activity scheduling, self-monitoring, goal setting)	Yes No
Primary outcome measure: Levels of depression/ depressive symptoms measured by validated assessments (e.g. measurement scales, clinician or researcher administered ratings)	Yes No
Reviewer	LT SG Other
Decision	Included Excluded
Reason for exclusion	

DATA EXTRACTION FORM (BLANK)

Study Characteristics	Title: Author(s) Year of publication: Follow-up period:
Setting and sampling	Setting: Country: Sampling technique
Study Design	
Study populations	Overall recruited (n): Age: Gender: Diagnosis and method of diagnosis:
Intervention	Intervention type: Duration of intervention: Number of sessions: Delivery: Allocated to intervention (n): Included in analysis (n): Number lost to follow-up (n):
Comparator	Comparator type: Duration of comparator: Number of sessions: Delivery: Allocated to comparator (n): Included in analysis (n): Number lost to follow-up (n):
Outcome measures and completion times	Primary: Secondary: Additional:

QUALITY ASSESSMENT SCALES

Cochrane risk of bias tool (Higgins et al, 2011)

Domain	Description	High risk of bias	Low risk of bias	Unclear risk of bias	Reviewer assessment
Selection bias Random sequence generation	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence	Random sequence generation method should produce comparable groups	Not described in sufficient detail	High Low Unclear
Selection bias Allocation concealment	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	Intervention allocations likely could not have been foreseen in before or during enrolment	Not described in sufficient detail	High Low Unclear
Reporting bias Selective reporting	Stated how the possibility of selective outcome reporting was examined by the authors and what was found	Reporting bias due to selective outcome reporting	Selective outcome reporting bias not detected	Insufficient information to permit judgment	High Low Unclear
Other bias Other sources of bias	Any important concerns about bias not addressed above	Bias due to problems not covered elsewhere in the table	No other bias detected	There may be a risk of bias, but there is either insufficient information to assess whether an important risk of bias exists or insufficient	High Low Unclear

				rationale or evidence that an identified problem will introduce bias	
Performance bias Blinding (participants and personnel)	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	High Low Unclear
Detection bias Blinding (outcome assessment)	Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	High Low Unclear
Attrition bias Incomplete outcome data	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported.				High Low Unclear

Moncrieff Quality rating scale (Moncrieff et al., 2001)

Criteria	Score and rating criteria
Objectives and specifications, main outcomes a priori	0 = objectives unclear 1 = objectives clear but main outcomes not specified a priori 2 = objectives clear with a priori specification of main method for assessment of outcome
Adequate sample size (n per group)	0 = inadequate 1 = moderate 2 = large or specified by power calculations
Appropriate duration of trial including follow-up	0 = too short 1 = reasonable length 2 = long enough for assessment of long-term outcomes
Power Calculations	0 = not reported 1 = mentioned without details 2 = details of calculations provided
Method of allocation	0 = unrandomized and likely to be biased 1 = partially or quasi randomized with some bias possible 2 = randomized allocation
Concealment of allocation	0 = not done or not reported 2 = concealment of allocation code detailed
Clear description of treatments (including doses of drugs used) and adjunctive treatment	0 = main treatments not clearly described 1 = inadequate details of main or adjunctive treatments 2 = full details of main and adjunctive treatments
Blinding of participants	0 = not done 1 = done but no test of blind 2 = done and integrity of blind tested
Source of participants described and representative sample recruitment	0 = source of participants not described 1 = source of participants given but no information on sampling or use of unrepresentative sample (for example, volunteers) 2 = source of participants described plus representative sample taken (for example, all consecutive admissions or referrals, or random sample taken)
Use of diagnostic criteria (or clear specification of inclusion criteria)	0 = none 1 = diagnostic criteria or clear inclusion criteria 2 = diagnostic criteria plus specification of severity
Record of exclusion criteria and number of exclusions and refusals reported	0 = criteria and number not reported 1 = criteria or number of exclusions and refusals not reported 2 = criteria and number of exclusions and refusals reported
Description of sample demographics	0 = little/no information (only age/sex) 1 = basic details (for example, marital status/ethnicity) 2 = full description (for example, socioeconomic status, clinical history)
Blinding of assessor	0 = not done 1 = done but no test of blind 2 = done and integrity of blind tested
Assessment of compliance with experimental treatments (including attendance for therapy)	0 = not assessed 1 = assessed for some experimental treatments
Details on side-effects	0 = inadequate details 1 = recorded by group but details inadequate 2 = full side effect profiles by group

Record of number and reasons for withdrawal by group	0 = no information on withdrawals by group 1 = withdrawals by group reported without reason 2 = withdrawals and reason by group
Outcome measures described clearly (and therefore replicable) or use of validated (or referenced) instruments	0 = main outcomes not described clearly 1 = some of main outcomes not clearly described 2 = main outcomes clearly described or valid and reliable instruments used
Information on comparability and adjustment for differences in analysis	0 = no information on comparability 1 = some information on comparability with appropriate adjustment 2 = sufficient information on comparability with appropriate adjustment
Inclusion of all participants in analyses ('intention to treat' analysis)	0 = less than 95% of participants included 2 = 95% or more included
Presentation of results with inclusion of data for re-analysis of main outcomes (for example, SDs)	0 = little information presented 1 = adequate information 2 = comprehensive
Appropriate statistical analysis (including correction for multiple tests where applicable)	0=inadequate 1= adequate
Conclusions justified	0 = no 1 = partially 2 = yes
Declaration of interests (for example, source of funding)	0 = no 2 = yes

(Please circle the appropriate score)

Total score _____

The SCED scale (Tate et al., 2008)



SCED Scale

Rating Scale for Single Participant Designs

For each item, please justify scoring (for both "yes" and "no" responses), by at least mentioning page and paragraph numbers in the field underneath the tick boxes.

	Rater 1:		Rater 2:		Consensus	
	yes	no	yes	no	yes	no
1. Clinical history was specified. <i>Must include Age, Sex, Aetiology and Severity.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	specify page & paragraph		specify page & paragraph		specify page & paragraph	
2. Target behaviours. Precise and repeatable measures that are operationally defined. <i>Specify measure of target behaviour.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Design 1: 3 phases. Study must be either A-B-A or multiple baseline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Design 2: Baseline (pre-treatment phase). Sufficient sampling was conducted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Design 3: Treatment phase. Sufficient sampling was conducted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Design 4: Data record. Raw data points were reported	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Observer bias: Inter-rater reliability was established for at least one measure of target behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Independence of assessors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Statistical analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Replication: <i>either</i> across subjects, therapists or settings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Evidence for generalisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EXCLUDED STUDIES (N=32)

Authors and Year	Reasons for exclusion
Armento (2011)	<90% 18 years or under
Armento et al. (2012)	<90% 18 years or under
Bilek & Ehrenreich-May (2012)	CBT-based therapy
Brent et al. (1999)	Systemic behavioural family therapy as treatment arm
Brent et al. (1998)	Systemic behavioural family therapy as treatment arm
Brent et al. (1997)	Systemic behavioural family therapy as treatment arm
Chu et al. (2015)	Not a behavioural treatment for depression
Davidson et al. (2014)	No measure of depression at follow-up
Dundon (2010)	Not a behavioural treatment for depression
Esposito (2005)	CBT-based therapy
Ettelson (2003)	CBT-based therapy
Gawrysiak et al. (2009)	<90% 18 years or under
Harmon et al. (1980)	<90% 18 years or under
Kitchen et al. (2015)	Ongoing study
Kauer et al. (2011)	Self-monitoring alone
Landback et al. (2009)	CBT-based therapy
Levin et al. (2010)	<90% 18 years or under
Ly et al. (2014)	<90% 18 years or under
Merry et al. (2004)	CBT-based therapy
Mohammadi et al. (2013)	<90% 18 years or under
Moradveisi (2013)	<90% 18 years or under
Nystedt (1977)	CBT-based therapy
Parker et al. (2011)	<90% 18 years or under
Pass et al. (2015)	Participants not diagnosed with depression at baseline
Proudfoot et al. (2013)	<90% 18 years or under
Reid et al. (2011)	Self-monitoring alone
Reynolds et al. (2011)	Participants not diagnosed with depression at baseline
Shaw et al. (1977)	<90% 18 years or under
Sobowale (2013)	Not a behavioural treatment for depression
Takagaki (2013)	<90% 18 years or under
Van Voorhees (2008)	Mixed BA and CBT approach
Velayudhan (2010)	<90% 18 years or under

DATA EXTRACTION FORMS FOR EACH INCLUDED STUDY

Study Characteristics	Title: Transdiagnostic Group Behavioural Activation and Exposure Therapy for youth anxiety and depression: Initial Randomised Controlled Trial Author(s): Chu et al Year of publication: 2016 Follow-up period: Pre-treatment, post-treatment, 4 months follow-up
Setting and sampling	Setting: 1 Public Middle School Country: USA Sampling technique: Double gated screening using the CES-D and SCARED
Study Design	RCT
Study populations	Overall recruited (n): 35 Age: 12-14 (mean: 12.03) Gender: 25 female, 10 male Diagnosis and method of diagnosis: Current clinical principal diagnosis of either a unipolar depression disorder or an anxiety disorder based on CDRS-R or ADIS-IV (no cut-offs specified)
Intervention	Intervention type: Group Behavioural Activation Therapy (GBAT) Duration of intervention: 10 weeks Number of sessions: 10 (1 hour each) Delivery: Face-to face (7 therapists: 1 clinical psychologist, 4 graduate students, 2 school counsellors) Allocated to intervention (n): 21 Included in analysis (n): 21 (ITT) Number lost to follow-up (n): 2
Comparator	Comparator type: Wait-list Duration of comparator: 15 weeks with no contact from study staff Number of sessions: N/A Delivery: N/A Allocated to comparator (n): 14 Included in analysis (n): 14 (ITT) Number lost to follow-up (n): 1
Outcome measures and completion times	Primary: CDRS-R, CES-D, ADIS-IV, SCARED (pre-treatment, post-treatment, 4 months follow-up) Secondary: N/A Additional: N/A

Study Characteristics	Title: The adolescent behavioural activation program: adapting behavioural activation as a treatment for depression in adolescents Author(s): McCauley et al Year of publication: 2015 Follow-up period: End of treatment, 6 months follow-up, 12 months follow-up
Setting and sampling	Setting: Hospital-based mental health clinic Country: USA Sampling technique: Clinically referred
Study Design	RCT
Study populations	Overall recruited (n): 60 Age: Mean: 14.9 Gender: 64% female, 36% male Diagnosis and method of diagnosis: Depressive disorder based on DSM IV criteria, or raw score of ≥ 45 (T score ≥ 65) on CDRS-R, and score of ≥ 11 on SMFQ
Intervention	Intervention type: Adolescent Behavioural Activation program (A-BAP) Duration of intervention: Not reported Number of sessions: 14

	<p>Delivery: Face-to-face (2 post-doctoral fellows, 2 faculty staff/psychologists, 1 social worker)</p> <p>Allocated to intervention (n): 35</p> <p>Included in analysis (n): 35 (ITT)</p> <p>Number lost to follow-up (n): 8</p>
Comparator	<p>Comparator type: Evidence-based practice for depression</p> <p>Duration of comparator: Not reported</p> <p>Number of sessions: Up to 14</p> <p>Delivery: Same as intervention</p> <p>Allocated to comparator (n): 25</p> <p>Included in analysis (n): 25 (ITT)</p> <p>Number lost to follow-up (n): 9</p>
Outcome measures and completion times	<p>Primary: K-SADS diagnostic interview, CDRS-R, SMFQ (Pre-treatment, Post-treatment, 6 months follow-up, 12 months follow-up)</p> <p>Secondary: MASC (Pre-treatment, Post-treatment, 6 months follow-up, 12 months follow-up)</p> <p>Additional: N/A</p>

Study Characteristics	<p>Title: A comparison of the relative efficacy of self-control therapy and behaviour therapy for the reduction of depression in children</p> <p>Author(s): Stark</p> <p>Year of publication: 1985</p> <p>Follow-up period: pre-treatment, post-treatment, 8 weeks follow-up</p>
Setting and sampling	<p>Setting: Elementary school</p> <p>Country: USA</p> <p>Sampling technique: Screening</p>
Study Design	RCT
Study populations	<p>Overall recruited (n): 29</p> <p>Age: 9-12 (mean 11.2)</p> <p>Gender: 55% male, 45% female</p> <p>Diagnosis and method of diagnosis: Depressive disorder based on CDI (≥ 16)</p>
Intervention	<p>Intervention type: Behaviour therapy</p> <p>Duration of intervention: 5 weeks</p> <p>Number of sessions: 12 sessions (45 mins)</p> <p>Delivery: Face-to-face (author, 1 clinical psychologist)</p> <p>Allocated to intervention (n): 10</p> <p>Included in analysis (n): 9</p> <p>Number lost to follow-up (n): 1</p>
Comparator	<p>Comparator type: Self-control therapy or wait-list control</p> <p>Duration of comparator: 5 weeks (self-control)</p> <p>Number of sessions: 12 sessions of 45 minutes (self-control)</p> <p>Delivery: Face-to-face group therapy</p> <p>Allocated to comparator (n): 9 (self-control), 9 (wait-list)</p> <p>Included in analysis (n): 9 (self-control), 9 (wait-list)</p> <p>Number lost to follow-up (n): 0 (self-control), 0 (wait-list)</p>
Outcome measures and completion times	<p>Primary: CDI, CDS, CDRS-R (Pre-treatment, Post-treatment, 8 weeks follow-up)</p> <p>Secondary: RCMAS (Pre-treatment, Post-treatment, 8 weeks follow-up)</p> <p>Additional: N/A</p>

Study Characteristics	<p>Title: Motivational interviewing assessment and behaviour therapy as a stepped-care approach to the treatment of adolescent depression</p> <p>Author(s): Douleh</p> <p>Year of publication: 2013</p> <p>Follow-up period: Pre-treatment; Post MIA (4 weeks post pre-treatment); Post FA (10 weeks post pre-treatment); Post VBBA (16 weeks post pre-treatment); 20 weeks post pre-treatment</p>
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Setting and sampling	Setting: 2 high schools Country: USA Sampling technique: Referral
Study Design	Within-participant design
Study populations	Overall recruited (n): 14 Age: 14-18 (mean: 15.71) Gender: 57% male, 43% female Diagnosis and method of diagnosis: Depressive disorder based on CDRS-R (≥ 45)
Intervention	Intervention type: Values-Based behavioural activation Duration of intervention: 6 weeks Number of sessions: 1-4 sessions Delivery: Face-to-face (study therapist) Allocated to intervention (n): 1 Included in analysis (n): 1 Number lost to follow-up (n): 0
Comparator	Comparator type: Motivational Interview (MI) Motivational Interview (MI) and Fun Activities (FA) Duration of comparator: MI: 4 weeks FA: 6 weeks Number of sessions: MI: 1-4 FA: 1-4 Delivery: Face-to-face (study therapist) Allocated to comparator (n): MIA: 14 MIA and FA: 7 Included in analysis (n): MIA: 11 FA: 4 Number lost to follow-up (n): MIA: 2 FA: 3
Outcome measures and completion times	Primary: CDRS-R, BDI-II, MINI-KID A1: Pre-treatment A2: Post MIA (4 weeks post pre-treatment) A3: Post FA (10 weeks post pre-treatment) A4: Post VBBA (16 weeks post pre-treatment) A5: 20 weeks post pre-treatment Secondary: HRQOL (but measure used not specified) Additional: N/A

Study Characteristics	Title: Identifying mechanisms of change: Utilizing single-participant methodology to better understand behaviour therapy for child depression Author(s): Riley & Gaynor Year of publication: 2014 Follow-up period: End of treatment, 2 months post NDT or 2 months post BT
Setting and sampling	Setting: 3 elementary schools, 1 middle school Country: USA Sampling technique: Referral by school counsellors
Study Design	Within-participant design
Study populations	Overall recruited (n): 11 Age: 8-12 (mean: 9.86, SD: 1.26) Gender: 9 males, 2 females Diagnosis and method of diagnosis: Depressive disorder based on CDRS-R (≥ 12) and CDI (≥ 40)

Intervention	Intervention type: Non-directive therapy (NDT) and behaviour therapy Duration of intervention: 3 weeks (NDT), 9 weeks (BT) Number of sessions: 3 (NDT), 9 (BT) Delivery: Face-to-face (Doctoral students) Allocated to intervention (n): 7 Included in analysis (n): 7 Number lost to follow-up (n): 0
Comparator	Comparator type: NDT only Duration of comparator: 3 weeks Number of sessions: 3 Delivery: Face-to-face (Doctoral students) Allocated to comparator (n): 4 Included in analysis (n): 4 Number lost to follow-up (n): 0
Outcome measures and completion times	Primary: CDRS-R, CDI (Pre-treatment, Post-treatment, 2 months follow-up) Secondary: FQOLS (Pre-treatment, Post-treatment, 2 months follow-up) Additional: N/A

Study Characteristics	Title: Behavioural Activation for Depressed teens: A pilot study Author(s): Ritschel et al Year of publication: 2011 Follow-up period: Pre-treatment, post-treatment
Setting and sampling	Setting: Outpatient adolescent mood clinic Country: USA Sampling technique: Flyers, radio advert, outpatients attending clinic offered study
Study Design	Case study
Study populations	Overall recruited (n): 6 Age: 14-17 Gender: 3 male, 3 female Diagnosis and method of diagnosis: Depressive disorder based on K-SADS or CDRS-R (≥ 45)
Intervention	Intervention type: Behavioural Activation Duration of intervention: 18 weeks (max) Number of sessions: 22 (max) Delivery: Face-to-face (2 doctoral level staff, 1 graduate student) Allocated to intervention (n): 6 Included in analysis (n): 6 Number lost to follow-up (n): 0
Comparator	Comparator type: N/A Duration of comparator: N/A Number of sessions: N/A Delivery: N/A Allocated to comparator (n): N/A Included in analysis (n): N/A Number lost to follow-up (n): N/A
Outcome measures and completion times	Primary: K-SADS, CDRS-R, BDI-II (Pre-treatment, Post-treatment) Secondary: N/A Additional: N/A

Study Characteristics	Title: Behavioural Activation for the treatment of rural adolescents with depression Author(s): Wallis et al Year of publication: 2012 Follow-up period: Baseline, 2 weeks, 3 weeks, 6 weeks, completion
Setting and sampling	Setting: Local mental health service Country: Australia Sampling technique: Referred by primary care

Study Design	Case study
Study populations	Overall recruited (n): 5 Age: 14-15 Gender: All females Diagnosis and method of diagnosis: Depressive disorder based on CES-D (no cut-offs specified)
Intervention	Intervention type: Behavioural Activation treatment for depression Duration of intervention: 10 weeks Number of sessions: 10 Delivery: Face-to-face (2 social workers) and workbooks Allocated to intervention (n): 5 Included in analysis (n): 5 Number lost to follow-up (n): 0
Comparator	Comparator type: N/A Duration of comparator: N/A Number of sessions: N/A Delivery: N/A Allocated to comparator (n): N/A Included in analysis (n): N/A Number lost to follow-up (n): N/A
Outcome measures and completion times	Primary: CES-D, BDI-II (Pre-treatment, 2 weeks, 3 weeks, 6 weeks, Completion) Secondary: N/A Additional: N/A

Study Characteristics	Title: Brief Behavioural therapy for pediatric anxiety and depression: Piloting an integrated treatment approach Author(s): Weersing et al Year of publication: 2008 Follow-up period: Pre-treatment, 12 weeks post-treatment, 24 weeks follow-up
Setting and sampling	Setting: Primary care practices Country: USA Sampling technique: Referral
Study Design	Case Study
Study populations	Overall recruited (n): 2 Age: 13 and 17 Gender: 1 female, a male Diagnosis and method of diagnosis: Depressive disorder based on CDI (≥ 13), or anxiety disorder SCARED (≥ 25)
Intervention	Intervention type: Integrated brief behavioural therapy for anxiety and depression (IBBT) Duration of intervention: 12 weeks (max) Number of sessions: 8 (30 mins) Delivery: Face-to-face (mental health specialists) Allocated to intervention (n): 2 Included in analysis (n): 2 Number lost to follow-up (n): 0
Comparator	Comparator type: N/A Duration of comparator: N/A Number of sessions: N/A Delivery: N/A Allocated to comparator (n): N/A Included in analysis (n): N/A Number lost to follow-up (n): N/A
Outcome measures and completion times	Primary: CDI, K-SADS (Pre-treatment, Post-treatment (12 weeks), 24-week follow-up) Secondary: SCARED Additional: N/A

Study Characteristics	Title: An initial description and pilot of group behavioural activation therapy for anxious and depressed youth Author(s): Chu et al Year of publication: 2009 Follow-up period: Pre-treatment, post-treatment (13 weeks)
Setting and sampling	Setting: Public Middle School Country: USA Sampling technique: Nominated by school counsellors
Study Design	Case study
Study populations	Overall recruited (n): 5 Age: 12-14 Gender: 2 males, 3 females Diagnosis and method of diagnosis: Current clinical principal diagnosis of either a unipolar depression disorder or an anxiety disorder based on CES-D (≥ 15) or ADIS-IV (no cut-offs specified)
Intervention	Intervention type: Group Behavioural Activation Therapy (GBAT) Duration of intervention: 13 weeks Number of sessions: 13 (40 mins) Delivery: Face-to-face (mental health specialists) Allocated to intervention (n): 5 Included in analysis (n): 5 Number lost to follow-up (n): 0
Comparator	Comparator type: N/A Duration of comparator: N/A Number of sessions: N/A Delivery: N/A Allocated to comparator (n): N/A Included in analysis (n): N/A Number lost to follow-up (n): N/A
Outcome measures and completion times	Primary: CES-D, ADIS-IV (Pre-treatment, Post-treatment) Secondary: MASC (Pre-treatment, Post-treatment) Additional: N/A

Study Characteristics	Title: Behavioural Activation for the treatment of low-income African American Adolescents with Major depressive disorder Author(s): Jacob et al Year of publication: 2013 Follow-up period: Pre-treatment, at each session (BDI-II), week 9 (CDRS-R), post-treatment (6 months)
Setting and sampling	Setting: Community mental health clinics, USA Country: USA Sampling technique: Clinic intake, flyers
Study Design	Case series
Study populations	Overall recruited (n): 3 Age: 14-17 Gender: 2 males, 1 female Diagnosis and method of diagnosis: Depressive disorder based on K-SADS, CDRS-R (≥ 45) and BDI-II (≥ 14)
Intervention	Intervention type: Behavioural Activation (adapted for low-income, African American adolescents) Duration of intervention: 6 months Number of sessions: 14-17 (length of time not specified) 1 hour Delivery: Face-to-face, manual Allocated to intervention (n): 3 Included in analysis (n): 3 Number lost to follow-up (n): 0
Comparator	Comparator type: N/A Duration of comparator: N/A Number of sessions: N/A Delivery: N/A

	Allocated to comparator (n): N/A Included in analysis (n): N/A Number lost to follow-up (n): N/A
Outcome measures and completion times	Primary: KSADS, CDRS-R, BDI-II, CGI-S Secondary: N/A Additional: N/A

Appendix B: Additional information relating to the qualitative study (Chapter Three)

QUALITATIVE STUDY PROTOCOL

Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people

Introduction

Background and rationale

Overview of the research

Depression is currently the leading cause of illness and disability in young people (World Health Organisation (WHO), 2014), with approximately 20% of adolescents having had at least one depressive episode by the time they reach the age of 18 years (Gladstone et al, 2011). It is important that young people experiencing depressive disorders are identified early and receive effective treatment for depression to reduce the negative symptoms of the condition and improve mood.

One therapy that has demonstrated its effectiveness in the treatment of depression in adults (Chartier & Provencher, 2013; Ekers, 2008, 2014; Cuijpers, 2007) is Behavioural Activation (BA). BA, a type of talking therapy focused on increasing activity, has been defined as '(a) structured, brief psychotherapeutic approach that aims to (a) increase engagement in adaptive activities (which often are those associated with the experience of pleasure or mastery), (b) decrease engagement in activities that maintain depression or increase risk for depression, and (c) solve problems that limit access to reward or that maintain or increase aversive control' (Dimidjian et al, 2011, p. 4). Despite extensive research supporting its use within adult populations, little research focuses on BA use with young people. A systematic review examining the effectiveness of BA for treating depression in adolescents (Tindall et al, 2017) found only ten studies that had examined this area. Although these ten studies highlighted some of the components of BA that are useful in treating young people with depression, qualitative research within this context is required to explore young people's views and preferences as to what such a programme should be like.

Computerised therapies with young people

Despite the reported high rates of depressive disorders amongst young people, a number of large-scale observational studies have suggested that only 35% seek help (Gladstone et al, 2015). This limited help-seeking behaviour may be influenced by various factors associated with treatments, including stigma (Gulliver et al, 2010;

Rickwood et al, 2005), negative attitudes about help-seeking (Rickwood et al, 2005) accessibility (Gulliver et al, 2010) and young people's reluctance to engage one-to-one with a therapist (Rickwood et al, 2010).

To avoid some of these barriers to therapy, it has been suggested that young people experiencing depression may be treated more effectively using computer-administered therapies as opposed to those delivered in a traditional face-to-face format. Therapies in a computerised format have increased availability and accessibility (Stallard et al, 2010), and can be delivered without stigma and in a format attractive to many young people. Thus far, much research has focused on the delivery of CBT in this form (e.g. Smith et al., 2015, Wright et al., 2014; Abeles et al., 2009), with computerised CBT (CCBT) representing an alternative form of therapy delivery, with the potential to enhance access to CBT at various stages of illness. However, to date, no computerised versions of BA have been developed to treat young people with depression.

The aim of this research is therefore to collect qualitative information as to what participants perceive to be the important components for inclusion in a computerised BA programme designed for use with young people experiencing depression. Including stakeholders in both the question and design of research is important to ensure relevance and feasibility (Glasgow et al, 2003; Tunis et al, 2002; Glasgow et al, 2006). Therefore, in the design of a computerised BA programme those deemed the best to inform the development include young people and the health professionals who may refer to and/or deliver such a programme.

In research involving children and young people, adults are normally the ones investigated despite it being expected that children would be the best sources of information relating to themselves (Forsner et al, 2005). An omission to collect this information first-hand may result in the misinterpretation of the needs of young people and/or a focus on the needs of adult representatives instead (Fox & Berrick, 2007). Consequently, qualitative methods are increasingly being used in order to capture the perspectives of children and young people as well (Irwin & Johnson, 2005).

According to Broome et al (2001) it is essential to fully understand the factors that influence children and adolescent's decisions about research and their satisfaction with participating, thus, obtaining their qualitative accounts within this context is vital.

Aims

The aim of this research is therefore to obtain the views of young people, and healthcare practitioners involved in their care, regarding what they perceive are the important components of a computerised BA programme for use with young people experiencing depression. The main areas of focus will be upon the components to include, individual perceptions about who could deliver such a programme and where, the client groups it could work best with and where a computerised BA programme would fit within the current care pathway. The findings of this qualitative research will inform the development of a computerised BA programme.

Principle research objectives/questions

1. To explore what elements young people, feel should be included within a computerised BA programme for young people with depression
2. To explore what elements, the healthcare providers of young people with depression feel should be included within a computerised BA programme designed for young people with depression

Secondary research objectives/questions

This research will also examine:

- Issues relating to the presentation of a computerised BA programme
- Delivery specific issues (i.e. setting of delivery, number/ length of sessions, who could deliver the programme, client groups it would work best with)
- What additional support may be required alongside programme delivery
- The best position for computerised BA programme within the care pathway
- Parental involvement, if any, required for the programme
- Training needs of health professionals (health professionals only)

Methodology

Study design

This research adopts an exploratory qualitative design. Two focus groups will be conducted; one with young people recruited from a community sample and one with healthcare practitioners working within Child and Adolescent Mental Health Service (CAMHS). In addition, up to 10 semi-structured interviews (lasting approximately 30 minutes) will be conducted with young people experiencing depression and currently accessing CAMHS.

Study participants

This qualitative study will employ two groups of participants – young people (both from a community sample and a service using sample) and healthcare practitioners working within CAMHS who have experience of working with young people with depression.

(i) Young people

Since research suggests that 65% of young people experiencing a depressive disorder do not seek help, a community sample of young people will be invited to take part in focus groups. A sample of young people receiving support through CAMH services for depression will also be recruited to attend face-to-face interviews with the researcher. Recruiting young people from both a community and a healthcare sample will allow maximum variation in the views collected. It is important to ensure that the young people taking part in interviews and focus groups are similar to those who the eventual programme will be designed for. Therefore, recruited young people will be a mixture of males and females aged between 11 and 16.

(ii) Healthcare Professionals

A sample of healthcare professionals working within CAMHS with experience of working with young people experiencing depression will be invited to attend a focus group. Any professionals who meet this criterion will be invited to attend with no further inclusion criterion imposed in order to obtain a varied sample of health professionals.

Sample size

According to Krueger and Casey (2015) between five and ten individuals are required for the successful running of a focus group. Therefore, we will aim to recruit ten individuals to each group to allow for withdrawals. Up to 10 individual face-to-face interviews will be conducted. Interviews will cease before 10 have been completed if data saturation is attained beforehand.

Recruitment

(i) Young people

Participants will be a convenience sample to ensure that rich information with individual meaning is collected. Through employing a convenience sample, it is hoped that a mixture of individual characteristics is represented within the focus groups and interviews (i.e. age, gender, severity of depression (if applicable), comorbidities (if applicable)).

Two different sampling techniques will be employed to obtain a community sample of young people to a focus group and a service-user sample to individual face-to-face interviews.

Community sample: Secondary schools in York will be approached. Wellbeing workers based within the schools will identify young people who may be interested in taking part in the study and supply them with information leaflets and consent forms for both themselves and their parent/guardian. As all young people in the study will be under the age of 16, they will need to provide their own consent along with that of their parent/guardian. Any young person who is interested in taking part will inform the wellbeing worker of this. Wellbeing workers will contact the researcher and inform them of any potential participants. The researcher will then arrange to visit the school and answer any questions the young person may have about participation and collect consent forms accordingly. The researcher will liaise with the wellbeing workers from each of the schools who will act as the main point of contact for the research.

Service user sample: Healthcare professionals currently working with young people experiencing depression within four CAMH services will be informed of the research and asked to refer any individuals whom they think would be interested in taking part. Health professionals will distribute information leaflets and consents to young people and their parent/guardian. As all young people in the study will be under the age of 16, they will need to provide their own consent along with that of their parent/guardian. Young people will be asked to express any interest in participation to their health professional who will then in turn inform the researcher. The researcher will then arrange to visit the young person within CAMHS and answer any questions they may have about participation and collect consent forms accordingly. In order to retain confidentiality for those currently accessing mental health services for depression, up to 10 individual face-to-face interviews will be employed.

(ii) *Healthcare Professionals*

Healthcare professionals involved in the care of young people with depression will be purposively sampled from CAMHS and the professional networks of the lead researcher. A standardised email will be sent to healthcare professionals explaining the aims of the study and inviting them to take part in a focus group. The researcher will then arrange to meet any health professionals who have expressed an interest in the study, answer any questions they may have about participation and obtain consent

accordingly. If an insufficient number express an interest in taking part in a focus group, a snowballing sampling approach will be employed.

Consent process

All individuals who express an interest in being part of the study will be given an information leaflet to read and at least 24 hours will be allowed to elapse before consent is sought. The information leaflets will outline the aims of the research and explain what will be expected of individuals if they opt to participate in the study. Information regarding the withdrawal process and data storage will be outlined, with all participants being informed of their right to withdraw at any time. In addition, all prospective participants will be informed that the focus groups and face-to-face interviews will be digitally recorded and transcribed. Pseudonyms will be used during the transcription process to maintain anonymity. Consent will be obtained from all individuals who express an interest in participation. Three different versions of both the information leaflet and consent form will be distributed: one for healthcare professionals, one for young people, and one for the parent/guardian of any prospective young people.

The information leaflets for young people and their parent/guardian will contain information about both focus groups and individual interviews with sections outlining what both will entail. Separation of the forms further into ones for interviews and ones for focus groups may be somewhat stigmatising for young people who are recruited through CAMHS and currently experiencing depression. Therefore, regardless of recruitment strategy all young people will receive the same study documentation. When approached to take part in the study the wellbeing workers and CAMHS clinicians will be able to inform young people of what participation will involve (interview or focus group attendance) based on whether they are experiencing depression or not.

Procedure

Both focus groups and all face-to-face interviews will be arranged at times most convenient to participants and will be conducted by the lead researcher who has undergone qualitative training for this study. The interviews and focus groups will be conducted within the schools and CAMHS sites where recruitment occurs.

Prior to all interviews and focus groups, attendees will be asked to complete a short questionnaire to provide the researcher with further information. For young people this will involve collecting basic demographic information (age, sex, ethnicity, etc.)

alongside information about their experiences of depression (if any). For health professionals, information will be collected as to their level of education, profession, years in practice, employment setting, age range, the number of young people they see with depression on a monthly basis and perceived proficiency with computer use.

All interviews and focus groups will be digitally recorded, with the permission of all participants and transcribed verbatim by the lead researcher. Immediately following transcription all audio recordings will be erased. All interviews and focus groups will closely follow one of two topic guides (one for use with young people and one for health care professionals) to ensure consistency. Topic guides will comprise a number of open-ended questions. All interviews and focus groups will ask participants about issues relating to the content and presentation of the BA computer programme. Young people will also be asked about their opinions of parental input whilst health professionals will be asked about training needs and their perceptions of who the end user will be.

Data analysis

Data will be analysed using thematic analysis. Transcripts will be read in the first instance to allow the researcher to become familiar with the data before emergent themes are identified. According to Braun and Clarke (2006) there are six phases in thematic analysis – these guidelines will be followed in the analysis of the collected data. The six phases are:

1. **Familiarisation with the data** (i.e. Transcription, reading and rereading, noting initial ideas)
2. **Generating initial codes** (i.e. Coding points of interest, collating relevant data)
3. **Searching for themes** (i.e. Collating codes into themes, collating data relevant to each theme)
4. **Reviewing themes** (i.e. Checking the themes work in relation to both the coded extracts and the entire data set, generating a thematic „map“ of the analysis)
5. **Defining and naming themes** (i.e. Refinement of specifics of each theme, generating clear definitions and names for each theme)
6. **Producing the report** (i.e. Selection of extract examples, final analysis of selected extracts, reporting of the analysis)

A second individual from the research team will be asked to code a selection of the interview and focus group transcripts to ensure that similar themes are detected. A third researcher will be consulted if any disagreements occur during this process.

Data storage and quality assurance

The audio-files, transcripts and any notes taken by the researcher will be stored safely in locked storage cabinets in locked offices at the University of York where only members of the research team can access them. The transcripts, notes and audio-files will be given a code allocated to each participant in order to safeguard confidentiality. Study data, personal data and information regarding the allocation of pseudonyms will be stored securely in separate locations. Any data stored on computers will be password protected and stored on secure servers at the University of York. Immediately following transcription all audio-files will be erased. At the end of the research the interview transcripts will be archived for five years as required by the National Institute for Health Research. All data will be treated in accordance with the Data Protection Act (1998).

Risks/ burdens to participants

Confidentiality and anonymity will be maintained for all participants. Full information about the purpose and uses of participants' contributions will be given in a participant information leaflet before consenting to the study and this will be clarified at the beginning of the interview. All information collected from participants will be kept confidentially as described above (data storage/ quality assurance). Participants will be free to withdraw from the study at any time, without having to give a reason, however any information provided up until the point of withdrawal will be kept, as agreed during the consent process. Due to the nature of this study it is not anticipated that participation would cause any distress to the participants or result in any adverse events. Despite this it is possible that some participants may choose to discuss issues relating to their own experiences (if any) of low mood/depression. If this occurs, it is possible that some participants may become distressed when discussing these experiences. Individuals trained to deal with distressed young people will be available immediately to provide support in such circumstances. These will include wellbeing workers (if participation occurs in schools) and child and adolescent mental health (CAMHS) clinicians (if participation occurs within CAMHS). In addition, Professor Barry Wright, one of the academic supervisors involved in this research, is very experienced in dealing with distressed young people and is well placed to either provide support himself or refer to other support, as necessary.

Dissemination

This protocol and the subsequent completion of the work outlined within it is part of a PhD thesis examining computerised BA use for treating young people with depression.

The findings of this work will be disseminated via publication to a high impact journal in order to inform those involved in the care of young people and policy makers to assist them in implementing any changes that might be indicated by the new evidence. As part of this research the subject of dissemination will be addressed within the focus groups to establish any further individuals/organisations who would benefit from being informed of any of the findings. In terms of the included participants, all will be asked whether they would like to receive information about the study findings and if so, will be sent a summary of the results.

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HEALTHCARE PROFESSIONAL INVITATION EMAIL

Invitation to Participate in a research study

Dear [health professional]

My name is Lucy Tindall and I am a PhD student within the Department of Health Sciences at the University of York. As part of my studies, I am hoping to develop and pilot a computerised Behavioural Activation (BA) therapy program to be used with young people (aged 11 to 16) experiencing low mood/depression.

Despite the high prevalence of depression in young people, very few seek help possibly due to factors associated with treatments (e.g. stigma, negative attitudes about help-seeking, accessibility, reluctance to engage one-to-one with a therapist, etc.). To avoid some of these barriers, young people may be treated more effectively using computerised therapies which have increased availability and accessibility, reduced stigma and can be delivered in a format attractive to many young people. One therapy that has demonstrated effectiveness in treating depression in adults is Behavioural Activation (BA) – a type of talking therapy focused on increasing activity. Although research supports its use with adults, little research has examined its use with young people and none in a computerised form. This study therefore aims to develop a computerised BA program designed for young people experiencing depression.

In order to develop this new therapy, I am hoping to speak with both young people and the clinicians involved in their care to ensure that the program developed suits the needs of those for whom it is designed. I am therefore contacting you to see whether you would be happy to take part in this research. Participation will involve attendance at a focus group with other health professionals which will last approximately 90 minutes. The focus group will be led by myself and will involve a discussion surrounding the development of a BA program. Although the focus group will be audio-recorded all responses will remain strictly confidential. Alternatively, if you would like to take part but would be unable to attend a focus group, a face-to-face interview could be arranged.

Please find attached to this email a copy of the participant information sheet, providing further information about the study and a consent form. If you would like to take part in the study, please complete the consent form and return it to me either by email or using the address below.

If you require any further information about the study or have any questions, please do not hesitate to contact me.

Yours Sincerely

Lucy Tindall

PARTICIPANT INFORMATION SHEETS

UNIVERSITY *of York*

The Department of Health Sciences



INFORMATION LEAFLET: Healthcare Professionals

Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people

What is the purpose of this study?

Depression is currently the leading cause of illness and disability in young people with approximately 20% of adolescents having had at least one depressive episode by the age of 18. Despite the importance of young people experiencing depressive disorders receiving effective treatment to reduce negative symptoms and improve mood, only 35% actually seek help possibly due to factors associated with treatments (e.g. stigma, negative attitudes about help-seeking, accessibility, reluctance to engage one-to-one with a therapist, etc.). To avoid some of these barriers, young people may be treated more effectively using computerised therapies which have increased availability and accessibility, reduced stigma and can be delivered in a format attractive to many young people. One therapy that has demonstrated effectiveness in treating depression in adults is Behavioural Activation (BA) – a type of talking therapy focused on increasing activity. Although research supports its use with adults, little research has examined its use with young people. To date no computerised versions of BA have been developed to treat young people with depression. The aim of this research is therefore to collect information regarding what individuals perceive to be the important components for inclusion in a computerised BA programme designed for young people experiencing low mood/depression.

Why have I been approached?

You have been approached as a clinician working with young people experiencing low mood or depression. We are looking to recruit a sample of health professionals to take part in a focus group about what they think should be included in a computerised BA programme. The programme will be developed for use with young people aged between 11 and 16 who are experiencing low mood/ depression.

Do I have to take part?

You are under no obligation whatsoever to take part. It is entirely voluntary. You are free to withdraw from the study at any time, without explanation. We will, with your permission, use the information we have collected up until this point. If you would not like us to use any information that you have given us that is fine, we will not use it and will destroy it. If you take part in a focus group, withdraw from the study, and do not give permission for us to use any information you have provided, we will only use the responses of others in the group for our research and not anything that you have said.

What will happen if I take part?

We will ask you to complete a consent form to say you are happy to take part in the research. You will then be invited to take part in a focus group to discuss what you perceive to be the important components for inclusion in a computerised BA programme

designed for young people experiencing depression. The focus group will last approximately 90 minutes and will be digitally audio recorded. The audio recording of the focus group will be transcribed by the researcher and then erased. During transcription, the researcher will use pseudonyms to maintain confidentiality. Prior to the focus group you will be asked to complete a short questionnaire to provide us with a small amount of information about yourself (e.g. your profession, employment setting, years of service etc.). We will not ask you to provide any information that would be able to identify you – all of your responses will remain anonymous.

What do I do if I want to take part?

If you are happy to take part in the study, then please contact Lucy Tindall who will arrange to meet with you and complete the consent form provided. Lucy will then organise the focus group and contact you with the details.

What are the possible risks and benefits of taking part?

We do not believe there are any risks of taking part in this research. Participation will provide you with the opportunity to give your opinions which will inform the development of a computerised BA programme.

Is the study confidential?

You will not be named in any research or reports produced from this study. Confidentiality will be maintained throughout the study, and any information kept will be done so anonymously. All study data will be securely stored in locked filing cabinets within the University of York which only immediate members of the research team will have access to. All personal information will be securely destroyed 3 months after the study ends and the rest of the information from the study will be destroyed after 5 years.

Who is organising and funding the research?

This research is being conducted as part of the completion of a PhD and has been organised by The Department of Health Sciences at the University of York. It has been funded by an Economic and Social Research Council (ESRC) grant.

Who has reviewed the study?

Before any research goes ahead, it has to be checked by a research ethics committee to ensure the research is safe and fair. This study has been reviewed (and approved) by the Health Sciences Research Governance Committee at the University of York. The research has also been reviewed and approved by East Midlands - Leicester South Research Ethics Committee (reference: 16/EM/0420).

Who can I contact if I want to learn more about the study?

If you would like further information about the study, please contact Lucy Tindall (lead researcher) (email: lucy.tindall@york.ac.uk, Tel: 01904 294 826). If you have any queries or concerns about the research or would like to make a complaint, please contact PALS (Patient advice and liaison service), (email: pals.lypft@nhs.net, Tel: 0800 052 5790).

Thank you for reading this. If you have any questions, please ask.

INFORMATION LEAFLET: Young people

Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people

We are asking if you would like to join in a research study to help us make a new computer programme to help young people with low mood or depression. Before you decide if you want to join in, it is important to understand why the research is being done and what happens if you decide to take part. So please read this leaflet carefully. Talk to your family, friends, and teachers if you want to.

Why are we doing this research?

Even though lots of young people experience low mood or depression many do not get help. One therapy that has been good at treating depression in adults is called Behavioural Activation (BA). This is a type of therapy that aims to help people take part in more activities to help them feel better. Although BA has helped adults with depression we do not know if it can help young people. We therefore want to make a computer programme of BA to see if it can help young people with low mood or depression. This study will help us to find out what young people think should be included in the computer programme that we are making to help young people with low mood/depression.

Why have I been invited to take part?

You have been asked to take part in this study as you are a young person aged between 11 and 16 years old. As the computer programme that we are making to help young people with low mood or depression will be used with people aged between 11 and 16 we think it is very important to ask others of the same age what they think should be included in it. This will help us to make sure that our computer programme meets the needs of young people.

What will happen if I take part?

We will ask you to sign a form called a consent form to say you are happy to take part. As you are under 16, we will also ask a parent/guardian to sign a form as well. You will then be asked to come along to either a focus group or an interview.

What will happen if I take part in a focus group?

If you take part in a focus group, we will ask you to come along to a meeting with between 4 and 9 other young people aged between 11 and 16 years old. You can also bring along a parent/guardian or carer to the focus group if you would like. The researcher will ask the group some questions about what they think should be included in a computer programme for young people with low mood/depression. The focus group will last about an hour and a half. There will be a short comfort break during the focus group, but we can pause the discussion at any time if you would like a break. We will audio record the focus group and write up what has been said. We will not write

your name on anything we write. Instead, we will use a made-up name so no one will be able to see what you have said. We will then delete the recording.

What will happen if I take part in an interview?

If you take part in an interview, we will ask you to meet with the researcher who will ask you some questions about what you think should be included in a computer programme for young people with low mood/depression. You can bring along a parent/guardian or carer to the interview if you would like. The interview will last about half an hour. We can pause the interview at any time if during it you would like a break. We will audio record the interview and write up what has been said. We will not write your name on anything we write. Instead, we will use a made-up name so no one will be able to see what you have said. We will then delete the recording.

What else will I be asked to do?

Before you take part in a focus group or interview, we will ask you a few questions so we can get a little bit more information about you such as how old you are and whether you are male or female. All of your answers will be private which means no one will know what answers you gave us.

Do I have to take part?

No, it is up to you. We will ask for your consent (agreement) and then ask if you would sign a form which means you agree to take part in the study. As you are under 16, we will also ask your parent or guardian to do this. You are free to stop taking part at any time without giving a reason. If you choose to drop out of the study, we will ask you if you mind us using any information you have given us already. If you would not like us to use any information that you have given us that is fine, we will not use it and will destroy it. If you take part in a focus group, drop out from the study, and do not want us to use any information you have given us, we will only use the responses of others in the group for our research and nothing that you have said.

What are the possible risks and benefits of taking part?

We do not think there are any risks of taking part in this research. The aim of the focus group/interview is to ask you and other young people what a computer programme to help young people with depression/low mood should look like. We will not ask you any private questions or anything which might upset you but if you did get upset, we would ask you if you wanted support with this or wanted to talk to someone such as a wellbeing worker, a Child and Adolescent Mental Health Services (CAMHS) practitioner or a qualified member of the research team. There would always be someone for you to talk to immediately if you did get upset.

Although the study may not help you it will help us to design a useful programme to help other young people in the future.

Is the study private?

Any information you give us will be kept private. We will not use your name in anything that we write about the research. Once we have all of the results they will be published in a medical magazine. If you tell us that you would like to know what we find in the

research, you will be given a summary by the same person who gave you this form – someone either at school or within CAMHS.

Who is organising and paying for the research?

This research is being conducted as part of the completion of a PhD and has been organised by The Department of Health Sciences at the University of York. It has been paid for by a special research grant.

Who has reviewed the study?

Before any research goes ahead, it has to be checked by a research ethics committee. These are people who make sure the research is safe and fair. This study has been reviewed (and approved) by the Health Sciences Research Governance Committee at the University of York. The research has also been reviewed and approved by East Midlands - Leicester South Research Ethics Committee (reference: 16/EM/0420).

Who can I contact if I want to learn more about this study?

If you have any questions about the study, you can talk to the person who gave you this form either a person in school or within CAMHS. You can also talk to this person if you are worried about the study.

Thank you for reading this. If you have any questions, please ask.

INFORMATION LEAFLET: Parents/Guardians

Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people

What is the purpose of this study?

Depression is currently the leading cause of illness and disability in young people with approximately 20% of adolescents having had at least one depressive episode by the age of 18. Despite the importance of young people experiencing depressive disorders receiving effective treatment to reduce negative symptoms and improve mood, only 35% actually seek help possibly due to factors associated with treatments (e.g. stigma, negative attitudes about help-seeking, accessibility, reluctance to engage one-to-one with a therapist, etc.). To avoid some of these barriers, young people may be treated more effectively using computerised therapies which have increased availability and accessibility, reduced stigma and can be delivered in a format attractive to many young people. One therapy that has demonstrated effectiveness in treating depression in adults is Behavioural Activation (BA) – a type of talking therapy focused on increasing activity. Although research supports its use with adults, little research has examined its use with young people. To date no computerised versions of BA have been developed to treat young people with depression. The aim of this research is therefore to collect information regarding what individuals perceive to be the important components for inclusion in a computerised BA programme designed for young people experiencing depression/low mood.

Why have I been approached?

You have been approached as the parent/guardian of a young person aged between 11 and 16. We are looking to recruit a sample of young people to take part in a focus group or an individual interview about what they think should be included in a computerised BA programme for young people with low mood or depression and what it should look like.

Does my son/daughter have to take part?

Your son/daughter is under no obligation whatsoever to take part. It is entirely voluntary. Your son/daughter is free to withdraw from the study at any time, without explanation. We will, with both your and their permission, use the information we have collected up until this point. If they would not like us to use any information that they have given us that is fine, we will not use it and will destroy it. If your son/daughter takes part in a focus group, withdraws from the study, and does not give permission for us to use any information they have provided, we will only use the responses of others in the group for our research and not anything that your son/daughter has said. If your son/daughter would like to take part, we will ask you both to complete a consent form.

What will happen if my son/daughter takes part?

We will ask your son/ daughter to complete a consent form to say they are happy to take part in the research. As your son/daughter is under the age of 16 we will ask you to

complete a consent form as well. Your child will then be invited to take part in a focus group or an individual interview to discuss what they perceive to be the important components for inclusion in a computerised BA programme designed for young people experiencing low mood/ depression.

Focus groups

If your son/daughter were to take part in a focus group, they would attend a meeting with between 4 and 9 other young people aged between 11 and 16 years old. Young people will be able to bring along a parent/guardian or carer to the focus group if they would like. Parents/guardians or carers who do attend would need to keep what has been discussed in the focus group confidential. The researcher will ask the young people as a group a variety of questions about what they think should be included in a computerised BA programme for young people with low mood/depression. Focus groups will last approximately 90 minutes and will be digitally audio recorded. There will be a short comfort break during the focus group, but the discussion can be paused at any time if a young person would like a break. The audio recordings of the focus group will be transcribed by the researcher and then erased. The researcher will use pseudonyms in all transcripts to ensure your son/daughter cannot be identified in any way. Prior to the focus group your son/daughter will be asked to complete a short questionnaire to provide a small amount of information about themselves (e.g. age, gender, experiences of depression (if any) etc.). We will not ask anyone to provide any information that would be able to identify them – all responses will remain anonymous.

Individual interviews

If your son/daughter were to take part in an individual interview they would meet with the researcher on a face-to-face basis. The young person will be able to bring along a parent/guardian or carer to the interview if they would like. Parents/guardians or carers who do attend would need to keep what has been discussed in the interview confidential. The researcher will ask your son/daughter a variety of questions about what they think should be included in a computerised BA programme for young people with low mood/depression. Individual interviews will last approximately 30 minutes and will be digitally audio recorded. The interview can be paused at any time if a young person would like a break. The audio recordings of the interview will be transcribed by the researcher and then erased. The researcher will use pseudonyms in the transcript to ensure your son/daughter cannot be identified in any way. Prior to the interview your son/daughter will be asked to complete a short questionnaire to provide a small amount of information about themselves (e.g. age, gender, experiences of depression (if any) etc.). We will not ask anyone to provide any information that would be able to identify them – all responses will remain anonymous.

What do I do if my son/daughter wants to take part?

If you are happy for your son/daughter to take part in the study, then please inform the person who gave this information to your son/daughter – either at school or within Child and Adolescent Mental Health Services (CAMHS). This person will then inform the researcher (Lucy Tindall) who will arrange to meet with yourself and your son/daughter to complete two consent forms. As your son/daughter is under the age of 16 we will ask you both to complete a consent form. Once these have been completed an interview or focus group will be arranged. Lucy will contact you to inform you of these details.

What are the possible risks and benefits of taking part?

We do not believe there are any risks of taking part in this research. The aim of the focus group and interviews is to collect information about what people believe should be included within a computerised BA programme for young people with depression and will not ask participants any personal or sensitive questions. Despite this it is possible that some participants may wish to discuss issues relating to their own experiences of depression/low mood (if any) which they may find distressing. If this were to occur, a professional (a wellbeing worker or a CAMHS practitioner) within the place where your son/daughter has attended an interview or focus group (either at school or CAMHS) will be available to talk to them and provide support. If for any reason this was not possible Professor Barry Wright (one of the academic supervisors on this study) who is very experienced in dealing with distressed young people will be informed. He will either provide support himself or be able to refer a participant to other support, as necessary.

Participation will allow your son/daughter with the opportunity to give their opinions which will inform the development of a computerised BA programme for young people with low mood/depression.

Is the study confidential?

Your son/daughter will not be named in any research or reports produced from this study. Confidentiality will be maintained throughout the study, and any information kept will be done so anonymously. All study data will be securely stored in locked filing cabinets within the University of York which only immediate members of the research team will have access to. All personal information will be destroyed 3 months after the study ends and the rest of the information from the study will be destroyed after 5 years.

Who is organising and funding the research?

This research is being conducted as part of the completion of a PhD and has been organised by The Department of Health Sciences at the University of York. It has been funded by a special research grant.

Who has reviewed the study?

Before any research goes ahead, it has to be checked by a research ethics committee to ensure the research is safe and fair. This study has been reviewed (and approved) by the Health Sciences Research Governance Committee at the University of York. The research has also been reviewed and approved by East Midlands - Leicester South Research Ethics Committee (reference: 16/EM/0420).

Who can I contact if I want to learn more about the study?

If you would like further information about the study, please contact Lucy Tindall (lead researcher) (email: lucy.tindall@york.ac.uk, Tel: 01904 294 826). If you have any queries or concerns about the research or would like to make a complaint, please contact PALS (Patient advice and liaison service), (email: pals.lypft@nhs.net, Tel: 0800 052 5790).

Thank you for reading this. If you have any questions, please ask.

CONSENT FORMS

UNIVERSITY *of York*
The Department of Health Sciences

ID:



CONSENT FORM: Health Professionals Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people

Please Initial

- I have seen and read a copy of the information leaflet (version: 2, 20.09.2016) explaining the research project
- I have had an opportunity to ask any questions that I have about the research and have been given the contact details of the researcher for if I have any questions
- I understand that taking part in this research will involve myself taking part in a focus group about what I believe may be the important elements in the inclusion of a computerised Behavioural Activation Programme
- I understand that the focus group that I take part in will be audio recorded, transcribed and then deleted but all participants will be given a pseudonym and my views will not be identifiable in any way
- I understand that before taking part in a focus group I will be asked to provide some brief information about myself (occupation, employment setting, years of service, etc.)
- I know that the research information will be kept strictly confidential. When the results are published no individual will be identified in any way
- I know this is entirely voluntary. If I do not wish to take part, I can withdraw now or at any time in the future without having to give a reason.
- I understand that if I choose to withdraw from the research, I will be asked if any information I have provided so far can be retained and used by the research team
- If I have any questions about the research, I know I can contact Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk, Tel: 01904 294 826. If I have any concerns about the study or would like to make a complaint, I know I can contact PALS (Patient advice and liaison service), (email: pals.lypft@nhs.net, Tel: 0800 052 5790).

I agree to take part in this research project

Name (Block capitals)

Signature: Date:

Consent taken by:..... Date:.....

Copy of this consent form for: Site file Participant

Thank you for your help

ID:

CONSENT FORM: Young People

**Perceptions and opinions on a computerised Behavioural Activation Programme
for the treatment of depression in young people** Please Initial

- I have seen and read a copy of the information leaflet (version 3: 04.10.2016) telling me about the research project
- I have been able to ask any questions that I have about the research and know who to contact if I have any questions
- I understand that taking part in this research will involve me taking part in an interview or focus group about what I think may be important in a computer programme for young people with depression.
- I understand that the interview or focus group will be audio recorded, written up and then deleted but the researchers will not write my name on anything in the research so no one will be able to see what I have said
- I understand that before taking part in an interview or focus group I will be asked some questions about myself including how old I am, whether I am male or female, whether I have any experience of depression, etc.)
- I know that the research information will be kept very private. When the results are published, I will not be identified in any way
- I know this is entirely voluntary. If I do not wish to take part, I can withdraw now or at any time in the future and do not have to give a reason.
- I know that if I want to drop out of the research I will be asked if I mind the researchers using any information I have already given
- If I have any questions or concerns about the research, I know I can talk to the person who told me about the research and gave me this form either in school or within Child and Adolescent Mental Health Services (CAMHS)

I agree to take part in this research project

Name of young person: (Block capitals)

Signature of young person:Date:

Consent taken by:..... Date:.....

Copy of this consent form for: Site file Participant CAMHS notes (if applicable)

Thank you for your help

CONSENT FORM: Parents/Guardians

**Perceptions and opinions on a computerised Behavioural Activation Programme
for the treatment of depression in young people**

Please initial

- I have seen and read a copy of the information leaflet (version: 2, 20.09.2016) explaining the research project
- I have had an opportunity to ask any questions that I have about the research and have been given the contact details of the researcher for if I have any questions
- I understand that taking part in this research will involve my son/daughter taking part in an interview or focus group about what they believe may be the important elements in the inclusion of a computerised Behavioural Activation Programme
- I understand that the interview/ focus group that my son/daughter takes part in will be audio recorded, transcribed and deleted but all participants will be given a pseudonym and their views will not be identifiable in any way
- I understand that before taking part in an interview/focus group my son/daughter will be asked to provide some brief information about themselves (age, gender, experiences (if any) of depression, etc.)
- I know that the research information will be kept strictly confidential. When the results are published no individual young person will be identified in any way
- I know this is entirely voluntary. If my son/daughter does not wish to take part, they can withdraw now or at any time in the future without having to give a reason.
- I understand that if my son/daughter chooses to withdraw from the research they will be asked if any information they have provided so far can be retained and used by the research team
- If I have any questions about the research I know I can contact Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk, Tel: 01904 294 826. If I have any concerns about the study or would like to make a complaint I know I can contact PALS (Patient advice and liaison service), (email: pals.lypft@nhs.net, Tel: 0800 052 5790).

I agree for my son/daughter to take part in this research project

Name of young person:(Block capitals)

Name of parent/guardian: (Block capitals)

Signature of parent/guardian:Date.....

Consent taken by:.....Date

Copy of this consent form for: Site file Parent/guardian

Thank you for your help

DEMOGRAPHIC QUESTIONNAIRES



ID:



DEMOGRAPHICS FORM: Healthcare Professionals

Date:
Location:
Participant ID

Before you take part in the focus group we would be very grateful if you could complete the questions below. All of your responses will be anonymous

What is the age range to which you belong?

18-30
 31-50
 51-70
 71+

Are you: Male
(please tick) Female

How would you describe your ethnicity? (please tick only one box)

<input type="checkbox"/> White	<input type="checkbox"/> Indian
<input type="checkbox"/> Black-African	<input type="checkbox"/> Bangladeshi
<input type="checkbox"/> Black-Caribbean	<input type="checkbox"/> Pakistani
<input type="checkbox"/> Black-Other	<input type="checkbox"/> Chinese
<input type="checkbox"/> Any other ethnic group (please specify):

What is the highest level of education that you have achieved?

- Secondary school completion
- Some college
- Trade/technical/vocational training
- Associate degree
- Bachelor's degree
- Master's degree
- Professional degree
- Doctorate degree
- Other advanced degree (please specify):

What is your profession?

.....

How many years have you been in practice?

.....

What employment setting are you based in?

.....

Approximately how many young people with depression do you see per month?

.....

How would you describe your proficiency with computer use?

- Poor
- Fair
- Good
- Very good

I would like a summary of the research findings to be sent to me.

- Yes No

Thank you for taking the time to complete this form

ID:

DEMOGRAPHICS FORM: Young People

Date:
Location:
Participant ID
Interview/ focus group

Before you take part in the focus group/interview we would like to learn a little bit more about you. We would be very grateful if you could complete the questions below. We will not ask you for your name so all of your responses will be anonymous

What is your age?

Are you: Male
(please tick) Female

How would you describe your ethnicity? (please tick only one box)

- | | |
|--|--------------------------------------|
| <input type="checkbox"/> White | <input type="checkbox"/> Indian |
| <input type="checkbox"/> Black-African | <input type="checkbox"/> Bangladeshi |
| <input type="checkbox"/> Black-Caribbean | <input type="checkbox"/> Pakistani |
| <input type="checkbox"/> Black-Other | <input type="checkbox"/> Chinese |
| <input type="checkbox"/> Any other ethnic group (please specify) | |

Have you ever experienced low mood or depression?

Yes No (please tick)

If you have experienced low mood or depression have you ever received any help?

Yes (if yes please state):
 No

I would like a summary of the research findings to be sent to me.

Yes No

Thank you for completing this form

TOPIC GUIDES

TOPIC GUIDE: Healthcare Professionals

- Awareness of any similar programmes that are currently available
- How we can make a programme attractive to young people
- Components to be included in a programme
- Target audience
- Length and number of sessions
- Location (Schools, home, GP surgeries)
- Position a programme could be placed within the current care pathway
- Supporting completion of a programme

TOPIC GUIDE: Young people

- Previous experience of accessing online help
- Program development (views and acceptability)
- Program components/activities (information, quizzes, homework)
- Suggestions for treatment-related activities/goals/organising time
- Length and number of sessions
- Presentation (Colour, interactive)
- Where best to complete a computerised programme (Schools, home, CAMHS)
- Are follow-up sessions required?
- Whether different versions are required depending on age
- Whether parental involvement is required for using the programme (parental sessions, sessions to be completed together)

INTERVIEW SCHEDULES

FOCUS GROUP/INTERVIEW SCHEDULE: Healthcare Professionals

Introduction

Interview process - (timescale, confidentiality, recording)

Overview of the research and study aims

Use of information

Re-emphasise participation is voluntary and healthcare professional can discontinue participation at anytime

[Topic] Awareness of any similar programmes that are currently available

1. Have you heard of or used behavioural activation or activity scheduling in clinical practice?
2. To what other online or other sources of help do you ever refer young people experiencing depression to?

[Topic] Components to be included in a programme

[Activity 1 – Healthcare professionals will be presented with a list of different types of activities that could be included in the programme and asked to select the things they think should be included]

3. What was missing from the list that should be in the programme?

*** COMFORT BREAK (5 minutes)***

[Topic] Target audience

4. Who do you think the proposed programme would work best with? *[prompts: age range, severity of depression]*

[Topic] Length and number of sessions

Based on your therapeutic experience:

5. How many sessions do you think the proposed programme should contain?
6. How long should sessions last?
7. How frequently should sessions be completed? *[prompts: monthly, weekly, bi-weekly]*

[Topic] Location (Schools, home, GP surgeries)

8. Should the computerised programme be available anywhere (i.e. online) or should it only be available in places like schools, doctor's surgeries etc.?

[Topic] Position: a programme could be placed within the current care pathway

9. How and where would the proposed programme fit within the current care pathway?

[Topic] Supporting completion of a programme

10. Who do you think should co-ordinate use of a computerised programme?

FOCUS GROUP/INTERVIEW SCHEDULE: Young people

Introduction

Interview process - (timescale, confidentiality, recording)

Overview of the research and study aims

Use of information

Re-emphasise participation is voluntary and young person can discontinue participation at anytime

[Topic] Previous experience of accessing online help

1. How many of you have/ have you ever accessed any online help? *[show of hands if applicable]*

For those of you who have accessed any online help:

2. Can you tell me a little about the types of help you have accessed?
3. In what ways was the online help useful?
4. Was there anything about the online help that you did not like?

For those of you who have not accessed any online help:

5. What are the reasons for why you have not accessed online help? *[prompts: accessibility, not interested, unaware it existed, etc.]*

[Topic] Program development (views and acceptability)

6. In what ways do you think young people of your age (between 11 and 16) would benefit from using a computerised programme like the one we are looking to make?

[Topic] Program components/activities

7. If you were to use a computer programme like the one we are planning to make what sorts of activities would you like to see on it? *[prompts: information? Quizzes? Homework? Rewards (i.e. certificates), handouts?]*

[Topic] Suggestions for treatment-related activities/goals/organising time

[Activity 1 – young people will be presented with a chart showing the different types of activities that could be included in the programme and asked to place stars next to the things they think should be included]

8. Was there anything that you think was missing from the list that should be in the programme?

*** COMFORT BREAK [5 minutes]***

[Topic] Length and number of sessions

9. How many sessions do you think the programme should have?
10. How long do you think each session should last?

[Topic] Presentation (Colour, interactive)

[Activity 2: Young people will be given a list showing a number of factors relating to the programme and asked to rate them in terms of importance as to what they think would be most important to make the programme attractive to them]

[Topic] Location (Schools, home, CAMHS)

11. Should the computerised programme be available anywhere (i.e. online) or should it only be available in places like schools, doctor's surgeries etc.?

[Topic] **Follow-up sessions**

12. Do you think there should be additional sessions to be completed after the programme has finished (like follow-up sessions, reminders of what you have learnt) or all sessions completed together?

[Topic] **Different versions for different ages**

13. Do you think one programme would be suitable for young people aged 11 to 16 or do you think we would need to make a number of programmes for different ages?

[Topic] **Parental involvement**

14. If you were to complete a computer programme like this would you like to have your parents involved too [*prompts: parental sessions, sessions to be completed together*]

HSRGC LETTER: CONDITIONS OF APPROVAL

UNIVERSITY *of York*

Department of
Health Sciences
c/o Department of Philosophy
Heslington
York YO10 5DD
Telephone (01904) 433253
Fax (01904) 321383
E-mail smh12@york.ac.uk

Dr Stephen Holland

www.york.ac.uk/healthsciences

8 July 2016

Miss L Tindall
University of York
Department of Health Sciences
Seebohm Rowntree Building
York
YO10 5DD

Dear Lucy

Behavioural Activation for depression in young people

Thank you for submitting the above project to the Health Sciences Research Governance Committee for approval. Your application was considered by the committee at its re-scheduled meeting on Wednesday, 6 July 2016.

The committee asked me to feedback the following points:

- Focus groups will include 12–18-year-olds, which is a wide age range. This might make it difficult to elicit interesting data (e.g., 12-year-olds may be intimidated by the presence of older adolescents). Might it be more fruitful to split the participants into narrower age bands, e.g., 12-14, 15-18?
- Related to this, the study documents are not entirely age-appropriate. For example, the Information Sheet for young people covers ages 12 to 18, but it is not written in a way that would be accessible to a 12-year-old. The committee recommends separate study documents for narrower age bands, e.g., 12-14, 15-18.
- Regarding consent, 'Any prospective participants under the age of 16 will need to provide parental consent, alongside their own consent, to be able to attend a focus group/individual interview'. This does not make reference to standard consent procedures for children, such as assent versus consent, and Gillick competence.

- Regarding the Information Sheet and Consent Form: 'Three different versions of both the information sheet and consent form will be distributed; one for healthcare professionals, one for young people, and one for the parent/guardian of any young person under the age of 16.' But the Information Sheets and Consent Forms run together the Focus Groups and Interviews (e.g., 'You will then be asked to come along to either a focus group or an interview', 'I understand that the interview/ focus group will be audio recorded ...' etc.). Separate Information Sheets and Consent Forms for interviews and focus groups, respectively, would be much better, because participation differs markedly between being interviewed and being part of a focus group.
- The committee were very concerned that participation may be upsetting, and that there may be incidental findings (such as that a young person is struggling with depression). This is addressed (e.g., A23) and the committee were reassured by the fact that the research team is so experienced. Still, a more detailed strategy, including how a distressed participant will be supported, and referral pathways for distressed participants, would enhance the submission.
- Consent Forms do not include a statement about what will happen to data collected from participants who withdraw. The committee advises that data collected up to the point of withdrawal can be retained, provided this is clearly stated on the Information Sheet and Consent Form.
- More details about audio-recording the focus groups and interviews should be included on the Information Sheet and Consent Forms (e.g., that the recordings will be transcribed then erased).
- It is a little unclear how the Information sheet gets to parents: are *all* parents contacted; or would it be better to send the Information sheet only to parents whose child has expressed an interest in participating?
- Under 'Who can I contact if I want to learn more about this study?' on the Information Sheet for young people, a specific name and contact details of who to contact if the participant is worried should be provided.
- According to the IRAS form, a young person interested in participating is to talk to the Wellbeing worker, but on the Information Sheet they are told to contact Lucy Tindall.
- The protocol states that 'Each questionnaire will be given an identifier code [so] as to maintain participant anonymity'. This is not on the IRAS form, where it is unclear how demographic data will be linked to Consent Forms and other data. Relatedly, It is unclear how participants will be contacted to receive a study summary (e.g., the demographics form does not have a place to record participants' contact details).

Although this is a lengthy list of feedback points, the committee recognise your supervisors' experience and expertise, so they are happy for you to take up these points in supervision and do not require seeing the IRAS form again. But if, in light of this feedback, you make any substantial amendments to the research, or have any questions regarding the committee's decision, then please contact me.

Yours sincerely

A handwritten signature in red ink that reads "S. Holland".

Stephen Holland

Chair: HSRGC

Cc: Dr Antonina Mikocka-Walus, Dr Dean McMillan, Prof Barry Wright

REC SUGGESTED STUDY CHANGES



Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 September 2016

Miss Lucy Tindall

The Department of Health Sciences

The University of York

York

YO10 5DD

Dear Miss Tindall,

Study title:	Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people
REC reference:	16/EM/0420
Protocol number:	N/A
IRAS project ID:	210240

Thank you for your letter of 21 September 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Rebecca Morledge, NRESCommittee.EastMidlands-LeicesterSouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

- 1) The Chair noted there was a missing word in the Young Persons PIS - 'if you take part in a focus group'.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where an NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see

"Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of insurance]		
Interview schedules or topic guides for participants [Topic Guide Health Professionals]	1	06 June 2016
Interview schedules or topic guides for participants [Topic Guide Young People]	1	06 June 2016
Interview schedules or topic guides for participants [Interview Schedule Young People (Interviews)]	1	26 July 2016
Interview schedules or topic guides for participants [Interview Schedule Health Professionals]	2	20 September 2016
Interview schedules or topic guides for participants [Interview Schedule Young People (Focus Group)]	2	20 September 2016
IRAS Application Form [IRAS_Form_07092016]		07 September 2016
IRAS Application Form XML file [IRAS_Form_07092016]		07 September 2016
IRAS Checklist XML [Checklist_21092016]		21 September 2016
Non-validated questionnaire [Demographic questionnaire Health Professionals]	1	06 June 2016
Non-validated questionnaire [Demographic questionnaire Young People]	1	06 June 2016
Other [HRA Statement of Activities]		
Other [HRA Schedule of Events]		
Other [REC response letter]		
Participant consent form [Consent Health Professionals]	2	20 September 2016
Participant consent form [Consent Young People]	2	20 September 2016
Participant consent form [Consent Parents]	2	20 September 2016
Participant information sheet (PIS) [PIS Health Professionals]	2	20 September 2016
Participant information sheet (PIS) [PIS Young People]	2	20 September 2016
Participant information sheet (PIS) [PIS Parents]	2	20 September 2016
Research protocol or project proposal [BA protocol]	1	06 June 2016
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		
Summary CV for supervisor (student research) [Supervisor CV (DMcmillan)]		
Summary CV for supervisor (student research) [Supervisor CV (AMikocka-Walus)]		
Summary CV for supervisor (student research) [Supervisor CV (BWright)]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/EM/0420

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely,



Mr John Aldridge (Chair)

Email: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Enclosures: “*After ethical review – guidance for researchers*”

Copy to: Dr Dean McMillan

Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation Trust

REC APPROVAL LETTER



Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

04 October 2016

Miss Lucy Tindall
The Department of Health Sciences
The University of York
York
YO10 5DD

Dear Miss Tindall,

Study title:	Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people
REC reference:	16/EM/0420
Protocol number:	N/A
IRAS project ID:	210240

Thank you for your letter of 04 October 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 September 2016

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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IRAS Checklist XML [Checklist_04102016]		04 October 2016
Participant information sheet (PIS) [PIS Young People]	3	04 October 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of insurance]		
Interview schedules or topic guides for participants [Topic Guide Health Professionals]	1	06 June 2016
Interview schedules or topic guides for participants [Topic Guide Young People]	1	06 June 2016
Interview schedules or topic guides for participants [Interview Schedule Young People (Interviews)]	1	26 July 2016
Interview schedules or topic guides for participants [Interview Schedule Health Professionals]	2	20 September 2016
Interview schedules or topic guides for participants [Interview Schedule Young People (Focus Group)]	2	20 September 2016
IRAS Application Form [IRAS_Form_07092016]		07 September 2016
IRAS Application Form XML file [IRAS_Form_07092016]		07 September 2016
IRAS Checklist XML [Checklist_04102016]		04 October 2016
Non-validated questionnaire [Demographic questionnaire Health Professionals]	1	06 June 2016
Non-validated questionnaire [Demographic questionnaire Young People]	1	06 June 2016
Other [HRA Statement of Activities]		
Other [HRA Schedule of Events]		
Other [REC response letter]		
Participant consent form [Consent Health Professionals]	2	20 September 2016
Participant consent form [Consent Young People]	2	20 September 2016
Participant consent form [Consent Parents]	2	20 September 2016
Participant information sheet (PIS) [PIS Health Professionals]	2	20 September 2016
Participant information sheet (PIS) [PIS Parents]	2	20 September 2016
Participant information sheet (PIS) [PIS Young People]	3	04 October 2016
Research protocol or project proposal [BA protocol]	1	06 June 2016
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		
Summary CV for supervisor (student research) [Supervisor CV (DMcmillan)]		
Summary CV for supervisor (student research) [Supervisor CV (AMikocka-Walus)]		
Summary CV for supervisor (student research) [Supervisor CV (BWright)]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/EM/0420

**Please quote this number on all
correspondence**

Yours sincerely,



Rebecca Morledge REC Manager

E-mail: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Copy to: *Dr Dean McMillan*
*Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation
Trust*

HRA APPROVAL LETTER



Health Research Authority

Miss Lucy Tindall
The Department of Health Sciences

Email: hra.approval@nhs.net

The University of York
York YO10 5DD

24 November 2016

Dear Miss Tindall,

Letter of HRA Approval

Study title:	Perceptions and opinions on a computerised Behavioural Activation Programme for the treatment of depression in young people
IRAS project ID:	210240
REC reference:	16/EM/0420
Sponsor	The University of York

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations

to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

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and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](http://www.hra.nhs.uk), and emailed to hra.amendments@nhs.net.

- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](#).

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **210240**. Please quote this on all correspondence.

Yours sincerely

Michael Higgs

Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Dean McMillan*
Dr Rachel Moser

NIHR CRN Portfolio Applications Team

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of insurance]		
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Participant consent form [Parents]	2	20 September 2016
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Participant information sheet (PIS) [Parents]	2	20 September 2016
Research protocol or project proposal	1	06 June 2016
Summary CV for Chief Investigator (CI) [L Tindall]		
Summary CV for supervisor (student research) [D McMillan]		
Summary CV for supervisor (student research) [A Mikocka-Walus]		
Summary CV for supervisor (student research) [B Wright]		

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Lucy Tindall

Email: lucy.tindall@york.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Participant Information Sheets and Consent Forms were amended to align with HRA Approval standards. Changes made were submitted after the REC favourable opinion as a non-substantial amendment.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. A Schedule of Events was completed detailing only the recruitment activities at NHS sites.

			The sponsor is not requesting, and does not require any additional
Section	HRA Assessment Criteria	Compliant with Standards	Comments
			contracts with study sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been sought.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	The East Midlands - Leicester South Research Ethics Committee gave the study a favourable ethical opinion on 26 September 2016.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments

6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments
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Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is a single site type at which recruitment of NHS service-users and staff will take place, and at which focus groups and interviews will be conducted by external researchers.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.**

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

The Chief Investigator will be responsible for research activities at the NHS site. Should the study be extended to further sites, an assessment of need for Principal Investigators or Local Collaborators will be required. No specific training will be provided.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks

that should and should not be undertaken

A Letter of Access and an enhanced DBS check should be in place for any researchers who are not employed by the Trust.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

FOCUS GROUP/INTERVIEW ACTIVITIES

ACTIVITY 1: HEALTHCARE PROFESSIONALS – Activities to be included in the programme

Below is a list of activities that could be included in the computer programme. Please place a tick next to the activities that you feel should be included

Activity	✓
Information presented in text form about depression, its causes and treatment	
Activity scheduling of activities the young person enjoys/ used to enjoy	
Problem solving by looking at what the young person is finding problematic and getting them to identify and practice strategies to resolve it	
Learning about coping skills and subsequently practicing them	
Goal setting – both identifying goals and looking at ways to achieve them	
Recording activities and moods and making links between the activity and how it has made the young person feel	
Identifying the barriers that may stop young people engaging in activities they used to engage in	
Learning relaxation techniques (such as guided imagery) to decrease stress	
Monitoring feelings of the young person at each session so they can see where improvements or increases in low mood lie throughout the programme	
Practicing new skills learned within the programme (e.g. coping skills)	
Playing games/ completing puzzles to make the programme more interesting and interactive	
Watching videos of others who have had similar experiences to see how they have overcome depression	
Completing homework tasks between sessions to allow young people to practice what they have learned and apply it to everyday life	
Completing quizzes at the end of each session to allow young people to see what they have learned	
Learning about relapse prevention to try and reduce relapses / promote remission	
Learning about effective communication to help improve mood	

In the space provided below please add any other activities that we may not have thought of that you think should be included in a computerised BA programme

ACTIVITY 1: YOUNG PEOPLE – Activities to be included in the programme

Below is a list of activities that could be included in the computer programme. Please place stars next to the activities that you think should be included

Activity scheduling

Doing activities we enjoy can make us feel good and doing activities that we do not enjoy (including doing nothing) can make us feel bad. Activity scheduling is making a list of things that you may enjoy and giving them a go.

Problem solving

Having problems can make people feel bad. Problem solving is looking at any problems you have, thinking of ways to solve the problem and giving them a go.

Reading about depression

Having some pages of text to read about:

- What depression is
- What causes depression
- How depression can be treated

Learning about coping skills

Coping skills are the things that we use to help us to make a situation better. Learning good coping skills can help us to be able to deal with stressful situations better.

Goal setting

Sometimes to help us feel better we can set ourselves goals and look at how we can achieve them to give us something to aim for

Recording activities and moods

Some activities make us feel good whilst others make us feel bad. Making lists of how activities make us feel can help us see why we might be feeling sad.

Identifying barriers

Sometimes when we feel sad, we stop doing things that we like for lots of reasons. Looking at what these reasons might be can help us start to do the things we used to enjoy again

Learning some relaxation techniques

By learning to relax we can reduce stress and help ourselves to feel better.

Monitoring how we feel

Sometimes it can help to see how our mood changes over time. Creating graphs to look at changes in mood from one week to the next can help us to see how we feel

Practicing new skills

After learning about a new skill such as a new coping strategy which may help us to feel better it is good to have a go at it and see if it works for us

Playing games/completing puzzles

Playing games and completing puzzles throughout the programme to make the programme more interesting and interactive

Watching videos of others who have had similar experiences

Watching videos of other young people who have experienced depression and how they have managed to overcome it

Completing quizzes

Doing quizzes at the end of each computer session could help to see what has been learned during the session and how much we understand

Completing homework tasks

Between computer sessions homework tasks could be set to encourage us to practice what we have learned and to apply what we have learned in our everyday lives

Relapse prevention

Looking at ways to make sure that when we start to feel better, we continue to do so and do not develop depression again


Learning how to communicate better

By learning to communicate well with others a person may be able to improve their mood and start to feel better

Are there any other activities that we have not thought about that you would think would be good for the computer programme?

ACTIVITY 2: YOUNG PEOPLE – Important elements for attractiveness

We are interested in what factors are the most important in making the computer programme attractive to young people. Below is a list of 10 things. We would like you to rate them in terms of which factor would be the most important factor to make the programme attractive to you and which would be the least. Place the number 1 next to the most important factor, 2 next to the next important and so on until every factor has been given a number between 1 and 10. For this activity you can only use each number between 1 and 10 once

1	2	3	4	5	6	7	8	9	10
Most important									Least important

Programme factors	Number (1 to 10)
The programme's colourfulness	
Level of interactivity (e.g. being able to type answers into the programme)	
The programme being available to complete anywhere	
The programme having additional follow-up sessions to do in the future	
The programme having lots of information about depression	
Gaining rewards for completing certain parts of the programme	
Having handouts that you can print off and take away with you	
The programme having games and puzzles to play and complete	
The programme containing videos to watch	
The programme having homework exercises to do	

TABLES OF EMERGENT TO FINAL THEMES

Young person (community sample) Thematic analysis: Development of final themes

Examples of Descriptive Codes	Emergent themes (1)	Emergent themes (2)	Final themes
<p>Uncertainty of where to obtain support Uncertainty of support available Previous experiences Negatives of online support Assumed help arranged by parents</p>	<p>Experience of self-help</p>	<p>Accessing self-help as an adolescent: Experiences and perceived challenges</p>	<p>Theme 1: Supporting autonomy Subthemes:</p> <ul style="list-style-type: none"> - Promoting awareness - Establishing a flexible treatment approach - Regulating the involvement of others
<p>Programme for secondary school ages Make programme suit developmental level of user Focus on ability and not age Create different presentations of the programme relative to developmental level Want information that is relevant</p>	<p>Developmental level of the programme user</p>	<p>Addressing the needs of adolescents in treatment design Subthemes:</p> <ul style="list-style-type: none"> - Selecting the correct end user - Allowing opportunities for autonomy (i. Choice, ii. Independence) - The importance of privacy, anonymity and discretion - Trust - The essential components for a successful BA programme - Access 	<p>Theme 2: Addressing treatment concern Subthemes:</p> <ul style="list-style-type: none"> - Fear of disclosure - Trust
<p>No homework – too much work to do already Choice in activities they complete Real-life experiences important Need to pitch programme at right level Optional elements throughout programme (audio, length of program, etc) Want flexibility</p>	<p>Essential elements required for a successful Behavioural Activation programme Subthemes:</p> <ul style="list-style-type: none"> - Activities - Logistics - Access - Trust - Privacy/anonymity 		<p>Theme 3: Adolescent appropriate treatment Subthemes:</p> <ul style="list-style-type: none"> - Contextually and developmentally appropriate - Incorporating appropriate content - Accessibility
<p>Want easy access Importance of trust, anonymity and privacy Need to have control over the situation</p>	<p>The involvement of parents and others</p>		<p><i>[descriptive codes moved to theme 1]</i></p>
<p>Want autonomy Limited involvement of parents unless serious problem Nomination of friend for support</p>			

Young person (service-user sample) Thematic analysis: Development of final themes

Examples of Descriptive Codes	Emergent Themes (1)	Emergent Themes (2)	Final Themes
<p>Online support never recommended Looked for help online when CAMHS line was closed Online help useful Online help can be automated and robotic</p>	<p>Experiences of online help</p>	<p>Experiences of online help</p>	<p>Constructive safe space Subthemes: Avoiding impersonal solutions Providing a safe space Promoting awareness</p>
<p>Young people don't want to talk to somebody face-to-face Concern of what others will think Easier to talk anonymously Can access things online any time and straightforward Young people focussed on technology Safe place talking through a phone/screen Want interactive activities and information to read Reading about depression may create worry No handouts – can be stressful and hard to keep track of Have session reminders Programme content suitable for all Make the programme simple Shorter attention spans when online Online therapy may not be as engaging Daunting if just left with no follow-up Make the programme available when people need it</p>	<p>Benefits of online help Programme attributes: Subthemes:</p> <ul style="list-style-type: none"> - Length - Format - Accessibility - Content - Dissemination - Presentation 	<p>Perceived benefits of online help The essential elements for a successful Behavioural Activation Programme Subthemes:</p> <ul style="list-style-type: none"> - Programme content - Programme presentation - Programme structure - Programme accessibility and dissemination - The impact of depression severity 	<p>Developmentally appropriate formatting Subthemes:</p> <ul style="list-style-type: none"> - Young person-friendly presentation - Incorporating appropriate content - Providing a positive narrative - Considerations for depression severity and progress
<p>Make different versions based on depression severity Length of programme based on depression severity If relapse repeat course if initially useful</p>	<p>Impact of depression/course of depression</p>	<p><i>[no final theme identified – descriptive codes moved to theme 3]</i></p>	<p>Accessibility Subthemes:</p> <ul style="list-style-type: none"> - Physical - Temporal <p><i>[Descriptive codes relating to development moved to theme 2]</i></p>
<p>More people would get help if no parental involvement Some young people won't talk if their parents are present Provide handouts for parents Involve parents in sessions Need to tell parents if things get serious</p>	<p>The role of parents</p>	<p>The involvement of parents</p>	<p>Regulating parental involvement Subthemes:</p>

Parent session to provide explanations			<ul style="list-style-type: none"> - Respecting relationships with parents - Parents as a source of support
<p>Advertise the programme via leaflets handed out by GPs</p> <p>Tell people about the programme through CAMHS and NHS sites</p> <p>Advertise the programme on social media</p>	Dissemination	<i>[no final theme identified]</i>	<i>[no final theme identified – descriptive codes moved to theme 1]</i>
<p>Optional as to how many sessions you do each week</p> <p>User chooses when to access programme and for how long</p> <p>Make printing optional</p> <p>Parental involvement optional</p> <p>Everyone different regarding number of sessions needed</p> <p>Personalise the programme to suit learning preferences</p> <p>Individual choice of where to complete the programme</p>	Personalisation and choice	<i>[no final theme identified – descriptive codes moved to theme 3]</i>	<i>[no final theme identified – descriptive codes moved to themes 1-4]</i>

Healthcare professional Thematic analysis: Development of final themes

Examples of Descriptive Codes	Emergent Themes	Final themes
<p>Previous experience of BA principles under a different name</p> <p>Experience of activity/mood monitoring</p> <p>Computers as conduits</p> <p>Varied approaches to using online resources</p> <p>Computerised therapy not practical for all</p>	<p>Familiarity with Behavioural Activation</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Experience - Examples - Opinions 	<p>Familiarity and experience of Behavioural Activation and online therapies</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Behavioural Activation - Online deliveries
<p>Goal setting vital</p> <p>Need regular mood monitoring</p> <p>Participation between sessions important</p> <p>Need opportunities to ask questions</p> <p>Need portability, remoteness and safety</p>	<p>Essential elements required for a successful programme</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Activities to include - Less important elements - Additional considerations 	<p>Essential elements required for a successful Behavioural Activation programme</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Goal setting - Mood/activity monitoring - Homework - Other
<p>Base programme on developmental level and not age</p> <p>Some flexibility but structure also required</p> <p>Need mixture of text and pictures</p> <p>Option of audio to be available</p> <p>Timings of sessions based upon young person</p> <p>Flexibility in session length</p>	<p>Individual differences and flexibility</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Individual differences and presentation considerations - Individual differences and delivery considerations - Target audience - Enhancing engagement 	<p>Developmental considerations and flexibility of the programme</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Programme presentation - Programme delivery
<p>Programme to treat mild/moderate low mood/depression</p> <p>Engagement affected by severity</p> <p>Programme could be used pre, during or post-treatment</p>	<p>Care pathway positioning</p>	<p>Depression severity and care pathway positioning</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Depression severity - Care pathway positioning
<p>Need to monitor risk throughout programme</p> <p>Computer to flag up if problems</p> <p>Need to inform someone of access</p> <p>Crisis numbers available on programme</p>	<p>Responsibility and care management of the programme</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - Responsibility of young people - Therapy coordination 	<p>Risk Monitoring</p>
<p>Balance between computer and therapist required</p>	<p>Systemic approach and collaborative working</p>	<p>Systemic approach and collaborative working</p>

<p>Therapeutic alliance essential Parental involvement required Importance of co-working to ensure success Flexibility of co-working</p>	<p>Subthemes:</p> <ul style="list-style-type: none"> - Collaboration with healthcare professionals - Collaboration with parents - Overall collaboration 	<p>Subthemes:</p> <ul style="list-style-type: none"> - Collaboration with healthcare professionals - Collaboration with parents - Collaboration of all
<p>Computers as conduits Computerised therapy not practical for all Can monitor risk via the computer Experience of referring young people to online resources Build risk monitoring into system</p>	<p>Computerised therapy delivery considerations</p> <p>Subthemes:</p> <ul style="list-style-type: none"> - The role of the computer in therapy delivery - Previous experience of computerised deliveries and strengths - Areas for consideration in the delivery of therapy via computers 	<p><i>[no final theme identified – descriptive codes moved to theme 1; familiarity and experience of Behavioural Activation and online therapies and theme 5; risk monitoring]</i></p>

Appendix C: Additional information relating to the non-randomised feasibility study (Chapter Five)

FEASIBILITY STUDY PROTOCOL

Computerised Behavioural Activation programme for the treatment of depression in young people: A non-randomised feasibility study

Protocol

Introduction

Background and rationale

Depression is the leading cause of illness and disability in young people globally (World Health Organization (WHO), 2013, 2014). In a large meta-analysis (Costello, Erkanli, & Angold, 2006) including 26 studies, which generated data on nearly 60,000 observations of children, the overall prevalence of depression was 2.8% for children under 13 years of age and 5.7% for those aged between 13 and 18 years. In a recent ten-year longitudinal study of health-related behaviours in nearly 17,000 young people in the UK (Patalay & Gage, 2019), 14.9% of the sample were above the threshold for depression. This was a 6% increase from 2005 (9%) to 2015 (14.9%).

It is important that young people experiencing depressive episodes are identified early and receive effective treatment to improve mood and reduce the risk of suicide, deal with the impact of their depression (i.e., on their family, social, and academic functioning) and reduce the likelihood or impact of future episodes (Birmaher & Brent, 2007). However, despite high rates of depressive disorders, few young people seek help (O'Dea, Calear, & Perry, 2015; Rickwood, Deane, Wilson, & Ciarrochi, 2005). This limited help seeking may be influenced by factors associated with treatments, including stigma (Gulliver, Griffiths, & Christensen, 2010; Rickwood et al., 2005), negative attitudes about help-seeking (Rickwood et al., 2005), accessibility (Gulliver et al., 2010), and young people's reluctance to engage one-to-one with a therapist (Rickwood, 2010). Of those who do seek help, few receive it from specialist mental health services (Richardson, Stallard, & Velleman, 2010), often because of limited clinician capacity and therapy availability (Roberts, 2013). In addition, with long waiting lists in Child and Adolescent Mental Health Services (CAMHS) over 50% of young people will wait for treatment longer than 4 months (Youngminds, 2018).

To overcome some of the barriers associated with accessing support, young people may be treated more effectively using computerised therapies. In recent years much research has focused upon Cognitive Behavioural Therapy (CBT) delivered online, with benefits of this method of delivery outlined elsewhere (e.g. March et al, 2009; Spence et al, 2006, 2008; Abeles et al, 2009, Wright et al, 2014).

An alternative therapy to CBT, which has similar effectiveness, is simpler and can be delivered by a wide variety of clinicians (Ekers et al, 2011) is Behavioural Activation (BA). This brief psychotherapeutic approach aims to treat depression by encouraging individuals to increase engagement in adaptive activities whilst decreasing engagement in activities that maintain or increase the risk of depression (Dimidjian et al, 2011). A wide variety of behavioural strategies are involved in the delivery of BA including activity scheduling and monitoring. BA has demonstrated both its effectiveness and efficacy when used to treat adults with depression and is included as an evidence-based treatment in the National Institute for Health and Care Excellence guidelines (NICE, 2009). Despite its effective use with adults, less research has been conducted to examine BA as a treatment option for young people.

In 2017, as part of this PhD project, a systematic review and meta-analysis was conducted to investigate whether BA was effective in the treatment of depression in young people aged ≤ 18 years (Tindall et al, 2017). Overall ten studies were included in the review; three RCTs (McCauley et al, 2015; Stark, 1985; Chu et al, 2016), two within-participant designs (Riley & Gaynor, 2014; Douleh, 2013) and five case studies/series (Ritschel et al, 2011; Chu et al, 2009; Wallis et al, 2012; Weersing et al, 2008; Jacob et al, 2013)). Although the studies had a number of methodological limitations there was some initial evidence that BA may be effective in reducing depression in young people with all studies reporting reductions in symptoms following BA. These reductions were reported using a range of depression measures across studies, several of which suggested that a number of participants no longer met specific diagnostic criteria for depression following therapy. In the meta-analysis of the included RCTs a statistically significant reduction in depression scores in favour of BA as measured by the Children's Depression Rating Scale-Revised (CDRS-R; Poznanski & Mokros, 1996) was found.

Given the preliminary findings suggesting that BA may be an effective treatment for young people experiencing low mood and depression but taking into consideration the barriers to treatment often evident with this age group, the present PhD project involved the development of an online BA programme: BALM (Behavioural Activation for Low Mood) for young people aged 11 to 16 who are experiencing low mood/depression. The development of BALM was based upon the findings of the systematic review and a qualitative study also completed as part of the PhD project. Within the qualitative study, interviews and focus groups were conducted with young people (both those accessing help for low mood and depression and those who were not) and CAMHS healthcare professionals to ascertain what they perceived to be the

important components of an online BA programme for young people experiencing depression. Specific focus was placed upon the components to include, delivery-related issues (e.g. setting of delivery, number/ length of sessions, time between sessions), the involvement of others (e.g. parents and healthcare professionals) and where the programme would fit within the current care pathway. Therefore, BALM is based upon previous BA models, as identified within the systematic review, adapted using the information gathered within the qualitative study. An in-depth examination of the biopsychosocial development of the user group has also been conducted, the findings of which have been carefully incorporated into BALM's content and its presentation to ensure it is developmentally appropriate.

Although research into the computerised delivery of BA in adults has started to emerge, the findings of the recent systematic review (Tindall et al, 2017) also demonstrated that no computerised versions of BA existed for young people with low mood/depression, making the development of BALM timely.

Aims and objectives

The primary aim of this non-randomised feasibility study is to 1) examine the acceptability of BALM in treating young people experiencing low mood/depression and 2) assess the feasibility of undertaking a pilot Randomised Controlled Trial (RCT) of the intervention. The study will provide key information to inform the RCT, including:

- The research methods to be employed in a pilot RCT
- Where in the care pathway BALM may be placed
- Any components of BALM for modification or removal to inform the development of future versions.

The findings of this research will allow us to refine the intervention and the research methods we employ in preparation for a pilot randomised controlled trial (RCT) of the new treatment.

Study Measures

Several outcome measures will be completed by participants throughout study participation. All measures can be found in appendix 1. Measures will be completed at baseline, on a session-by-session basis and on completion or withdrawal from the programme. Information will also be collected at fortnightly intervals during programme use to gather additional information about compliance. Completion of these follow-up measures will be optional. Each of the study measures and the time points they will be completed by participants can be seen in table 1.

Demographic information

At baseline all participants will complete a demographic questionnaire which gathers further information about themselves (e.g. age, gender, etc.) and their experience of low mood/depression (duration, treatments received). As part of this young people will also be asked whether they would like to be informed of the study findings. The demographic questionnaire is a novel form which has been specifically developed for use in the research.

Acceptability and feasibility

Evaluation Questionnaires

To assess the acceptability of the programme all users will be asked to complete a short-evaluation questionnaire at the end of each BALM session that they complete. The questionnaire comprises a mix of open and closed questions to ascertain what the young people thought of each therapy session (the time they spent on sessions, whether they completed any work outside a session, what information they found useful, what was not useful and how the session could be improved). Further satisfaction with programme content will also be collected on a session-by-session basis using a 5-star rating system. At the end of each section of information within the programme young people will be able to select how satisfied they were with the information by awarding it a star rating out of 5.

A further, longer evaluation questionnaire will be completed on completion or withdrawal of the programme. This questionnaire asks young people about how they found the BALM programme overall. Questions include the overall number of sessions they attended, what they found the most and least useful components, whether they felt anything was missing from the programme or any components needed to be removed, whether they felt the programme had had an impact on their mood and how satisfied they were with a variety of programme features including language used, length, accessibility, etc.).

The evaluation questionnaires have been specifically designed for the research with the help of a qualitative expert. All evaluation questionnaires will be completed on the online programme.

Feasibility will be measured by establishing the percentage of people who were eligible for inclusion and consented to the study, adherence to the intervention and frequency

of session attendance. The number and reasons for withdrawal will also be assessed as well as the acceptability of the programme through an examination of the evaluation questionnaire responses.

Other outcomes

The Mood and Feelings Questionnaire (MFQ; Angold & Costello, 1987)

The MFQ is a 33-item screening measure of depression which can be used with young people aged 6 to 18 years. The measure comprises descriptive statements describing how a young person has been feeling or acting in the preceding two weeks. To complete the questionnaire young people read each statement and decide whether each has applied to them using the responses 'true', 'sometimes' or 'not true'. A score of ≥ 20 indicates the presence of any depressive disorder (Daviss et al, 2006).

The MFQ has demonstrated good reliability and validity (Wood et al, 2005, Daviss et al, 2006) with a Cronbach's alpha of .95 being reported and suggesting the measure's high internal consistency. The 33-item MFQ will be used to assess eligibility for study entry.

The Short Mood and Feelings Questionnaire (SMFQ; Angold, Costello, Messer, et al. (1995)

The SMFQ is a 13-item, self-report, measure of depression derived from the longer (33-item) measure developed by Angold et al (1987). The SMFQ comprises 13-items, which are used to assess the depressive symptoms of children and adolescents (aged 8 to 18 years) and has demonstrated good internal reliability (Cronbach's alpha = 0.85) (Angold et al., 1995).

In a study by Abeles (2009), the SMFQ was used with the addition of 2 items from the 33-item MFQ (question 5: 'I thought about death and dying' and question 10: 'I thought about killing myself') which were used to monitor suicidality. This approach has been taken within this study also with all young people completing the original SMFQ with the addition of these two questions. As with the MFQ, to complete the questionnaire young people will select a response ('true', 'sometimes' or 'not true') in relation to 15 descriptive statements. Participants will complete this measure each time they enter BALM to monitor their mood throughout the programme and assess risk. Although in the 33-item MFQ young people are asked to consider the responses based on the preceding 2 weeks, in this study responses will relate to the period since last accessing the programme. According to Angold et al (1995) a score of 8 or more on the 13-item

SMFQ is considered to be clinically significant. The scoring of the SMFQ will not include the scores for the 2 additional questions.

Knowledge

All young people will answer ten questions pertaining to their knowledge of low mood and depression. This short measure has been designed by the research team to elicit how much young people know about the condition and comprises both multiple choice and true and false based questions. All correct questions will be assigned 1 point. Young people will complete the questions at baseline and then following treatment (either at the point of completion or withdrawal). This will determine whether any knowledge about low mood and depression has been gained during programme completion irrespective of whether it has helped with mood.

Follow-up questions about compliance

At the baseline visit all young people will be asked whether they would be happy to be contacted by the lead researcher at fortnightly intervals during their time using the programme to discuss their participation. These follow-up questions will focus upon the barriers and facilitators to compliance with the programme and will not seek to gather any additional personal information. All questions will be telephone-administered by the lead researcher. Completion of these questions will not be a requisite of participation in the feasibility study and can be discontinued at any time.

Table 1: An overview of the outcome measures administered during the study

Measure	Time-point completed	Delivery method
The Mood and Feelings Questionnaire	Screening	Self-completion
Demographic questionnaire	Baseline	Face-to-Face, over the telephone or returned via email
Knowledge Questions	Baseline Completion/withdrawal from treatment	Baseline: Face-to-face, over the telephone or returned via email At completion or withdrawal: Online
Short (15-item) Mood and Feelings Questionnaire (SMFQ)	Completed at the start of each session	Online
Bespoke evaluation questionnaire about programme	Short version: Completed following each session Long version completed at study completion or withdrawal	Online

Follow-up questions pertaining to compliance (optional)	Completed at fortnightly intervals post-baseline	Telephone-administered
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Methodology

Study design

This non-randomised feasibility study is essential developmental work needed to inform a pilot RCT of the clinical effectiveness of BALM. This preparatory work adopts a mixed methods approach and seeks to further our understanding of the delivery of the new intervention.

Eligibility criteria

Young people who are experiencing mild to moderate low mood or depression will be recruited.

Inclusion criteria:

- Aged between 11 and 16 years at the date of consent
- Experiencing low mood or depression symptoms as defined by a score of ≥ 20 on the MFQ
- In agreement that their primary care provider and parent/guardian can be informed of any concerns the lead researcher has about their wellbeing during participation

Exclusion criteria:

- Within the normal range on the measure of depressive symptoms (i.e. attaining a score of ≤ 19 on the MFQ)
- Experiencing severe low mood or depression symptoms (A cut-off score on the MFQ will not be applied here instead this will be ascertained by the individual referrer)
- Having a comorbid mental health diagnosis of Bipolar Disorder or Psychosis.
- Non-English speaking (due to the small scope of this study, with limited resources, we did not feel the option of providing translated versions of the BA programme and outcome measures would be feasible)
- Deemed to be actively at risk of self-harm or suicide
- Have no access to the internet and therefore no programme access

Sample size

As this is a non-randomised feasibility study, no sample size calculation has been undertaken. A sample size of 10 to 15 participants recruited through both wellbeing workers based within local schools and two CAMH services will be sufficient to meet the feasibility objectives. It is hoped that the study will provide sufficient data for a larger pilot study which will allow a power calculation in the subsequent full-scale RCT.

Recruitment

Young people will be purposively sampled to ensure those recruited represent a variety of ages, sexes and levels of depression severity. Young people might be included from a variety of positions within the care pathway including those presenting with symptoms of low mood and depression to the wellbeing worker service within schools, those currently on the waiting list and awaiting treatment in CAMHS for low mood/depression and those who have received therapy for symptoms of low mood/depression within CAMHS but have not responded to it (here BALM will be offered as an alternative to medication).

Recruitment to the study will occur via two different channels; by healthcare professionals currently working within two local CAMH Services (Humber NHS Foundation Trust and Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV)) and wellbeing workers based within local schools. Both these can be accessed by referrers through the single point of access outlined in the government Green paper about organisation of child mental health services in the UK (Department of Health and Social Care and Department for Education (2017)). Both the healthcare professionals and wellbeing workers will be informed of the study and asked to discuss it with any young people who they feel may be both eligible for study participation and interested in taking part. If a young person expresses an interest, they will be given two participant information leaflets – one for themselves and one for their parent/guardian. Different versions of the participant information leaflets are available based upon the age of the young person being considered for entry into the study. There are two information leaflets available for young people (one for those aged 11 to 13 years and one for those aged 14 to 16 years) and two versions available for parent/guardians (one for those whose son/daughter is aged 11 to 13 years and one for those whose son/daughter is aged 14 to 16 years). The healthcare professional or wellbeing worker will ensure the correct information leaflets are provided based on the young person's age.

Alongside the information leaflets all young people who express an interest in participating will be given a copy of the Mood and Feelings Questionnaire (MFQ) to complete in their own time.

After reviewing the study information, those interested in taking part in the research will be instructed by their healthcare professional or wellbeing worker to complete an expression of interest form (containing their contact details). This form, alongside the completed MFQ will be passed on to the lead researcher (LT) by the healthcare

professional or wellbeing worker. Expression of interest forms and completed MFQs can be returned directly to the researcher by email if this method is preferred. The contact details of the lead researcher are included on the information leaflets who can be contacted directly if any young people and/or their parent guardian has any specific questions.

Consent process

Following receipt of an expression of interest form and completed MFQ the lead researcher will ascertain whether a young person is eligible for study inclusion. Those attaining a score of ≥ 20 will be considered for entry to the study. Anyone obtaining a score lower than this will be informed that they do not meet the threshold for the study and will not be entered. If a young person's score is particularly high on the MFQ and the lead researcher has concerns that this may be indicative of severe depression, this will be discussed with the person who referred them to the study (e.g. the wellbeing worker in school or CAMHS clinician). The individual referrer would make a clinical decision as to whether they feel the young person can enter the study. Whether they enter the study or not, all young people will be able to access services as usual in the normal ways.

The lead researcher will then allow at least 24 hours to elapse before seeking to obtain consent for eligible young people. This will give the young person and their parent/guardian sufficient time to review the information leaflets and make an informed decision about whether they would like to take part in the research. The information leaflets will outline the aims of the research and explain what will be expected of individuals if they opt to participate in the study. Information regarding the withdrawal process and data storage will be outlined, with all participants being informed of their right to withdraw at any time. The different versions of the information leaflets ensure that the research is explained in language deemed appropriate for each participant based upon their age.

The researcher will contact the young person and their parent/guardian and, if they are still interested in participating, will arrange to meet them to discuss the research in more detail or to discuss the research over the phone. If face-to-face, this meeting will be held at the place where the individual was referred from (i.e. school or CAMHS site) or at a mutually convenient location. At this meeting, the researcher will answer any questions and reiterate what study involvement entails. Interested individuals will then be asked to complete a consent/assent form. Where necessary, consent can be

completed electronically. The consent process will differ depending on the age of the young person in question:

Participants aged 11 to 13 years

All young people aged 11 to 13 who wish to take part in the research will be required to complete an assent form with consent for them to take part in the study obtained from a parent/guardian. During the consent process the parent/guardian will be required to agree to support their son/daughter when they are using the programme, have any instances of risk reported to them and agree to seek additional help for their son/daughter if necessary.

Participants aged 14 to 16 years

All young people aged 14 to 16 will be required to sign a consent form to say they are happy to take part in the research. Although young people aged 14 to 16 will be able to consent to the study themselves, given the nature of the study it is important that they have support during their time on the programme. Therefore, in order for them to enter the study a parent/guardian will have to consent to support them during their time using the programme and agree to be notified if any instances of risk occur.

As part of the consent process, prospective participants and their parent/guardian will be asked for permission to inform their GP if they choose to enter the study.

Procedure

All young people who are eligible and have consented to the study will be asked to complete two baseline measures at their initial meeting with the lead researcher. If this meeting takes place over the phone, these measures will be distributed and returned electronically. These are a demographic questionnaire and some knowledge questions. Both measures are brief to ensure little burden is placed upon the participant with times expected to complete the measures being approximately 5 minutes. Further information about these measures is presented above. The young person will then be given access to BALM and given a unique username and password. When they first enter the programme, they will be able to change their password to ensure their access is secure. Alongside this, the young person will be given a demonstration (either in person or verbally over the phone) of how to navigate through the programme and be able to set specific preferences (e.g. background colour, audio on or off, etc.) by the lead researcher. Access to the programme will only be given to the young person (although they will be able to decide whether they invite others (e.g. parent/guardians or friends) to complete sessions with them).

At the initial meeting with the lead research, either face-to-face or completed over the phone, young people will be asked whether they would like to receive reminders from the study team about completing sessions. If they would like to receive reminders, they will be asked to specify how they would like reminders to be sent (either through email or text message) and asked to provide the relevant contact details to enable this. Young people will also be asked whether they would be happy to complete follow-up questions regarding compliance at fortnightly intervals during their time using the programme.

The online BA programme: BALM

BALM is an online BA programme for use with young people experiencing low mood/depression comprising 10 treatment sessions. The initial sessions include psychoeducation about low mood/depression and provide information about BA and the treatment rationale. These early sessions are preparatory in that they demonstrate the connections between activity and mood and encourage young people to assess their current activity levels, set goals and make plans for scheduling activities that they find themselves no longer engaging in. The later sessions are practical and encourage the young person to engage in their pre-selected activities, with support and guidance provided to maximise success. The final session comprises information about relapse prevention with an additional follow-up session available one month after programme completion to assess progress and determine the next steps (i.e. making goals for the future). All sessions are presented in a combination of written text and interactive activities with small 'homework' assignments given to maintain progress between sessions. All the programme content is based upon previous BA models, the findings of the qualitative study and an examination of the biopsychosocial development of the user group.

All sessions are designed to last between 30 and 45 minutes but may vary in length for each user depending on how much content they choose to view, the length of time it takes them to complete activities and the amount of information they enter. Young people can access the programme when they wish although they are advised to allow between 3 days and 1 week to lapse between sessions to allow activities to be completed sufficiently. This flexible approach is designed to ensure the programme is as adaptable to the needs of the user as possible. A more detailed outline of the programme sessions and their content can be seen in appendix 2 whilst an overview of the programme structure is presented in table 2.

Table 2: Overview of the BALM Programme structure

Session	Overview of content
Session 1: Introduction	Programme welcome, information about depression and the aims of BA
Session 2: Goal setting	Assessment of goals and values and information about using the environment to support BA
Session 3: Picking activities to try	Selection and planning of activities to complete
Sessions 4-8 Let's get activated	Review of activity progress and selection and planning of additional activities
Final Session (9): Relapse	Information about relapse, it's prevention and what to do if it happens
Additional Session (10): Follow-up	An overall review of progress and the planning of future goals

There are also several pieces of supplementary information presented on the homepage of BALM. This material is optional to view but provides users with additional information that they might find useful. The supplementary material includes:

- Additional areas of support including links to websites and useful telephone numbers
- Information for parents/guardians and friends about low mood and depression and how best to provide support
- Information to assist with communication and conflict resolution
- Information about problem solving

A summary of all the information presented in the programme is also available for young people to take away with them for future reference.

On completion or withdrawal from the programme, the lead research will ask participants to repeat the knowledge questions that they completed at baseline. These questions will be completed online.

When a participant completes or withdraws from the programme, the individual who referred them to the research will be informed as will their parent/guardian.

Clinician-recruitment survey

In order to gather additional information pertaining to the barriers and facilitators to recruitment to the feasibility study and the potential impact of the COVID-19 pandemic clinicians recruiting to the study will be invited to complete a short survey about their experiences of offering the research to young people. The survey will be hosted on the Qualtrics Platform and can be completed online or telephone-administered by the chief investigator (depending upon clinician preference and availability). The survey takes

approximately 10 minutes to complete and comprises a series of short open and closed questions about study recruitment. No personal information is collected as part of this. (See appendix 1 for the clinician survey).

Data analysis

As this a non-randomised feasibility study, no analyses of effectiveness will be undertaken. All information will be provided in the form of descriptive summaries.

Information will be provided relating to:

- Demographic information
 - The overall questionnaire response rates
 - The percentage of those eligible who consented to the study
 - Number and reasons for withdrawal
 - Session adherence
 - Session attendance (frequency)
- Responses on all measures completed (including baseline, session-by-session, end of treatment – either completion or withdrawal).

Ethical considerations

Risk Monitoring

Although BA is not known to have any serious adverse effects, inherent to low mood/depression is the risk that a young person may become distressed during the research or experience a worsening in their symptoms. The research has therefore been developed with measures in place in either of these situations.

Firstly, young people will only be eligible to use the programme if they are experiencing mild to moderate low mood or depression. No one who has severe depression or anyone where concerns have been raised that they may have any thoughts about self-harm or suicide will be entered into the study. In addition, young people will not be entered into the study if they are experiencing any comorbid mental health diagnoses. Although mood can change significantly in a short period of time and symptoms can worsen it is hoped that the clinicians who have referred the young people to the programme are confident that they will be able to receive online therapy and access it independently relative to the severity of their low mood/depression. If a young person scores particularly highly on the initial MFQ completed to assess their eligibility, the lead researcher will discuss this with their primary care provider. The primary care provider will then need to make a clinical decision as to whether they feel the young person should enter the research.

Within BALM information is provided to young people about what to do if they experience a worsening of their symptoms or feel they need to talk to someone. There is a help section within the programme which contains several links to external providers of support – this includes both websites with further information about low mood and depression and telephone helplines. As part of this there is the number linking them to their local CAMH service. During the demonstration of the programme on an individual's first log in they will be shown this section. Throughout the programme young people will also be reminded of what to do if they have any concerns and will be directed to this information.

As the programme is delivered online, young people can access it at any time of day, and it will not be possible to monitor the responses they enter on a 24/7 basis. The lead researcher will however ensure that user's responses on the Short Mood and Feelings Questionnaire (SMFQ) that they complete at each session log in is monitored daily. If a score on the SMFQ is regarded as particularly high and therefore indicative of a decline, or a participant responds 'true' to the questions 'I thought about killing myself' or 'I thought about death or dying' BALM has been programmed to send an automated email to the research team. The lead researcher will then contact the primary care provider and the parent/guardian of the user as soon as possible and ask them to speak to the young person about this response as a matter of urgency. On entry to the study, and as part of the consent process, all participants will be made aware of this and will give permission for the lead researcher to contact their care provider and parent/guardian if they have any concerns. If their primary care provider is not available, the young person (and their parent/guardian) will be advised to contact their GP, or in serious events present to their A&E department or call 999. This will be an essential part of the consent process and anyone not agreeing to this will be unable to enter the study. In addition, all young people entering the study will agree to access additional support if they feel they may be at risk or their mood has significantly declined.

The SMFQ will be the only information monitored regularly by the research team. This is outlined in the participant information leaflets to inform participants and their parent/guardian that other information entered in the programme will not be reviewed until the end of the research.

Data storage and quality assurance

All personal details provided to the lead researchers on the expression of interest forms will be stored safely in locked storage cabinets in locked offices at the University of

York where only members of the research team can access them. All personal identifiable information will be securely destroyed at the end of the research.

All study data will be pseudonymised using a unique identifier for each participant. The majority of study data will be completed and stored electronically. This will be stored on secure servers at the University of York, password protected and only accessible by members of the research team. Datasets will be transferred from software platforms to a restricted-access shared University drive via secure encrypted, GDPR-compliant methods. For the purposes of analysis, some of this data may be printed off and, in these instances, also stored safely in locked storage cabinets in locked offices at the University of York with access limited to members of the research team. This information will be stored separately from any participant identifiable data.

Where study data has been collected in a paper format (i.e. the demographic and knowledge questions completed at baseline) this data will be stored in locked cabinets in secure accommodation at the University of York, where only members of the research team have access. This data will be stored separately from any participant identifiable data. All research data generated from the study will be archived for 10 years as required by the National Institute for Health Research.

The University of York's data protection policy will be adhered to at all times with all personal data collected as part of the study treated in accordance with General Data Protection Regulations and the Data Protection Act (2018). Information is provided in the participant information leaflets about the safe and secure storage of their personal data. In addition, as per HRA advice, a link to further information about the requirements of GDPR is included.

Confidentiality and anonymity

Confidentiality will be maintained for all participants throughout the course of the study. Full information about the purpose and uses of participants' contributions will be given in a participant information leaflet before consenting to the study and this will be clarified during the consent process. All information collected from participants will be kept confidentially as described above (data storage and quality assurance).

To access the programme all young people will be given a username and password which is individual to them. The usernames will be based upon a participant ID number and not contain any information that could identify a participant. On first log-in to the programme each user will be asked to change their password which will ensure that

only they have access to their individual account. During completion of the programme each user will only have access to their individual data and at no point will they be asked to enter any identifiable information. Any reminders sent to users relating to the programme will be based on pre-specified preferences given to the research team at the start of the programme. No communication will provide any information about what the programme is being used for.

Any information collected throughout the study will simply be identified using a participant ID number. The descriptive analysis of the results will not include any information that would allow a participant to be identified in any way.

Study withdrawal

Participants will be free to withdraw from the study at any time, without having to give a reason, however any information provided up until the point of withdrawal will be kept, as agreed during the consent process. All participants will also be informed that withdrawal from the research will have no impact upon any treatments they are currently receiving or any future care they may receive. If a young person chooses to withdraw from the research, their primary care provider and parent/guardian will be notified.

Burdens to participants

Young people who consent to the study will be expected to spend time receiving the intervention and completing all associated outcome measures. This will be made clear to all young people during the consent process and will be clearly outlined in the participant information leaflet.

Benefits of participation

We cannot be certain that BALM will be an effective treatment. However, it is hoped that young people taking part in the research will find BALM beneficial in helping with the symptoms of their low mood/depression and provide them with techniques that they can practice in the future. In addition, during their participation all consenting young people will be closely monitored for any worsening of their symptoms or any deemed suicide risks and directed to appropriate care immediately.

As a thank you for taking part, all young people who complete all sessions of the BALM programme and the associated outcome measures will be entered into a prize draw. A £50 "Love to Shop" voucher will be awarded to the winner and a £20 "Love to Shop" voucher awarded to one runner up.

Dissemination

This protocol and the subsequent completion of the work outlined within it is part of a PhD thesis examining the use of online BA for treating young people with depression. The findings of this work will be disseminated via publication to a high impact journal (e.g. the British Journal of Psychiatry) to inform those involved in the care of young people and policy makers to assist them in implementing any changes that might be indicated by the new evidence. All included participants will be asked whether they would like to receive information about the study findings and, if so, will be sent a summary of the results.

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ALL FEASIBILITY STUDY OUTCOME MEASURES

Screening questionnaire: The Mood and Feelings Questionnaire

This form is about how you might have been feeling or acting **recently**. For each question, please check (✓) how you have been feeling or acting in the **past two weeks**

If a sentence was not true about you, check NOT TRUE.

If a sentence was only sometimes true, check SOMETIMES.

If a sentence was true about you most of the time, check TRUE.

	TRUE	SOMETIMES	NOT TRUE
1. I felt miserable or unhappy			
2. I didn't enjoy anything at all			
3. I was less hungry than usual			
4. I ate more than usual			
5. I felt so tired I just sat around and did nothing			
6. I was moving and walking more slowly than usual			
7. I was very restless			
8. I felt I was no good anymore			
9. I blamed myself for things that weren't my fault			
10. It was hard for me to make up my mind			
11. I felt grumpy and cross with my parents			
12. I felt like talking less than usual			
13. I was talking more slowly than usual			
14. I cried a lot			
15. I thought there was nothing good for me in the future			
16. I thought that life wasn't worth living			
17. I thought about death and dying			
18. I thought my family would be better off without me			
19. I thought about killing myself			
20. I didn't want to see my friends			
21. I found it hard to think properly or concentrate			
22. I thought bad things would happen to me			
23. I hated myself			
24. I felt I was a bad person			
25. I thought I looked ugly			
26. I worried about aches and pains			
27. I felt lonely			
28. I thought nobody really loved me			
29. I didn't have any fun in school			
30. I thought I could never be as good as other kids			
31. I did everything wrong			

32. I didn't sleep as well as I usually sleep			
33. I slept a lot more than usual			

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Demographics form

Before you take part in this research study, we would like to learn a little bit more about you. We would be very grateful if you could complete the questions below. We will not ask you for your name so all of your responses will be anonymous

What is your age?

Are you: Male Prefer not to say
 (please tick)
 Female

How would you describe your ethnicity? (please tick only one box)

White:		Asian/Asian British:	
<input type="checkbox"/>	English	<input type="checkbox"/>	Indian
<input type="checkbox"/>	Welsh	<input type="checkbox"/>	Pakistani
<input type="checkbox"/>	Irish	<input type="checkbox"/>	Bangladeshi
<input type="checkbox"/>	Scottish	<input type="checkbox"/>	Chinese
<input type="checkbox"/>	Northern Irish	<input type="checkbox"/>	Other (please specify)
<input type="checkbox"/>	Other (please specify)		
Mixed/Multiple Ethnic Groups:		Black / African / Caribbean / Black British:	
<input type="checkbox"/>	White and Black Caribbean	<input type="checkbox"/>	African
<input type="checkbox"/>	White and Black African	<input type="checkbox"/>	Caribbean
<input type="checkbox"/>	White and Asian	<input type="checkbox"/>	Black British
<input type="checkbox"/>	Other (please specify)	<input type="checkbox"/>	Other (please specify)
<input type="checkbox"/>		<input type="checkbox"/>	
Other Ethnic Group:			
<input type="checkbox"/>	Arab	<input type="checkbox"/>	Prefer not to say
<input type="checkbox"/>	Other (please specify)	<input type="checkbox"/>	

How long have you had low mood/depression for?

<input type="checkbox"/>	Less than 1 month
<input type="checkbox"/>	Between 1 and 6 months
<input type="checkbox"/>	Between 6 and 12 months
<input type="checkbox"/>	Over a year
<input type="checkbox"/>	Prefer not to say

Please Tick

What help have you received for your low mood/depression in the past?

<input type="checkbox"/>	None
<input type="checkbox"/>	Cognitive Behavioural Therapy (CBT)
<input type="checkbox"/>	Counselling

Please Tick

	Medication
	Family Therapy
	Other (please specify)

Are you currently receiving any help for your low mood/depression?

- (please tick) Yes (if yes please state):.....
- No

When the research has ended would you like a summary of what we find?

- (please tick) Yes
- No

Knowledge questions

We would like to ask you some questions about low mood and depression. Your answers are anonymous and will not be shown to anyone. How you answer the questions will not affect any care you will receive now or in the future.

Please complete the questions below by circling the answer that you think is right.

1. How many young people will have had low mood or depression by the time they reach 18 years old?
 - a. 1%
 - b. 5%
 - c. 20%
 - d. 50%

2. True or false – depression can affect anyone at any time?
 - a. True
 - b. False

3. Which of the following is NOT a symptom of depression?
 - a. Feeling very sad or irritable
 - b. Not having much energy
 - c. Being able to concentrate on things better
 - d. Having a very sad mood

4. True or false – it is normal to feel sad from time to time?
 - a. True
 - b. False

5. What are coping skills?
 - a. The things we do to deal with a situation
 - b. A treatment for low mood or depression

- c. A symptom of low mood or depression
 - d. When your depression goes away and comes back again
6. True or false – If you have recovered from low mood or depression it will never come back?
- a. True
 - b. False
7. Which of the following is NOT an example of avoiding a situation?
- a. Missing lessons in school
 - b. Not meeting your friends to go shopping
 - c. Talking to a parent about feeling sad
 - d. Not doing your homework
8. A relapse of low mood or depression is when....?
- a. You first start to notice you are feeling down
 - b. You start to feel better and then feel down again
 - c. You feel better after having low mood
 - d. You are too tired to get out of bed
9. True or false – relapses of low mood or depression are common (they happen to a lot of people)?
- a. True
 - b. False
10. A treatment for depression is called BA. BA stands for?
- a. Behavioural Activation
 - b. Being Active
 - c. Being Avoidant
 - d. Behavioural Action

Risk monitoring questionnaire: Short Mood and Feelings Questionnaire (15-Item)

This form is about how you might have been feeling or acting recently. For each question, please cross how much you have felt or acted this way in the past week.

If a sentence was true about you most of the time, cross TRUE.

If it was only sometimes true, cross SOMETIMES.

If it was not true about you, cross NOT TRUE.

	TRUE	SOMETIMES	NOT TRUE
1. I felt miserable or unhappy			
2. I didn't enjoy anything at all			
3. I felt so tired I just sat around and did nothing			
4. I was very restless			
5. I thought about death and dying			
6. I felt I was no good any more			
7. I cried a lot			

8. I found it hard to think properly or concentrate			
9. I hated myself			
10. I thought about killing myself			
11. I was a bad person			
12. I felt lonely			
13. I thought nobody loved me			
14. I thought I could never be as good as other kids			
15. I did everything wrong			

Short evaluation questionnaire (sessions 1-9)

What session did you do today?

<input type="checkbox"/>	Session 1
<input type="checkbox"/>	Session 2
<input type="checkbox"/>	Session 3
<input type="checkbox"/>	Session 4
<input type="checkbox"/>	Session 5
<input type="checkbox"/>	Session 6
<input type="checkbox"/>	Session 7
<input type="checkbox"/>	Session 8
<input type="checkbox"/>	Session 9 (relapse prevention)

Please Tick

1. How long did you spend roughly on the session?

<input type="checkbox"/>	Less than 10 minutes
<input type="checkbox"/>	10 to 20 minutes
<input type="checkbox"/>	20 to 30 minutes
<input type="checkbox"/>	30 to 40 minutes
<input type="checkbox"/>	40 to 50 minutes
<input type="checkbox"/>	50 to 60 minutes
<input type="checkbox"/>	Over an hour

Please Tick

2. Did you do any work outside of the programme before the session?

<this will only be relevant for session 2 onwards>

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Please Tick

If Yes – what work did you do?

<input type="checkbox"/>	Completed an activity diary
<input type="checkbox"/>	Picked some goals to work towards
<input type="checkbox"/>	Looked online for some activities you might like to do
<input type="checkbox"/>	Took part in 1 activity
<input type="checkbox"/>	Took part in 2 activities
<input type="checkbox"/>	Took part in 3 activities
<input type="checkbox"/>	Took part in more than 3 activities
<input type="checkbox"/>	Other (Please specify):

Please tick all that apply

3. Did you look at any of the extra information in today's session?

<input type="checkbox"/>	Yes	Please Tick
<input type="checkbox"/>	No	

If Yes – what did you look at?

Additional Information	
<input type="checkbox"/>	More help
<input type="checkbox"/>	Information for parents/guardians
<input type="checkbox"/>	Information for friends
<input type="checkbox"/>	Communication and conflict resolution
<input type="checkbox"/>	Problem solving

Please Tick

4. How useful did you find today's session overall? Please rate the session with a number from 1 to 10 (with 1 being not useful at all and 10 being very useful).

5. Did you print off any of the information you looked at in today's session?

<input type="checkbox"/>	Yes	Please Tick
<input type="checkbox"/>	No	

If Yes – what did you print?

Session 1	
<input type="checkbox"/>	Welcome and introduction
<input type="checkbox"/>	Low mood and depression: The facts
<input type="checkbox"/>	Introducing BALM
Session 2	
<input type="checkbox"/>	Recap of session 1: The goals of BALM
<input type="checkbox"/>	Values and goals
<input type="checkbox"/>	Making changes to our environment
Session 3	
<input type="checkbox"/>	Recap of session 2
<input type="checkbox"/>	Picking activities to try
<input type="checkbox"/>	Tips for picking activities
Sessions 4-8	
<input type="checkbox"/>	Activity review
<input type="checkbox"/>	Next steps
Relapse	
<input type="checkbox"/>	Information about relapse
<input type="checkbox"/>	Next steps and introduction to follow-up
Follow-up session	
<input type="checkbox"/>	Progress review: Looking to see if your low mood symptoms have changed
<input type="checkbox"/>	Progress review: Looking to see if your mood scores have changed
<input type="checkbox"/>	Progress review: Looking to see if your activity diaries have changed
<input type="checkbox"/>	Programme recap
<input type="checkbox"/>	Next steps and the future
Additional Information	

Please tick all that apply

	More help
	Information for parents/guardians
	Information for friends
	Communication and conflict resolution
	Problem solving

6. Can you think of any ways we could make today's session better?

7. Any other comments?

Long evaluation questionnaire (treatment completion or withdrawal)

1. How many sessions did you do in total?

	1
	2
	3
	4
	5
	6
	7
	8
	9
	10
	More than 10

Please Tick

2. What session did you find the most useful?

	Session 1: Introduction
	Session 2: BA Preparation
	Session 3: Activity Scheduling
	Sessions 4 to 8: Let's Get Active
	Session 9: Relapse Prevention
	Session 10: Follow-Up

Please Tick

3. Why did you find this session the most useful?

4. What session did you find the least useful?

	Session 1: Introduction
	Session 2: BA Preparation
	Session 3: Activity Scheduling
	Sessions 4 to 8: Let's Get Active
	Session 9: Relapse Prevention
	Session 10: Follow-Up

Please Tick

5. Why did you find this session the least useful?

6. Would you recommend the programme to a friend if they had low mood or depression?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No
<input type="checkbox"/>	Don't know

Please Tick

Please say why

7. Did you feel there was anything missing from BALM?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Please Tick

If yes, please say what you thought was missing

8. Did you feel there is anything that is not needed in the programme and could be taken out?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Please Tick

If yes, please say what you thought should be taken out and why

9. Did you include anyone else in completing any of the sessions? (e.g. parent/guardians, friends, teachers)

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Please Tick

If yes, who did you include?

10. Did you feel that BALM made a difference with your low mood?

<input type="checkbox"/>	I felt it made my mood a lot better
<input type="checkbox"/>	I felt it made my mood a little better
<input type="checkbox"/>	I did not notice a change in my mood
<input type="checkbox"/>	I felt it made my mood a little worse
<input type="checkbox"/>	I felt it made my mood a lot worse

Please Tick

11. What do you think about the length of the BALM programme?

<input type="checkbox"/>	I felt it was too long
<input type="checkbox"/>	I felt it was too short
<input type="checkbox"/>	I felt it was just the right length

Please Tick

If you felt the programme was too long or too short, how many sessions do you think the programme should have been overall?

.....sessions

12. Was there anything from the BALM programme that you think you would use again?

	Yes
	No

Please Tick

If yes, what would you use again?

13. We are interested to know how satisfied you were with a number of parts of the BALM programme. In the table below please tell us how satisfied you were with each of the things listed

	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
How the programme looked					
The different ways information on the programme was presented					
How easy it was to use the programme					
The amount of information in the programme					
The amount of work to do on the programme					
The programme being able to help you with your low mood or depression					
The wording used in the programme					

14. We have called the programme BALM but can you think of a better name?

15. Any other comments?

Participant follow-up call questions (optional)

1. Are you managing to work through the programme?

[If yes go to question 2/ if no, go to question 4]

If Yes

2. How are you finding it?

3. Are you managing to access it as much as you would like?

(If yes move to question 8/ If no move to question 4)

If No

4. What are the reasons for not accessing the programme? Are there any specific barriers? (e.g. lack of time, lack of motivation, disinterested, etc.)
5. Do you have regular access to the programme – e.g. access to a computer/internet at all times or is this restricted?
6. Are you planning to complete the sessions?
7. Is there anything we could change to make it more likely that you would access the programme?

Questions to all

8. Have you recently returned to school/college?
9. Do you feel this has had an impact on accessing the computerised programme?
[If yes – how?]
10. Do you feel that COVID has impacted upon your use of the programme? If so how?
[If yes – how?]
11. Do you have any other comments or any feedback you would like to give us?

HEALTHCARE PROFESSIONAL SURVEY

Computerised Behavioural Activation programme for the treatment of depression in young people: A non-randomised feasibility study: Clinician survey

Introduction

As part of our feasibility work examining a new computerised Behavioural Activation programme for the treatment of depression in young people, we are keen to gather some information about the barriers and facilitators of recruiting young people to research of this type. We are therefore contacting clinicians based within our recruiting services and asking them to complete a short survey about this. We are hoping that this information will allow us to gain a better understanding of how our research study has been received within your service, enabling us to make changes to the current study and future work in this area. **You do not need to have discussed our research with young people to take part.**

We are contacting you because we believe you may be in a position to help us gather information for this purpose. If you do not feel you are the right person, please feel free to forward this invite to a more appropriate colleague(s).

Below is a link to a questionnaire which should take no more than 10 minutes to complete. All personal data will be handled in accordance with the principles of the Data Protection Act 2018 and the General Data Protection Regulations (GDPR) (for more information please see: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance>). All questionnaire responses will remain confidential and you will not be named in any reports we produce as part of this study. Data will be stored electronically on secure servers at the University of York, password protected and only accessible by members of the research team.

If you have any questions or require any further information, please feel free to contact Lucy Tindall (l.tindall@nhs.net).

In clicking the link below to access the questionnaire you confirm that you are willing to take part in the research and for your data to be stored as described above.

The questionnaire can also be completed over the phone and therefore, if you would like to take part but would prefer a telephone call to discuss this please contact Lucy Tindall(l.tindall@nhs.net)

Many thanks for your help with this project.

QUESTIONNAIRE LINK:

https://york.qualtrics.com/jfe/form/SV_6F3CQhjo7EQtJBP

Survey questions

1. General clinician/service information

(a) Name/type of service:

(b) Clinician role:

(c) Years in service:

(d) Approximately how many young people with low mood/depression do you see per month?

(e) How did you hear about the study we are conducting?

- I attended a meeting where the researcher was present and talked about the study
- Other clinicians within my service told me about the study
- A young person within my service enquired about the study
- Other *[please specify]*

(f) On a scale of 0 to 10 where 0 is 'not at all' and 10 is 'extremely well' to what extent do you feel that you understand the aims of the current study?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Not at all Extremely well

2. Recruitment to the feasibility study

(a) On a scale of 0 to 10 where 0 is 'not at all' and 10 is 'extremely well' to what extent do you feel that you understand the study's eligibility criteria?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Not at all Extremely well

(b) On a scale of 0 to 10 where 0 is 'not at all' and 10 is 'extremely well' to what extent do you feel that you understand the study's recruitment process (i.e. what to do if you feel a young person is eligible, the information to provide young people with, etc.?)

0	1	2	3	4	5	6	7	8	9	10	
Not at all								Extremely well			

(c) Have you discussed the feasibility study we are conducting with any of the young people within your service?

Yes *[Go to question 2d]*

No *[Go to question 2m]*

If yes:

(d) Approximately how many young people have you discussed the study with?

(e) Approximately how many of these have you then passed study information to?

(f) How many of these young people have gone on to participate in the study?

(g) Do you feel that you have had sufficient time to be able to dedicate to talking to young people about the study?

Yes

No

(h) Where in your service have the young people with whom you have discussed the study been identified?

Via the single point of access (young people new to service)

Current patients in my care

Current patients on a waiting list to receive therapy

Young people due to be discharged from the service

Other *[Please specify]*

[Please tick all that apply]

(i) Where young people have taken part in the study what do you think were the main factors that influenced their decision?

They have been motivated to receive additional support for their low mood/depression

They wanted to receive therapy in a computerised format as opposed to face-to-face with a clinician

They were interested in learning about an alternative type of therapy

They felt that participation would please a parent

They felt that participation would please a clinician

Other *[please specify]*

[Please tick all that apply]

(j) What do you feel are the main barriers for young people taking part?

Lack of interest

- Lack of motivation
- The young people have not been eligible
- Lack of time
- Alternative pressures (e.g. school/college work)
- Other *[Please specify]*

[Please tick all that apply]

(k) Thinking about compliance, what do you feel are the factors that influence whether young people will log on to the programme and complete sessions?

- They are motivated to get help with their low mood/depression
- They are keen to learn about an alternative type of therapy
- They want to please a parent
- They want to please a clinician
- Other *[please specify]*

[Please tick all that apply]

(l) What do you feel are the main barriers to compliance?

- Lack of interest
- Lack of therapist presence
- Lack of motivation
- Lack of time
- Concerns about additional 'screen time'
- Alternative pressures (e.g. school/college work)
- Other *[Please specify]*

[Please tick all that apply]

If No:

(m) What are the reasons for not discussing the research with young people?

- I did not feel I had enough information to offer it to young people
- I have not deemed the young people I have seen to be suitable
- I have not had the time to discuss the study with young people
- I do not support the study/ see it as relevant
- Other *[Please specify]*

[Please tick all that apply]

3. The impact of COVID-19

COVID-19 and the BA study

(a) On a scale of 0 to 10 where 0 is 'not at all' and 10 is 'extremely' to what extent do you feel that the COVID-19 pandemic has impacted upon you recruiting young people to the study?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Not at all
Extremely

Please explain your response

(b) On a scale of 0 to 10 where 0 is 'not at all' and 10 is 'extremely' to what extent do you feel that the COVID-19 pandemic will have impacted upon compliance by young people to the study?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Not at all Extremely

Please explain your response:

COVID-19 and own service delivery

(a) Due to COVID-19 do you feel that referrals to your service have:

- Decreased
- Stayed the same
- Increased

(b) Due to COVID-19 do you feel that compliance with treatment in your service has:

- Decreased
- Stayed the same
- Increased

(c) Due to COVID-19 do you feel that instances of 'did not attend' in your service have

- Decreased
- Stayed the same
- Increased

(d) Due to COVID-19 do you feel that contacting young people has:

- Been easier
- Remained unchanged
- Been more difficult

4. Increasing recruitment and compliance

(a) Do you feel that your service is well placed as a recruitment site for this study or do you feel it should be positioned elsewhere in the care pathway?

Well placed in my service

Well placed in my service but recruitment could be expanded elsewhere *[please specify]*

Better placed elsewhere *[please specify]*

(b) Can you suggest any ways in which we could look to increase recruitment to the study?

(c) Can you suggest any ways in which we could look to increase compliance with the study?

5. Additional feedback and future contact

(a) Are there any other comments you would like to make?

(b) Would you be happy for us to contact you again to discuss any of the issues covered in this survey if we were to examine them in more detail?

Yes *[please supply contact information]*

No

BALM PROGRAMME OUTLINE

Computerised BA programme 'BALM' structure and content

PRE-PROGRAMME

Using BALM during the Coronavirus outbreak

The BALM programme is based upon a type of therapy called Behavioural Activation. This type of therapy aims to try and help you start doing activities that you used to enjoy before you had low mood/depression. Since the BALM programme was written there have been lots of changes around us that have meant that, for now, we cannot do some of the activities that we used to enjoy. We have therefore updated BALM to be useful also in situations where social distancing has become necessary to stay safe. Different activities will apply in different situations. Therefore, you might have to use the programme a little bit differently from what you might have done a few weeks or months ago.

In the programme, you will be asked to plan and do some activities. It is very important that the activities you pick keep yourself and others safe and also follow any rules that have been put in place. Therefore, you might have to change a few activities to make them suitable. For example, instead of arranging to meet with your friends in person you could meet them online or call them on the phone. Instead of playing a sport with friends you could find exercises to do at home with other people in your house or on your own. It helps to do things that make you feel more fulfilled or relaxed or part of a group.

Even if these activities are a little different from what you are used to doing, they can still help you to improve your mood.

Staying safe is the most important thing.

Programme tools

Glossary – All words in bold can be clicked on and the definition appear. There will also be a link to a dictionary here in case the glossary does not cover a term a young person does not understand

Forward and back buttons – allows users to skip non-relevant material or return to sections where necessary

Save button – gives users the flexibility to complete sessions at times more convenient

Mood monitoring area – At each session users will be asked to complete the short mood and feelings questionnaire (used to suggest risk also). There will be a link where users will be able to monitor their mood throughout their time on the programme

Settings – ability to change colour, font size, etc

Audio button – ability to have the content read aloud

Help – Two-fold – help with completing the programme and also additional help with Low mood/depression – e.g. useful numbers. Throughout the course of the programme young people may have specific questions that the programme will not answer. There will be a section on the programme where young people will be able to enter questions which will be linked to a specific email address set up for the study team. Here the study team can respond to the young person. If the study team are unable to answer the questions, they will be able to consult a relevant professional on behalf of the young person and respond. The young people will be made aware that this is not a 24/7 service and that there may be a delay in them receiving a response. However, the study team will ensure that this email inbox is checked daily.

Notifications -at the start of the programme the young person will be able to decide whether they wish to receive automated notifications about session attendance. They will be able to decide how they receive the notifications (i.e. by supplying an email address or telephone number so they can receive texts). This will be optional

Tabs: Tabs will be visible on the homepage to take young people to supplementary information. Each of these tabs will be referred to throughout the text where necessary

SESSION STRUCTURE

SESSION 1 – INTRODUCTION

SESSION 1 OUTLINE

- Welcome and introduction
- Completion of mood measure 1
- Low mood and Depression: The facts
- Introducing BALM
- Goals before the next session (Homework) – activity log and enjoyment ratings
- Session 1 evaluation

SESSION 2: GOAL SETTING

SESSION 2 OUTLINE

- Introduction to session 2 and 'Goals before the next session' review
- Completion of mood measure 2
- Recap of session 1: The goals of Behavioural Activation
- Values and goals
- Making changes to our environment
- 'Goals before the next session - continuation of goals and values assessment
- Session 2 evaluation

SESSION 3: PICKING ACTIVITIES TO TRY

SESSION 3 OUTLINE

- Introduction to session 3 and 'Goals before the next session' review
- Completion of mood measure 3
- Recap of session 2
- Picking activities to try
- 'Goals before the next session'
- Session 3 evaluation

SESSIONS 4-8: LETS GET ACTIVE

SESSION OUTLINE(S)

- Introduction to sessions (4-8)
- Completion of mood measures (4-8)

- Activity review
- Next steps
- Goals before the next session
- Session (4-8) evaluation

FINAL SESSION: RELAPSE

SESSION OUTLINE

- Introduction to session
- Completion of mood measure
- Relapse
- Next steps and introduction to follow-up session
- Session evaluation

FOLLOW-UP

SESSION OUTLINE

- Introduction to session
- Completion of mood measure
- Progress review
- Programme recap
- Next steps and the future
- Completion of final evaluation

SUPPLEMENTARY MATERIALS

Supplementary 1: More help

Supplementary 2: Information for parents/guardians and friends

Supplementary 3: Communication and Conflict resolution

Supplementary 4: Problem Solving

Supplementary 5: Programme recap

SESSION 1: INTRODUCTION

SESSION 1 OUTLINE

- Welcome and introduction
- Completion of mood measure 1
- Low mood and Depression: The facts
- Introducing BALM
- Goals before the next session
- Session 1 evaluation

WELCOME AND INTRODUCTION

Hello <name>! Welcome to BALM. You will have been told about BALM as you have been feeling down. Everybody feels sad at times but for some people this can be really bad and make lots of parts of life very hard. This is sometimes called **depression**. When people have **depression** or feel very low, they can stop doing things that they enjoy. This can make them feel even worse. BALM aims to try and make people feel better and to start doing activities that they used to like doing. When you have felt very down, feeling better again can take a bit of time. Working through this programme may take a few weeks or even a few months but by the end of it we hope you will feel much better.

When we feel low there are lots of things that we can do ourselves to make us feel better. BALM will show you some of the things you can do. Sometimes you might not feel like doing what the BALM programme has asked. That is OK but the more you can do the better you might feel. Sometimes even when you are doing the programme you

still might feel very low. If this happens it is important that you tell someone. There are always people you can talk to. If you need some extra help click on the button called 'More help' [[supplementary 1](#)].

MOOD MEASURE

At each session we will ask you some questions about how you are feeling. Every time you do this you will be able to see how your mood has changed between sessions. If your mood goes very low, it is important that you talk to somebody about this. Let's start by filling in the first set of questions about how you have been feeling lately. It is really important you fill this in honestly. You can see your mood graph [here](#).

Before we start looking at ways we can make ourselves feel better let's look a little bit at what low mood and **depression** is.

LOW MOOD AND DEPRESSION: THE FACTS

What is low mood and depression?

Everybody feels sad at times and this might be for lots of reasons – you might fall out with a friend or do badly on a test in school. Feeling sad is a normal part of life and it affects everybody. However, some people might feel sad a lot or all of the time even if nice things are happening around them. If this is really bad this is sometimes called **depression**. It does not matter who you are, how old you are, where you are from...**depression** can affect anybody. **Depression** can happen at any time.

How do I know if I have got low mood or depression?

Feeling low or having **depression** can affect people in lots of different ways – not everyone will feel the same but some of the things people might notice are:

- Having a very sad mood
- Not being interested in or enjoying activities
- Feeling very tired
- Not taking part in activities as much
- Not being able to concentrate or pay attention as much
- Not having much energy
- Having less **self-esteem** and/or **self-confidence**
- Feeling guilty or **worthless**
- Feeling negative about the future
- Hurting yourself or thinking about it
- Thinking about suicide
- Having problems with sleeping (sleeping too much or not enough)
- Having problems with eating (eating too much or not enough)
- Feeling very sad or irritable
- Missing school a lot or not doing very well in your schoolwork
- Drinking alcohol or taking drugs
- Feeling angry or unfriendly
- Taking part in dangerous behaviours or activities

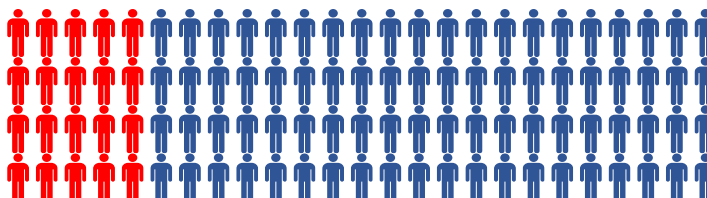
ACTIVITY (1): From this list can you tick all of the things that you have noticed when you feel low? Are there any things that you feel or do that are missing? Please write these down in the space below the list.

Am I the only one feeling down?

No! Everybody feels low from time to time and this is very normal. You can feel sad for lots of reasons – you might have watched a sad film, fallen out with a parent, or missed going for a walk because you are ill. Sometimes there may not even be a clear reason why you feel sad – you might just be having a bad day! But for some people feeling

low might not go away even when things are going well. This can make lots of things very hard.

It is hard to know how many young people have, or will have, low mood or **depression**, but we know that it is very **common**. As many as 20% of young people will have had **depression** at least once by the time they are 18 years old. That is 1 out of every 5 people or 20 people out of 100. To see this better look at the picture below which shows 100 people. We have coloured in 20% of the group in red.



Lots of young people do not tell anyone that they are feeling low. Therefore, it can sometimes feel like you are the only one with low mood or **depression** when there will be lots of people around you feeling the same.

INTRODUCING BALM

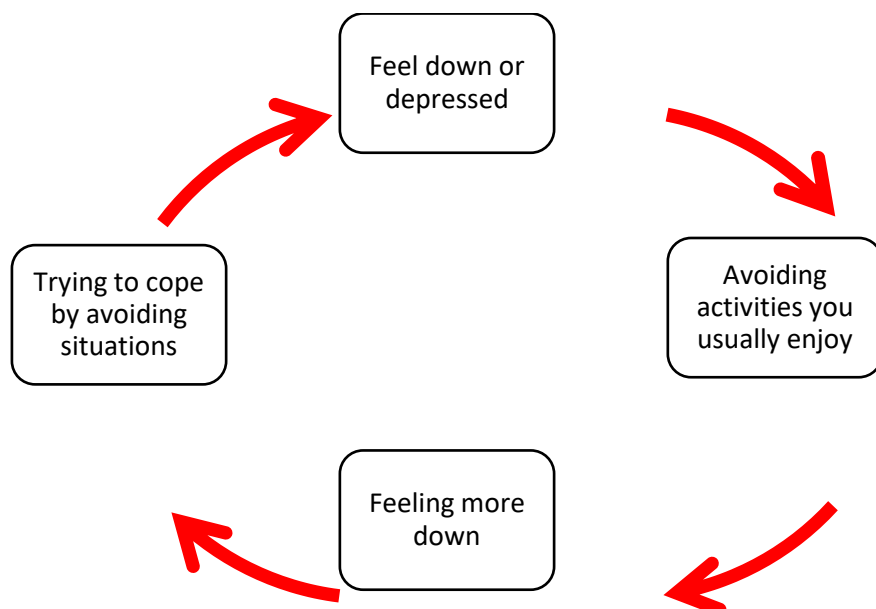
Now that we have learned what low mood and **depression** is and can spot the signs of it, we can look at how we might make ourselves feel better. There are different types of treatments for people with low mood and **depression**. Some of these might include talking to a person like a doctor or counsellor. Some treatments involve us making some small changes in our lives like doing activities that might make us feel better. BALM is based on a type of therapy called **Behavioural Activation** which is a type of treatment like this.

So, what is Behavioural Activation?

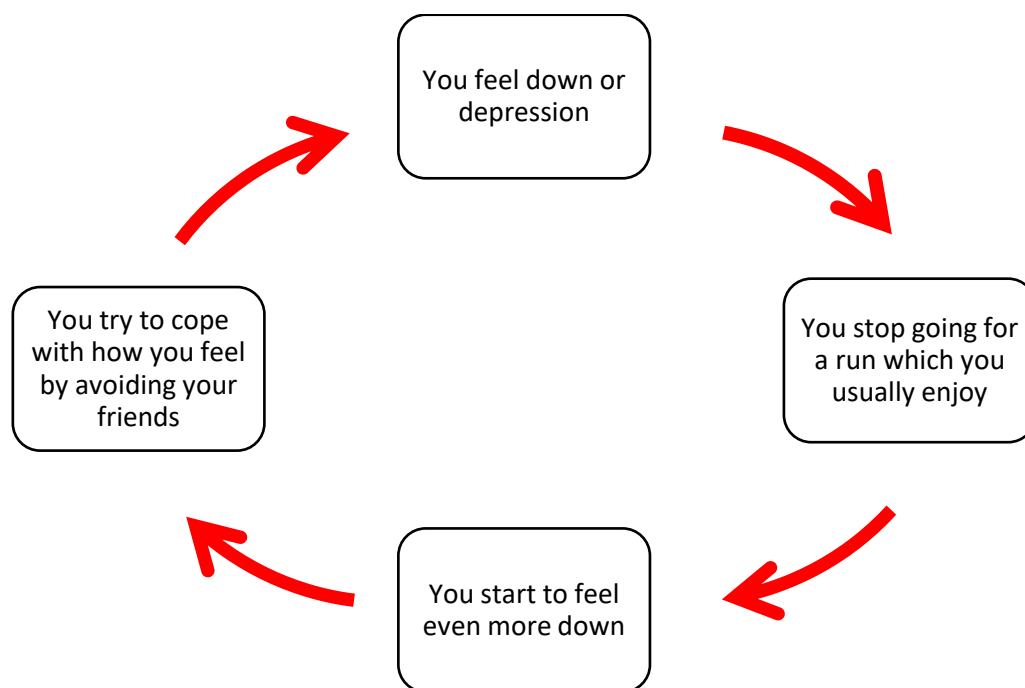
Behavioural Activation is a type of treatment which tries to make you feel better by making some changes to your behaviour and the environment around you. When people feel down two things can happen:

1. **People can stop doing things that they used to enjoy.** This might be anything from playing a favourite sport to listening to some music.
2. **People can start avoiding situations.** This could be things like not catching up with your friends or not exercising each day.

By not doing activities that you enjoy and avoiding situations you can make yourself feel worse and get into what we call a **vicious cycle**. Unless you break this **vicious cycle**, it is very hard to make yourself feel better. You can see how the **vicious cycle** of depression works below.

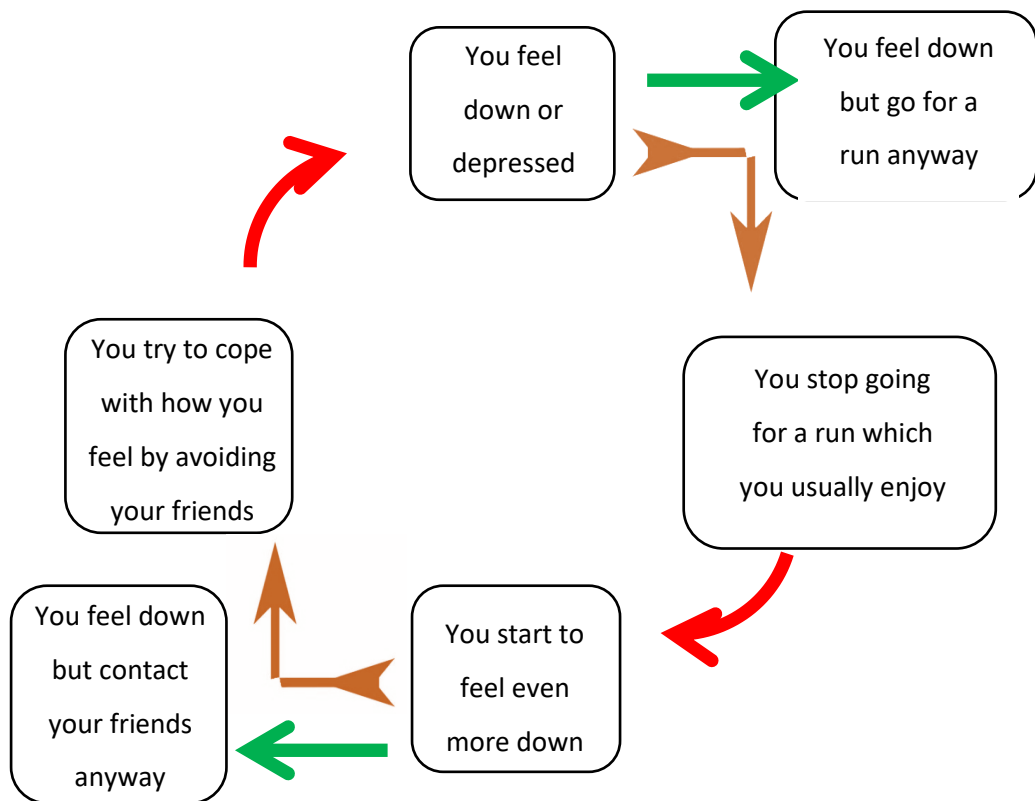


Let's look at this using an example:

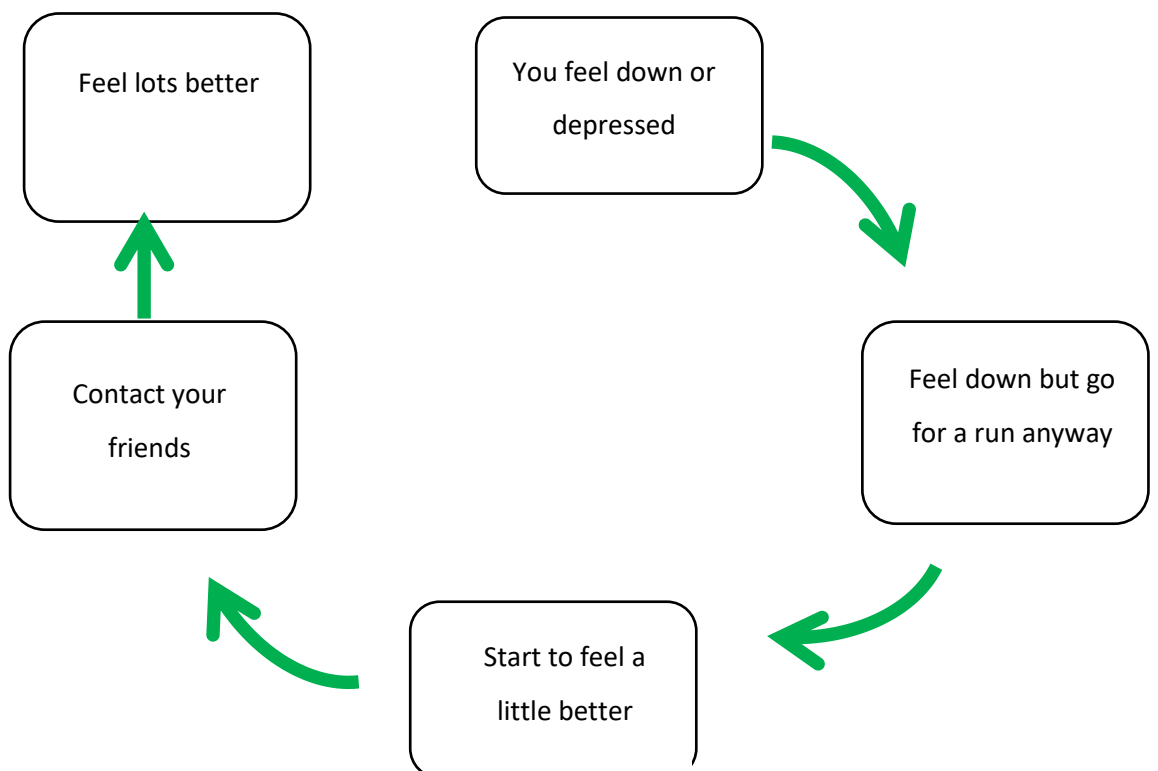


You can see in the example how stopping doing the things you enjoy can make you feel worse. You might really enjoy going for a run but, because you feel down you have stopped doing it. This makes you feel worse. Because you then feel worse you start avoiding other situations like contacting your friends. In the **short-term** you might feel better because you don't have to talk to your friends when you are feeling down. However, in the **long-term** you might find that you stop being invited to go running or to contact your friends because people feel that you don't want to talk to them. This can then make you feel even worse – you might get more depressed and become even more lonely. This will make it even less likely that you will go running or contact your friends.

Behavioural Activation can help you to break this cycle in two ways. It can help you to start doing activities that you used to enjoy and help you to stop avoiding situations and find different ways to deal with them.



Through BALM you will hopefully be able to break the depression cycle by changing some of your behaviours. Like in the picture, BALM will help you to try and keep doing activities you enjoy even if you are feeling down. It will also help you to not avoid situations. Through doing this you will hopefully start to feel much better.



Even though you might feel that you can change your behaviour on your own it is really useful to get help from the people around you like your friends and family. So, BALM will also help you to use the environment around you and the people in it to support you in feeling better.

Therefore, there are 3 goals of BALM. These are to:

1. Help you to start doing activities you enjoy
2. Help you to stop avoiding activities
3. Help you to use the environment around you and the people in it to help you to feel better

How will BALM work?

As we have seen, sometimes when you feel low you can find yourself in a **vicious cycle**. You stop doing things to make yourself feel better but in the **long-term** you can make yourself feel worse. BALM helps to break down this **vicious cycle**. Instead of stopping doing things when you are feeling down, it will help you to plan and do activities that might make you feel better.

BALM is not about trying to find out why you feel down (that is something you might never get to the bottom of!). It is about understanding what you do when you feel down and making changes to help you to feel better. BALM will help you to look at the things you are doing (or not doing) when you feel down and help you to start doing some activities that might make you feel better. If you start doing activities that are important to you and that you enjoy you will hopefully start to feel better.

A lot of BALM is about you picking activities that you enjoy, planning how you might do them and then doing them. There is also other information in the programme that we think you might find useful. How you use BALM is up to you - you can pick how much of the information you look at. The first few sessions are about finding out a bit more about the things you do now. BALM then moves on to you doing some activities that you have picked. At the end of each session you will be given something to do or think about called 'Goals before the next session'. These activities will help you to get ready for the next session and are really useful.

Will BALM work?

This type of treatment has been around for a long time and has been tested with people with low mood or **depression**. A lot of this testing has been done with adults and it has been good at treating their low mood and **depression**. Less testing has been done with young people, but we think it can work. Everybody is different and what works for one person might not work for somebody else. Therefore, even though we hope that BALM will help you to feel better, we cannot be sure that it will.

What do I need to do?

BALM is about doing activities that you might have stopped doing because you feel down. Sometimes you might not want to take part in the programme or do the things that it is asking you to do. This is normal. However, the more you do on the programme the more likely it will be to work and hopefully make you feel better. The important thing is to give things a go even if you are feeling low. Do not put off an activity until you are feeling better or happier. Sometimes you might find the programme hard to do but that is not a problem – you can try again another time. Everything in BALM will be picked by you so you will never be asked to do something you do not want to. When you use BALM and how long you spend on it is also up to you. You might want to use it every few days or maybe once a week – that is your choice.

GOALS BEFORE THE NEXT SESSION (1)

In today's session we have looked at what low mood and **depression** is and how it can make you feel and behave. We have also looked at how doing things that you enjoy might make you feel better. Before we start planning some activities to do, we need to see what you are already doing. We would like you to fill in a diary of the activities you do in a normal week. We want to know about all activities even if you don't think they are important like sleeping or watching TV. It does not matter how many activities you do or when you do them. Try and fill this in as correctly as you can because it will really help the next session. How many days you would like to write your activities down for is up to you. Try and record activities for 3 days if you can. If you can record a full week that would be great.

We want to see how much you enjoy the things you do. Therefore, next to each activity you put in the diary give it a number between 0 and 10 where 0 is not enjoyable at all and 10 is really enjoyable. Tell us also how you feel each day. Give your mood a score from 0 to 10 where 0 is that you are feeling really low/negative and 10 is you are feeling really happy/positive. You do not have to record your mood all day just at the end of each day.

This will not be shown to anyone else. The first part of the diary has been filled in with an example of how to do this. You might like to fill in the diary as you go through the day or fill it in on an evening before you go to bed – this is your choice. You can fill in the diary on the computer or, if it is easier you can print it off and fill it in by hand – just remember to bring this to the next session. If you do fill it in by hand it would be great if you could copy it onto the diary on the computer before the next session.

EVALUATION FORM

We would like to know how you have found today's session so it would be great if you could answer a few questions. This will only take a couple of minutes but will really help us to make BALM better.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to look at some of the other information in the programme. You will find this on the homepage. If you have any questions or comments about BALM or today's session, please email us at balm-study@york.ac.uk. We will try and get back to you as soon as possible. See you next time!

Related supplementary information:

- Information for parents/guardians and friends
- More support

SESSION 2: GOAL SETTING

SESSION 2 OUTLINE

- Introduction to session 2 and 'Goals before the next session' review
- Completion of mood measure 2
- Recap of session 1: The goals of BALM
- Values and goals
- Making changes to our environment
- 'Goals before the next session'
- Session 2 evaluation

INTRODUCTION TO SESSION 2 AND GOALS BEFORE THE NEXT SESSION REVIEW

Welcome to session 2 of BALM. We hope you have had a good week. Did you fill in the diary?

Yes – That's great! We will be using this later in today's session. If you have filled the diary in by hand it would be great if you could now copy this onto the computer.

No - Do not worry if you could not do this. It is important that the diary is filled in for this session so if you could fill it in now that would be great. Do not worry if you cannot remember everything you did last week, and the exact times just try to fill in as much as you can. If it is easier just fill in a diary for yesterday and today

MOOD MEASURE

Before we start, we would like to see how you have been feeling since the last session so would like you to answer a few questions. This helps us to see if your mood has changed. It is important that you answer the questions honestly and, if you are feeling very low, that you talk to somebody about this. You can see your mood graph [here](#).

RECAP OF SESSION 1: THE GOALS OF BALM

In the last session we looked at the three goals of BALM. These were to:

1. Help you to start doing activities you enjoy
2. Help you to stop avoiding activities
3. Help you to use the environment around you and the people in it to help you to feel better

Today we are going to look more closely at these goals and how you can give yourself the best chance of BALM working. We will:

1. Look at the things that are most important to you to help you choose some activities to do
2. Set goals of what you would like to aim for when using BALM
3. Look at ways to help you not avoid activities
4. Look at how you can involve other people to make you feel better.

GOAL 1: HELPING YOU TO DO ACTIVITIES THAT YOU ENJOY
--

VALUES AND GOALS

In the next session you are going to plan some activities that you would like to do. By making some changes to your behaviour and the activities that you do, you can make changes to your mood as well. There are two things that you need to do here – figure out what things are important to you and make some goals of how you will achieve the things you would like.

What is important to me?

Let's start by looking at what things in your life are important to you. To give you the best chance of BALM helping it is vital that the activities you choose in the next session are ones that are important to you. If you pick things that you do not think are important you are not going to do them. There are different parts of our lives that are important to us like:

Relationships: The part of your life that includes others. These might be your friends, your family, a boyfriend or girlfriend, even a pet

Education: Everything about your school life – it might also be your ambitions for the future

Hobbies and interests: All of the things that you like to do in your spare time like hobbies that you enjoy, groups/teams that you are part of or any volunteering that you do

Health: Everything to do with both your physical and mental health

Low mood and **depression** can affect different parts of life. Therefore, when you pick your activities in the next session it is important to pick ones that involve different parts of your life also. Have a think about each of the areas listed and the things in each that are important to you.

What goals would I like to set myself?

When we have low mood or **depression**, we can stop doing things that we enjoy and avoid situations. This is because we decide what to do based on how we feel. This is called **mood-directed behaviour**. We saw an example of this in session 1 when we talked about **vicious cycles**. For example, you might feel down and decide to avoid your friends. In the **short-term** you feel better because you don't have to talk to them when you are feeling down. But, in the **long-term** your friends might stop contacting you because they don't feel that you want to talk to them. This can make you feel even worse – you may become lonely and even more depressed.

When people feel down, they sometimes want to wait until they feel better to take part in activities. This is a bad idea. Instead, you should take part in activities that might make you feel better. To do this we can set some goals to work towards and focus on these instead of how we feel. This is called **goal-directed behaviour**. In the example from before, in **goal-directed behaviour** you might feel down and not want to talk to your friends but set yourself the goal of contacting them anyway. You enjoy talking to them and feel a bit better.

We can set both **short-term** and **long-term** goals. A **long-term goal** might be to go to university. To do this you might set yourself some smaller (or **short-term**) goals like spending extra time on your homework or spending time each week reading about things you find really hard.

ACTIVITY (2): On the sheet called 'values' write down some **short-term** and some **long-term** goals that you would like to aim for in the boxes. Try to write down at least 1 **long-term** goal and 2 or 3 **short-term** goals for each life area listed. It might be that you think of more than this and that is great. One form has been filled in to help you {see example form 2}.

Now that you know what is important to you and set yourself some goals let's move on to look at the second goal of BALM:

GOAL 2: HELPING YOU TO STOP AVOIDING ACTIVITIES

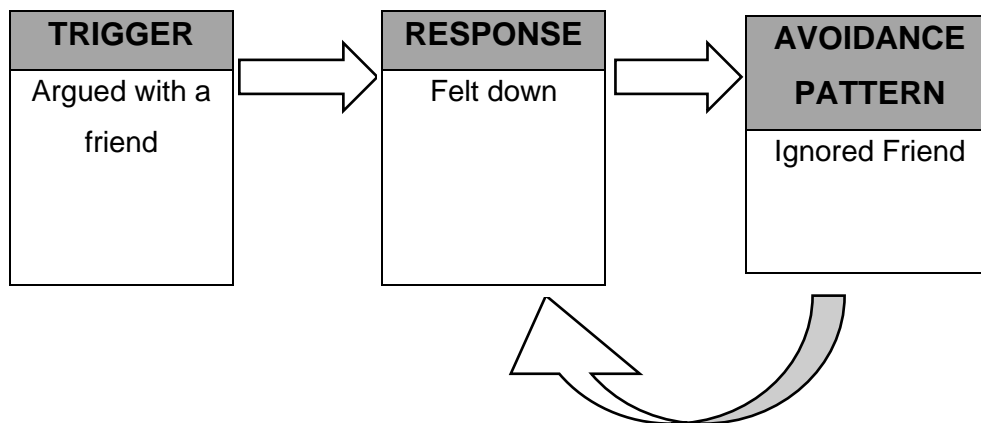
For BALM to help it is important to take part in activities that might help you to reach your goals and feel better. Before doing this, you need to look at how the activities you take part in can affect your mood but also how your mood can affect your activities. This will help you to make some changes to make reaching your goals a bit easier.

The different ways we deal with things are called **coping skills**. Sometimes **coping skills** can be positive like relaxing or talking to someone about how we feel. But when we have low mood or **depression** the **coping skills** that we use can be negative and can make us feel worse – not better! Examples of negative **coping skills** are thinking over and over about upsetting things (**ruminating**) or doing dangerous things. All of these involve us avoiding the situation. Sometimes we might think that if we avoid a situation, we will feel better. This might be true in the **short-term** but not in the **long-term**.

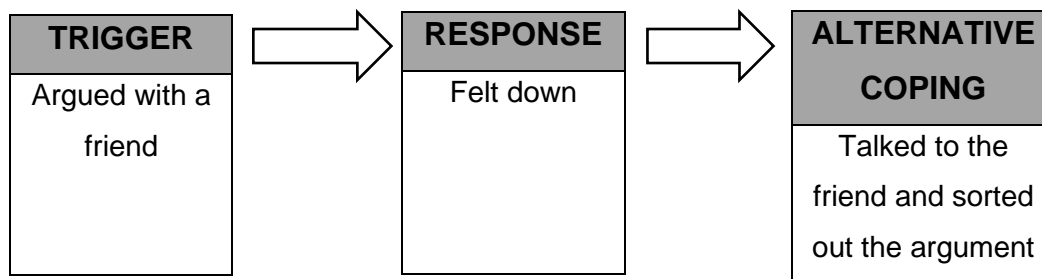
How can we break the cycle?

One way to break this cycle is to use the **TRAP vs TRAC** model. In this model each of the letters of **TRAP** and **TRAC** stand for something. This is called an **acronym** and is the same as when you use PTO to mean please turn over or call the United States of America the USA.

TRAP stands for **T**rigger (the situation we are in), **R**esponse (how the situation makes us feel), **A**voidance **P**attern (how we deal with the situation by avoiding it) and is a good way of looking at the **vicious cycle**. Let's look at the example of falling out with a friend:



Like in the example – by avoiding the friend after the argument you become more down. To break the cycle, we need to turn **TRAP** into **TRAC** which stands for **T**rigger (the situation we are in), **R**esponse (how the situation makes us feel), **A**lternative **C**oping (Finding a different way to deal with the situation). Lets now look at the example if we turn **TRAP** into **TRAC**:



Here, instead of avoiding your friend a different way of dealing with the situation (talking to the friend) has been chosen. Unlike with **TRAP**, this does not make you feel worse instead it helps you sort out what made you feel down in the first place.

ACTIVITY (3): Think of something that has made you feel down or unhappy – this might be something that has happened recently or something from a while ago. What did you do? How did you feel? Now using, **TRAP vs TRAC** think about how you could

do things differently to make the result better. Fill in the boxes (**TRAP** to **TRAC**) to show how you would change what you would do.

<p>GOAL 3: HELPING YOU TO USE THE ENVIRONMENT AROUND YOU AND THE PEOPLE IN IT TO HELP YOU FEEL BETTER</p>
--

MAKING CHANGES TO OUR ENVIRONMENT

The third goal of BALM is to help you use the environment around you and the people in it to help you to feel better.

Getting help from others

Even if you feel like you can make changes to your behaviour it will be much easier if you have help. It can help to talk to other people, like family and friends about the way you are feeling and tell them about the programme. You might ask a parent to sit with you when you do a session or talk to them about what you are doing on BALM. You might also find it useful to ask someone to help you with activities – this might be helping you to plan when to do them or suggesting some activities that you can do. If you can, asking someone to do an activity with you might make it more fun. But if you would prefer not to include anyone that is fine.

Sometimes it is hard to tell people when you are feeling low and ask for their help. You can find some information on the homepage that you might find useful and might help you to talk to others. [\[supplementary 2\]](#) [\[supplementary 3\]](#). In the section called 'information for parents and friends' there is some information that can be printed off. This explains what depression is and gives some information about how BALM works. You might find it easier to give this information to your parent/guardian(s) or friend(s) if you are finding it hard to talk to them.

GOALS BEFORE THE NEXT SESSION

During this session we have looked at the things that are important to you and picked some **short-term** and **long-term** goals to work towards. Before the next session, think about the activities that might help you to reach your goals. For example, one of your **short-term** goals might have been to contact your friend more often. Activities that you might do to help with this could be arranging to talk to them on the phone, arranging to meet them on Skype or zoom. Put any activities that you think of in the column called 'activities I might do' on the sheet called 'values'. We will be using this in the next session, so it would be great if you are able to do it. You might find it useful to spend some time before the next session looking on the internet for some ideas of activities that you might like to do.

EVALUATION FORM

We want to know how you have found today's session, so it would be great if you could answer a few questions. This will only take a couple of minutes but will really help us to make BALM better.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to look at some of the extra information in the programme. You will find this on the homepage. If you have any questions or comments about BALM or today's session, please email us at balm-study@york.ac.uk. We will try and get back to you as soon as possible. See you next time!

Related supplementary information:

Information for parents/guardians and friends
Communication and Conflict resolution
More support

SESSION 3: PICKING ACTIVITIES TO TRY

SESSION 3 OUTLINE

- Introduction to session 3 and 'Goals before the next session' review
- Completion of mood measure 3
- Recap of session 2
- Picking activities to try
- 'Goals before the next session'
- Session 3 evaluation

INTRODUCTION TO SESSION 3 AND GOALS BEFORE THE NEXT SESSION REVIEW

Hello <name> and welcome back to BALM. We hope you have been well since last logging in. Did you fill in the values table?

Yes – That's great! We will be using this later in today's session. If you have filled the form in by hand it would be great if you could now copy this onto the computer.

No - Do not worry if you could not do this. It is important that the table is filled in for this session so if you could fill it in now that would be great.

MOOD MEASURE

Before we start, we would like to see how you have been feeling since the last session so would like you to answer a few questions. This helps us to see if your mood has changed. It is important that you answer the questions honestly and, if you are feeling very low, that you talk to somebody about this. You can see your mood graph [here](#).

RECAP OF SESSION 2

In the last session we looked at the goals of BALM and how you can give yourself the best chance of it helping you by:

- Looking at the things in your life that are most important to you
- Making goals to aim for through BALM
- Looking at how you might stop avoiding situations
- Looking at how you might involve other people in BALM to make it easier.

PICKING ACTIVITIES TO TRY

It is now time to start planning some activities that you are going to do. This is called **activity scheduling**. To do this you will pick some activities to do, choose when you will do them and decide how much time you will spend doing each one. You will pick some easy activities to start with and see how you get on. When you feel happy that you have been able to do the activities you have picked you will move on to some that are a bit harder. It is important that you do the activities at your own pace and only move onto new activities when you feel happy to.

Picking activities

We would like you to choose 12 activities that you are going to try and do over the next few weeks or months. This might sound a lot but remember we are not going to do them all at once! Look at the activities you wrote down in the values table. If you have 12 on there, you might pick these to do. If not have another think about some activities you could do – you could look on the internet for some ideas to help or come up with some more of your own.

You might choose to do some activities more than once but change how hard it is to do. For example, you might set yourself the goal of going for a walk for 30 minutes and

then, when you are happy that you can do this, choose walking for an hour. It might also be that you choose to break some activities down to make them easier. For example, if you choose to cook a meal for your family, your first activity might be to decide what you would like to cook and find a recipe. You might then make a list of all of the ingredients you need. By doing this, the activity of cooking a meal might be easier because you will have done it in stages

Tips to help with picking activities

Pick activities that will help you to reach your goals: In the last session you looked at what things were important to you and set some goals. Pick activities that will help you to reach these goals.

Pick activities that are SIMPLE and that you can do: Make sure you pick activities that you think you will be able to do – do not put pressure on yourself to do something that is really hard. It is also important that the activities you pick are ones that you can easily do. If you pick things that you are not able to do very easily you are setting yourself up to fail. Make sure the times you choose to do an activity are suitable as well.

Pick activities that are ENJOYABLE: Pick activities that you will enjoy. If you pick things that you do not enjoy, you will not want to do them again and could make yourself feel even worse.

Pick activities that are SAFE: It is really important that the activities you pick could not harm you or someone else

Pick activities that are ABOUT YOU: This is about helping you to feel better. All activities must be for you to do and not about doing something that you think someone else might enjoy

Involve others (if you are happy to): Even though BALM is about helping you to feel better, getting help from other people might make it easier to do some activities. If you have people around you that you are happy to talk to about how you are feeling (like family or friends) talk to them about the activities you are doing (Don't forget there is some information on the homepage that you can always give to a parent/guardian or a friend if you are finding it hard to talk to them: [Supplementary 2](#))

Break activities down: Sometimes it will be easier to break an activity down into smaller chunks. For example – you might choose reading a book as an activity that you would like to do. This does not mean that you have to read the whole book at once. You might start off by setting yourself the goal of reading a few pages and then, when you have done that, try to read a chapter.

Give yourself time for things to work: It takes time to feel better when you have been feeling down so don't worry if you do not notice a difference straight away.

Don't be upset if you cannot do an activity: Sometimes you might find that you cannot do an activity you have planned. This could be for lots of reasons –something might come up; you could feel unwell or just do not feel like you can face it. This is normal. Try and pick another time to try with the activity or, if you are finding the activity too hard, change it for something easier or break it down.

Try not to plan too much at once: It is important that you do not try and plan to do too much at once. This could make you feel worse.

The Coronavirus Outbreak

If you are doing the BALM programme during the coronavirus outbreak only plan activities that you are allowed to do. It is very important to keep yourself and others safe and to follow any rules that have been put in place.

ACTIVITY (4): Selecting 12 activities

Choosing the order of activities

Now you have picked the activities you want to do, put them in order of how hard they are. **ACTIVITY (5):** Look at your list and pick what you think is the easiest. Next to this put a 1. Now look for the next hardest and put a 2. Keep going until you have given all of the activities a number. You might find it easier to pick the easiest activity and the hardest activity first and then place the rest in between. When you have finished you will have what is called an **activity hierarchy**.

Planning activities

ACTIVITY (6): Now plan when you are going to give each activity a go. After session 1 you filled in a diary about all of the things you did each day. Use the same diary to plan when you are going to take part in the activities you have picked. On the diary sheet write in the first 3 activities you have picked. Make sure that the times you have picked to do the activities are suitable and that you have given yourself enough time to do them. You also need to make sure that the activity is planned at times when you are free and not going to disturb other things that you have to do. Put all 3 activities in the diary at least once. You might like to do an activity more than once but do not give yourself too much to do.

GOALS BEFORE THE NEXT SESSION

Before the next session try to do the first 3 activities that you have picked. When you have done an activity put a tick next to it in the diary. We would like to see how much you enjoyed each of the activities you did. Therefore, next to each one put a number between 0 and 10 where 0 is not enjoyable at all and 10 is really enjoyable.

If you cannot do an activity that is not a problem. If this happens put a cross next to the activity in the diary. If you can, try and pick another day or time to have another go. Try and remember why you could not do the activity – maybe you ran out of time, something came up or you just did not feel like doing it.

EVALUATION FORM

We would like to know how you have found today's session, so it would be great if you could answer a few questions. This will only take a couple of minutes but will really help us to make BALM better.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to look at some of the extra information in the programme. You will find this on the homepage. If you have any questions or comments about BALM or today's session, please email us at balm-study@york.ac.uk . We will try and get back to you as soon as possible. See you next time!

Related supplementary information:

Information for parents/guardians and friends
Problem Solving

SESSIONS 4-8: LETS GET ACTIVE

SESSION OUTLINE(S)

- Introduction to sessions (4-8)
- Completion of mood measures (4-8)
- Activity review
- Next steps
- Goals before the next session
- Session (4-8) evaluation

INTRODUCTION TO SESSION

Hello <name> and welcome back to BALM. We hope you have been well since last logging in.

Session Introduction (1: when session 4)

In the first few sessions we looked at what low mood and **depression** is and how doing activities can make us feel better. You then picked some activities to try to help you reach your goals and planned when you would do them. The next few sessions are more practical and involve you looking at the activities you have been doing, seeing how you have found them and planning more activities. This might be moving onto some harder activities or having another go at some if you have not been able to do them. By the end of the next few sessions you will hopefully have been able to do all 12 of the activities that you picked in the last session.

We would like you to try and do 3 activities between each session, but this is only a guide. You might do more than this or less than this – it does not matter which as BALM is for you to do at your own pace. Therefore, how many 'let's get active' sessions you do is up to you.

In today's session we will see how you are getting on with your activities and decide if it is time to plan some new ones or have another go at the same ones again. If you have printed off the diary and written down your activities, please copy it onto the computer – don't forget to include your enjoyment ratings!

Session Introduction 2 (when session 5-8)

In today's session we will look at how you are getting on with your activities and decide if it is time to plan some new ones or have another go at the same ones again. You might have now done all 12 of the activities that you planned. If so, we will talk a little about the next session. If you have printed off the diary and written down your activities, please copy it onto the computer – don't forget to include your enjoyment ratings!

MOOD MEASURES (4-8)

Before we start, we would like to see how you have been feeling since the last session so would like you to answer a few questions. This helps us to see if your mood has changed. It is important that you answer the questions honestly and, if you are feeling very low, that you talk to somebody about this. You can see your mood graph [here](#).

ACTIVITY REVIEW

In the last session you picked 3 activities that you wanted to try and do and picked times when you would do them. We want to know how you got on!

How many of your 3 activities did you do?

0 1 2 3

Did you do any of the activities more than once?

<Go to 'goals before the next session '(B))

IF THE ACTIVITIES WERE NOT COMPLETED SUCCESSFULLY

Do not worry that you could not do the activities you had planned. It can be really hard to do things when you are feeling low. It might take time to start doing things that you enjoy again. The important thing is that you try and have a go – the more you try the more likely you will be to do the activities you have planned. The important thing is to see why you could not do the activities you had planned. That way you can make some changes that might help you next time and you can try again. Let's look at some reasons why you might not have been able to do the activities you picked:

Reasons for not completing an activity: *(on the programme users will just see boxes with the headings and will only reveal the text if they click on them)*

I felt too low to have a go

As we saw in session 1 when we feel down, we can stop doing things that we enjoy and avoid situations. Sometimes we might feel that by avoiding a situation we can make ourselves feel better. This might be true in the **short-term** but not in the **long-term**. We saw this in the diagram of the **vicious cycle** in session 1. It is important that you try and break this cycle even when it feels really hard to do. Doing activities might make you feel better and so it is important that you try even when you feel down – do not wait to feel better.

The activity was not enjoyable

It is important that the activities you choose are things that you enjoy – if they are not you will not want to do them. If this happened, choose some other activities that you think you will enjoy.

The activity was too hard

Maybe you have found an activity too hard. If this happened, there are some things you can do. Firstly, look at the other activities you have put in the **activity hierarchy**. You might have put some easier activities further up the **activity hierarchy** and started with some harder ones. If this has happened, move the activities around and start with the easier activities first.

If you found an activity too hard to do it might be that it can be broken down into a few, easier parts. Look back at the 'tips for planning activities' section in session 3 for more information.

Maybe you need to find some new activities that are easier - that is not a problem. Delete any activities you have found too hard from the **activity hierarchy** and pick some easier ones. You might come back to these later.

There was not enough time to do the activity

Maybe you did not have enough time to do an activity. It is important to find time to fit them in. Look at your diary and see if there are some better times when you can do them. You might have planned to do an activity during the week and then had lots of things to do. Is there more time on a weekend?

I changed my mind about wanting to do the activity I had chosen

You might have changed your mind about the activities you have picked. If this happens delete these from the **activity hierarchy** and pick some other activities that you would like to do. Make sure these are as hard as the ones you had planned and will help you to work towards your goals. Remember to check the 'tips on planning activities' section to make sure the new activities are suitable.

I need extra support

As we saw in session 2 sometimes having help from others makes doing activities easier. An activity you are finding hard might be easier if you could talk to someone about it or ask someone to help you to plan it. If this is true is there someone you could talk to? Could a friend or parent/guardian help? Try asking someone you trust and are happy talking to for help.

Other

There might have been another reason why you could not do an activity that is not listed here. You may find extra information on the programme that could help. Look at the information called 'Problem Solving' ([supplementary 4](#)) You can find this information on the homepage.

(If we have not listed the reason why you could not do an activity here and have not been able to offer any help we would like to know. Let us know when you answer the questions at the end of the session)

Picking the next activities to do

Now we have looked at why you might not have been able to do an activity, we can pick what activities to do next. Let's look back at your **activity hierarchy** <to have original hierarchy displayed and options to edit>.

If you are happy to have another go at the activities you picked last time, plan when you will do them using the diary. If you have changed these, edit the **activity hierarchy** and put the new activities and when you will do them into the diary. Remember to plan any activities at suitable times and do not disturb other things you need to do. Like before when you have done an activity put a tick next to it in the diary and give each activity you do a score of how much you enjoyed it (0 is not enjoyable at all and 10 is really enjoyable). If you cannot do an activity that is not a problem. If this happens put a cross next to the activity in the diary. Try and pick another day or time to have another go. Also try to remember why you could not do the activity – maybe you ran out of time, something came up or you just did not feel like doing it. Remember to check the 'tips for planning activities' section from last session and make sure the activities you have chosen are suitable.

<Go to 'goals before the next session '(A)>

GOALS BEFORE THE NEXT SESSION

(A) (completing more activities)

Now you have picked your next 3 activities and planned when you will do them try and do these before the next session. If you find yourself feeling very low, it is important that you talk to someone and ask for more help. There is information including useful links and phone numbers in the section called 'more help' [[supplementary 1](#)].

(B) (completed all 12 activities)

You have now done all 12 activities– well done! We really hope that you are starting to feel better. Feeling better after low mood or depression can take time and it is really important that you carry on doing activities like you have been doing when using BALM. Have a go at picking some new activities to do or do some of the ones you have already managed to do again. If you have found the tools in BALM useful – keep using them.

Some people who have had low mood or **depression** can find that they can feel better and then start to feel down again. This is sometimes called a **relapse**. In the next session we will look at **relapse** and what to do if it happens.

Remember that if you find yourself feeling very low it is important that you talk to someone and ask for help. There is information including useful links and phone numbers in the section called 'more help' [[supplementary 1](#)].

EVALUATION FORM

We would like to know how you have found today's session, so it would be great if you could answer a few questions. This will only take a couple of minutes but will really help us to make BALM better.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to look at the extra information in the programme that you might find useful. You can find this on the homepage. If you have any questions or comments about BALM or today's session, please email us at balm-study@york.ac.uk. We will try and get back to you as soon as possible. See you next time!

Related supplementary information:

Problem Solving

More support

FINAL SESSION: RELAPSE

SESSION OUTLINE

- Introduction to session
- Completion of mood measure
- Relapse
- Next steps and introduction to follow-up session
- Session evaluation

SESSION INTRODUCTION

Hello <name> and welcome back to BALM. We hope you have been well since last logging in.

You will have now done all 12 of your activities in the **activity hierarchy** and this is fantastic! Well done. We really hope that you have enjoyed the activities you have been doing and are starting to feel better. Doing the 12 activities is a great achievement but it is important that you keep up the good work. If you have found the tools in BALM useful keep using them. It takes time to start feeling better when you have been down. Therefore, keep doing activities to give yourself the best chance of feeling better and keeping it that way.

Some people who have had low mood or **depression** can find that they can feel better and then start to feel down again. This is sometimes called a **relapse**. In this session we are going to look at **relapse** and talk about what it is, how to spot it and what to do if it happens.

MOOD MEASURE

Before we start, we would like to see how you have been feeling since the last session so would like you to answer a few questions. This helps us to see if your mood has changed. It is important that you answer the questions honestly and, if you are feeling very low, that you talk to somebody about this. You can see your mood graph [here](#).

RELAPSE

What is a relapse?

Sometimes when you have had low mood or **depression** you can start to feel better again and think that the low mood or **depression** has gone for good. This is a great

feeling! For some people, even though they might feel sad sometimes they might never have low mood or **depression** again. Sadly, for a lot of people they can become very low or depressed again. This is sometimes called a '**relapse**'. **Relapses** are **common** – when you have had low mood or **depression** there is a chance it might come back. This might sound worrying but there are things that you can do to try and stop this from happening and to help if it does happen.

How do I know if I am going to have a relapse?

In session 1 we looked at some of the **symptoms** of low mood and depression – these are the things that happen when we feel down. You looked at a list and picked which of the **symptoms** you had noticed when you had felt down. This might have been having a very sad mood, finding it hard to concentrate or pay attention or not being interested or enjoying activities [table completed in session 1 to appear]. By looking at this list and ticking what happened when you felt low, you should be able to spot the signs of low mood or **depression** if it happens again. This is important because, the sooner you can spot the **symptoms** the sooner you can do something about it.

If you do have low mood or **depression** again it could be different next time. Therefore, by remembering the **symptoms** from the list, you might be able to spot if you are feeling low again.

What do I do if I have a relapse?

It is important to remember that **relapse** after having low mood or **depression** is **common** – it happens to a lot of people. It can be very upsetting to have started to feel better and then start to feel low again, but **relapse** is very normal when you have been low or depressed before. Remember that relapses can be very **temporary** if you deal with them as soon as you notice them happening.

By doing BALM, we hope that you have started to feel better and noticed your mood improving. If you do feel low again, look back on the activities you have done in the programme to try and help you to feel better. You do not have to do the whole programme again, but there might be things that will be helpful if you feel low again.

1. Set some goals

When we feel down, we often take part in **mood-directed behaviour** where we decide what to do based on how we feel. Often when we feel down, we stop doing activities that we enjoy because we don't feel up to it. The key is to turn this **mood-directed behaviour** into **goal-directed behaviour**. Have a think about what you would like to do and set yourself some goals, then like we have done in the programme, pick some activities to help you reach these. These goals might be brand new, or you might carry on with some that you set in the programme and have not reached yet. If you have found the diaries useful keep using them. You might find a different way works better for you and that is fine!

2. Look at how you can make some changes

In session 2 we looked at how the activities we do can affect our mood but also how our mood can affect our activities. Here we saw how if we avoid situations, we might feel better in the **short-term** but will feel worse in the **long-term**. You picked something that had made you feel sad or unhappy and what you did. You then used **TRAP vs TRAC** to see how you could change what you did to make things better. This is a helpful activity to use. If you start feeling low, think about what could be making you feel down. It might be lots of things. Using **TRAP vs TRAC** find different ways of dealing with things to try and make each situation better.

3. Talk to people

If you start feeling low again it is important that you tell someone how you are feeling. When we feel low or depressed, we can stop talking to other people. This can make us

feel lonely and make our mood worse. Even though it is sometimes hard to talk about the way we are feeling, other people can really help us to feel better.

4. Do activities that you enjoy

Hopefully, BALM will have shown you that by doing activities that you enjoy you can start to feel better. It is important to keep this up. You have been able to do 12 activities when using BALM and that is fantastic so why not make it more? Think about more activities that you can do or even do some of the activities you have enjoyed again.

NEXT STEPS AND INTRODUCTION TO FOLLOW-UP SESSION

We hope that you have found BALM useful and have enjoyed doing some activities. It is important that you keep up the good work and keep doing activities that you enjoy. This will help to avoid a **relapse**. If you do have a **relapse**, we hope you feel happy that you have some information that will help you in the future.

The final session is a follow-up. In this session we would like to see how you have been doing since starting BALM. We would like you to do this in about a month's time. This will be around *{date to appear}*. We will send you a reminder about this if you have asked us to. In the meantime, keep up the great work and continue to do activities.

EVALUATION FORM

We would like to know how you have found today's session, so it would be great if you could answer a few questions. This will only take a couple of minutes but will really help us to make BALM better.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to look at the extra information in the programme. You can find this on the homepage. If you have any questions or comments about BALM or today's session, please email us at balm-study@york.ac.uk. We will try and get back to you as soon as possible. See you next time!

Related supplementary information:

More support

FOLLOW-UP

SESSION OUTLINE

- Introduction to session
- Completion of mood measure
- Progress review
- Programme recap
- Next steps and the future
- Completion of final evaluation

INTRODUCTION TO SESSION

Hello [name]! Welcome to the follow-up session of BALM. We hope you have been well since last logging in. Today is the final session of BALM. It has been a whole month since you last logged in and so in today's session, we would like to see how you have been getting on. In this session we will look back to how you were feeling when you first started using BALM and see if this has changed. We will also look at the progress you have made in your **activity scheduling** and look back at the goals you set in session 2.

MOOD MEASURE

Before we start, we would like to see how you have been feeling since the last session so would like you to answer a few questions. This helps us to see if your mood has changed. It is important that you answer the questions honestly and, if you are feeling very low, that you talk to somebody about this. You can see your mood graph [here](#) which will show you how your mood has changed since you started using BALM.

PROGRESS REVIEW

We have done a lot in BALM from looking at your low mood and **depression** symptoms back in session 1 to you completing 12 activities. Along the way you have been telling us about how you have been feeling, the goals you would like to reach and the activities you would like to do. In the first part of today's session we would like to look at the progress you have made from starting BALM until now. Let's start with the symptoms of low mood or **depression** that you had.

Have my symptoms of low mood/depression changed?

In session 1 we looked at some of the symptoms of low mood and **depression** and you filled in a table to say which ones you had noticed. We want to see if any of these have changed. **ACTIVITY (7):** The table below shows all of the symptoms that you had when you started BALM. In the column called 'now' put a tick next to any of the symptoms that you still have. If you have any new symptoms since the start of the programme add them in too.

Can you see a change in your symptoms? Are they the same as when you started BALM or have they changed? If they have changed are there more or less symptoms than you had at the start?

If symptoms have improved: It is great that you have seen a change in your symptoms! We hope this means you are feeling better. It is important to remember the symptoms you have had when feeling low because you will be able to see if you are feeling low again. If this happens, don't forget to talk to someone and use what you have learned in BALM to help.

If symptoms are the same/ got worse: When you have been down, it takes time to feel better again -this is normal. Do not feel that you have not made progress when using BALM– you have done 12 activities and that is a great start in feeling better. If your **symptoms** have got worse, it is important that you talk to someone about this as you might need some support ([supplementary 1](#)). It is important to keep working towards your goals, set more goals and carry on with the activities you have been doing.

Has my mood changed?

At every session you have answered some questions about how you have been feeling. Let's now look at the final graph which shows your mood scores from session 1 to your mood today. The lower the scores on the graph – the better your mood.

ACTIVITY (8): [Mood Graph to appear]

Can you see a change in your mood from session 1? Has it stayed the same or changed? If it has changed, is it better or worse than when you started the programme?

If mood has improved: It is great that your mood is looking better. We hope this means you are feeling better too! Were there times in the programme when your mood was really good? If so, look at what you were doing that week. Were you doing any activities that made you feel better? Try and remember the things that were going on when you felt your mood improve – then if you feel low again you will know some of the

things that have helped you before. Remember to talk to someone if you start to feel low again and keep using what you have learned in BALM.

If mood is the same/ got worse: When you have been down, it takes time to start feeling better again- this is normal. Do not feel that you have not made progress when using BALM – you have done 12 activities and that is a great start in feeling better. If your mood has got worse, it is important that you talk to someone about this as you might need some support ([supplementary 1](#)). It is important to keep working towards your goals, set more goals and carry on with the activities you have been doing. Look at the graph again – were there times in the programme when your mood was good? If so, look at what you were doing that week. Were you doing any activities that made you feel better? Try and remember the things that were going on when you felt your mood improve – that way if you feel low again you will know some of the things that have helped you before.

Has my day-to-day life changed?

At the end of session 1 you filled in a diary of the things you were doing each day. You rated how much you enjoyed each activity and gave each day a mood rating. Let's look at the first diary you filled in.

{original diary to appear}

When planning activities, you have been using the same diary, rated how much you enjoyed each activity and gave each day a mood rating. Let's see how much your diaries have changed from session 1. **ACTIVITY (9):** Pick one of the diaries you filled in later in BALM (drop-down box to appear to select one). Now look at the diary you did in session 1 and the one you have picked. Can you see any changes? Are you doing more activities now than before? What about the enjoyment ratings? Have these improved? Look at your mood scores for each diary – can you see any changes? Which diary did you give the highest mood rating?

If mood was better in later diary: Why do you think you had a better mood score on this diary than the one you did in session 1? Have you been doing more activities or doing more activities that you enjoy? If so, that is great! It is important to keep doing the things that you enjoy. If you have found the diaries useful keep using them. It can be useful to keep a list of the activities that you have done and how they have made you feel. That way, if you feel low again you can do some of the activities that you have enjoyed the most and that have helped your mood.

If your mood was better in diary 1: Why do you think you had a better mood score on this diary than the one you did later in the programme? Were you doing more things than that you enjoyed? Look at the different activities in the diaries and pick out the ones that you enjoyed the most. Maybe you enjoyed the activities you were doing at the start of the programme more – if this is true think about whether these activities will help you reach the goals you set earlier in the programme. If so, try and keep doing activities that you both enjoy and that will help towards reaching your goals. If this is not the case, maybe your mood has got worse when you have been using the programme? Look back at your mood graph [here](#) to see. As we saw in session 1 BALM might not work for everyone and a different treatment might be better for you. It is important that you talk to someone about this as you may need some support ([supplementary 1](#)). Remember that feeling better after having low mood or **depression** does take time and this is normal.

PROGRAMME RECAP

In the last session we looked at how, even if you start to feel better, you can start to feel low again and have a **relapse**. We hope that you have found BALM helpful. If so,

carry on using what you have learned to help with your mood and prevent a **relapse**. You can use the information on BALM at any time and can print a lot of it out. However, because this is the final session, we thought it would be useful to go over the important bits that we hope you will take away with you. You can find a copy of this (called 'programme recap') on the homepage that can be printed off. ([supplementary 5](#))

Session 1: We looked at low mood/**depression** and gave you some information about **Behavioural Activation**. The main things to remember are:

- Feeling sad is a normal part of life but when it happens for a long time it might be called **depression**
- Low mood/**depression** can happen to anyone and is very **common**. This means that lots of people may have low mood or **depression**
- When you have low mood or **depression** you can get into a **vicious cycle** where you stop doing things because you feel down, and this makes you feel worse
- Sometimes avoiding situations can make us feel better in the **short-term** but in the **long-term** we will feel worse
- To help with making yourself feel better and break the low mood/**depression vicious cycle** it is important to start doing activities again and trying not to avoid situations

Session 2: We started looking at the things that are important to us and setting some goals. The main things to remember are:

- It is important to make our behaviour **goal-directed** and not **mood-directed**. When we have low mood or **depression**, we can let our mood stop us from doing things (**mood-directed**) it is important to make our behaviour **goal-directed** and set ourselves goals to reach
- We need to set goals that are about things that are important to us. These might be our relationships, education, hobbies and interests and our health.
- Low mood and **depression** affect different areas of our lives and so when we set goals, we need them to be about different things in our lives and not just one area
- It is important to try not to avoid situations when we feel down. We can use **TRAP vs TRAC** to look for different ways to cope
- Having other people there to help us when we feel low can be really important

Sessions 3 to 8: We picked activities to do and planned when we would do them. Then we gave the activities a go. The main things to remember are:

- It is important to pick activities to do that you can do and are enjoyable. If you don't enjoy them or pick things that will be too hard you are setting yourself up to fail
- Do things slowly – pick easy activities to do first and only move onto harder ones when you are ready

- Don't be upset if you don't notice differences in your mood straight away – when you have low mood or **depression** it takes time to start feeling better again. Don't give up!
- If you find activities hard try and look for ways to make them easier for yourself. Break them down or ask others who you trust for help

Final session: Relapse: We looked at how after having low mood or **depression**, you might become low again (**relapse**). The main things to remember are:

- **Relapse** is very **common** and can be **temporary** if you get help and start looking at ways, like the programme has shown you, to help improve your mood
- Remember what having low mood and **depression** is like for you (e.g. what symptoms you have) so you can see if you might be going to have a **relapse** or are having one and be able to do something about it
- If BALM has helped with your low mood or **depression** it is important to keep using what you have learned in it. This is important if you feel you might have a **relapse**

NEXT STEPS AND THE FUTURE

In session 2 we said that different things work for different people. We hope that BALM has worked for you and that you are feeling better. Feeling better after having low mood or **depression** takes time. It is important that you continue doing activities to help improve your mood and stop you from feeling low again.

The final part of today's session is to look at how you have got on with the goals you set in session 2 and make some plans for the future. In session 2 we looked at how it is important to set goals and focus on these and not your mood. By doing this, you will start doing activities that are important to you and hopefully feel better. You picked some **short-term** goals and some **long-term** goals. Let's look at the goals that you picked

{Original goals to appear}

How many of your goals have you reached? Because BALM is short you might not have reached any of your goals yet, especially not the long-term ones and that is not a problem. The important thing is that you have been doing activities that help you to work towards these goals. If you have reached any of your goals that is great! Carrying on with activities and trying to reach goals is really important and so before you finish this session, we would like you to set some goals for the future. Look at the first goals you set. These might have changed since the start of BALM and that is fine.

ACTIVITY (10): In the table called 'looking at original goals and making new ones' write down the goals you have reached (if any) since starting BALM. Then write down some to work towards in the future. If you have not reached the goals that you set in session 2 and still want to do these, put these as the goals you plan to do. You might have already reached the goals from session 2 or want to pick some new ones – that is fine. After BALM has ended keep working towards your goals. Remember to set both **short-term** and **long-term** goals. Over time the things that are important to you might change. For example, instead of making goals about school it might be about a job – set goals that are important to you.

EVALUATION FORM

We would really like to know how you have found today's session. Also, because this is the last session, we would like to know how you have found BALM overall. We would

therefore be grateful if you could answer some questions. This will only take a couple of minutes but will really help us to make BALM better in the future.

SESSION CLOSE

Thank you for doing the session today – we hope you have found it useful. Although the session has now finished, feel free to read the extra information in the programme. You can find this on the homepage. If you have any questions or comments about BALM or today’s session, please email us balm-study@york.ac.uk. We will try and get back to you as soon as possible.

Related supplementary information:

More support
Programme recap

Glossary

Acronym	A word made from the first letters of other words. For example, when you say PTO instead of Please Turn Over – you have taken the first letter of each word and made a new word
Activity Scheduling	When you pick activities that you would like to do and plan when you will do them
Activity Hierarchy	Something we can use to help us put the activities we would like to do in an order from easiest to hardest. You start with the easiest and then work your way up the hierarchy until you have reached the hardest activity
Behavioural Activation	A type of talking therapy that helps you to start doing things you used to enjoy again to help improve your mood
Common	Something which happens a lot
Coping skills	The things that we do to help us to deal with a situation.
Depression	A type of mood disorder where you feel very down for a long time and struggle to do the things you would normally do
Goal-directed behaviour	When you decide how to behave based on trying to reach a goal
Long-term	Something which lasts for a long time or takes a long time to get to
Mood-directed behaviour	When you decide how to behave based on how you feel.
Relapse	When you have started to feel better and then feel bad again. When you have low mood or depression this would be when you start to feel happier and then you start to feel down again.
Ruminating	To think about something over and over again
Self-esteem	Where you feel good about yourself. If you have high self-esteem you might feel proud of what you can do and believe in yourself.
Self-confidence	How much you like yourself the way you are
Short-term	Something which lasts for a short time or does not take a long time to get to
Symptoms	The things that you notice happening when you have low mood or depression
Temporary	When something happens for a short time and does not last forever
TRAP vs TRAC	An acronym used to help you to stop avoiding a situation and to try and find a better way of dealing with it

Vicious Cycle	When a problem or difficult situation causes even more problems or difficult situations. These then make the original problem happen again or make it worse. For example, when you have low mood or depression you feel down and stop seeing your friends. You then feel lonely which makes your low mood/depression even worse.
Worthless	A feeling that you are not important

There may be other words that we have used in BALM that you do not understand and that are not listed here. Here is a link to a dictionary to help you: <https://www.lexico.com/en>. If you are struggling with something that you do not understand you can also email us at: balm-study@york.ac.uk. We will try to get back to you as soon as possible.

Tools for completing therapy

Session- Specific Activities

ACTIVITY (1): Symptom selection (Session 1)

Tick the boxes next to all of the symptoms you have noticed. Add any things that you have noticed that are not listed at the end

Feeling very sad		Having less energy	
Lost interest and enjoyment in activities		Feeling very tired	
Not taking part in activities as much		Not being able to concentrate or pay attention as much	
Having less self-esteem		Having less self-confidence	
Having feelings of guilt		Having feelings of worthlessness	
Having negative views about the future		Hurting yourself or thinking about it	
Thinking about suicide		Having problems with sleeping	
Having problems with eating		Feeling very irritable	
Being away from school a lot		Struggling with schoolwork	
Drinking alcohol		Taking drugs	
Feeling angry or unfriendly		Taking part in dangerous behaviours or activities	

ACTIVITY (2): Values (session 2)

LIFE AREA 1: RELATIONSHIPS		
My short-term goals	My long-term goal(s)	What activities can I do?

LIFE AREA 2: EDUCATION		
My short-term goals	My long-term goal(s)	What activities can I do?

LIFE AREA 3: HOBBIES AND INTERESTS		
My short-term goals	My long-term goal(s)	What activities can I do?

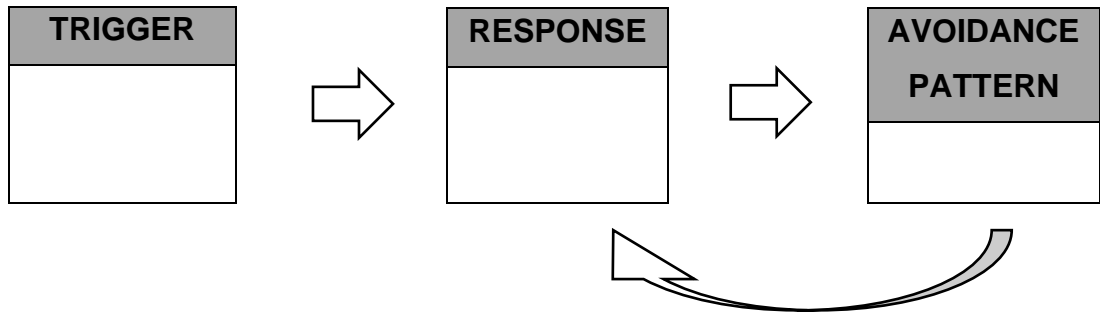
LIFE AREA 4: HEALTH		
My short-term goals	My long-term goal(s)	What activities can I do?

Values (completed example)

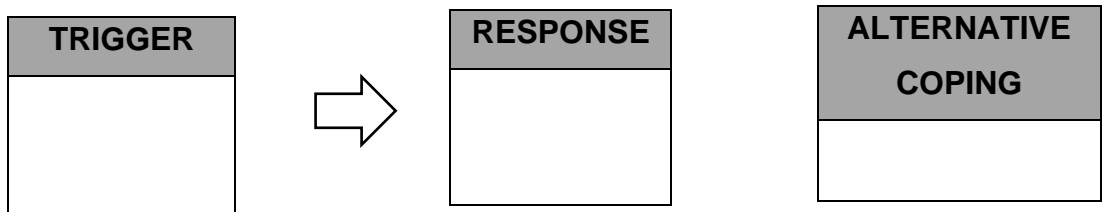
LIFE AREA 1: RELATIONSHIPS		
My short-term goals	My long-term goal(s)	What activities can I do?
Contacting my friend more often Being a good support to my friend Spending more time with my dog	Being a better friend Taking better care of my dog	Phoning my friend twice a week Meeting my friend on Skype or Zoom once a week Taking the dog for a walk for 30 minutes each evening
LIFE AREA 2: EDUCATION		
My short-term goals	My long-term goal(s)	What activities can I do?
Getting my college application in on time Improving my grades in French	Getting into sixth form college Going to University	Spend an extra 30 minutes on my homework each night Work for 30 minutes on my college application between now and the deadline Practice my French speaking twice a week
LIFE AREA 3: HOBBIES AND INTERESTS		
My short-term goals	My long-term goal(s)	What activities can I do?
Be able to cook a meal for my family Be able to play a whole song on the piano	Learn to cook well Learn to play the piano well	Help to prepare family meals once a week Practice the piano for 30 minutes every other evening
LIFE AREA 4: HEALTH		
My short-term goals	My long-term goal(s)	What activities can I do?
Be able to run 1K Finding more time to be able to relax	Be able to run 5K Be able to relax more	Going for a run Wearing my favourite clothes Listening to my favourite music

ACTIVITY (3): TRAP to TRAC (session 2)

TRAP

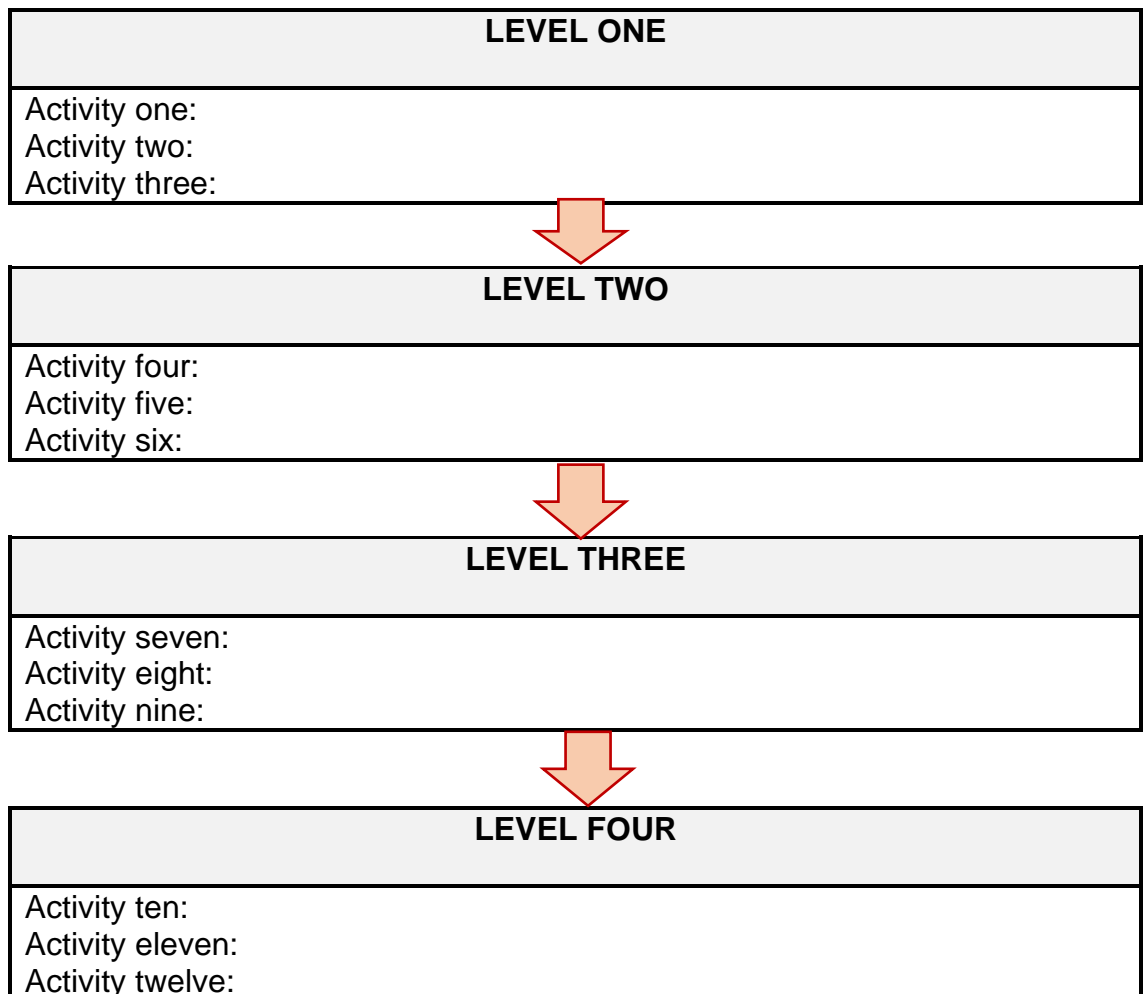


TRAC



ACTIVITY (4): Picking 12 activities to try (session 3)

ACTIVITY (5): Activity hierarchy (session 3)



ACTIVITY (6): Planning activities (Session 3)

{Original diary to appear for completion}

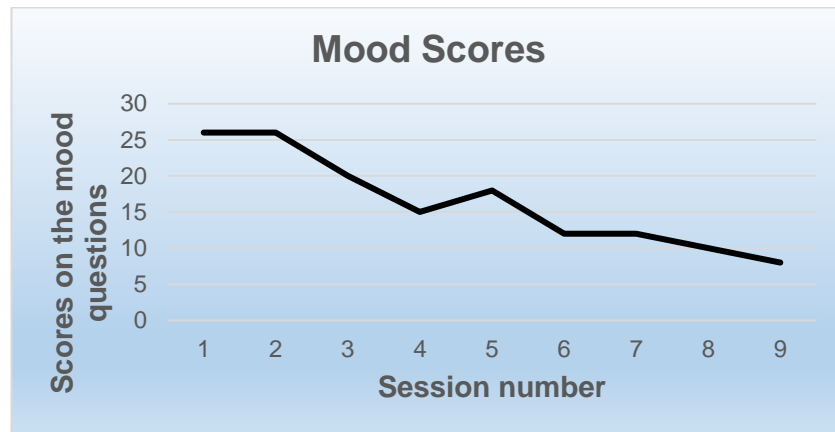
ACTIVITY (7): Symptom Review (Follow-up session)

Tick the boxes next to all of the symptoms you have now. Add any things that you have noticed that are not listed at the end

	Programme start	Now		Programme start	Now
Feeling very sad			Having less energy		
Lost interest and enjoyment in activities			Feeling very tired		
Not taking part in activities as much			Not being able to concentrate or pay attention as much		
Having less self-esteem			Having less self-confidence		
Having feelings of guilt			Having feelings of worthlessness		
Having negative views about the future			Hurting yourself or thinking about it		
Thinking about suicide			Having problems with sleeping		
Having problems with eating			Feeling very irritable		
Being away from school a lot			Struggling with schoolwork		
Drinking alcohol			Taking drugs		
Feeling angry or unfriendly			Taking part in dangerous behaviours or activities		

Anything missing? List anything that you think is missing from the table above

ACTIVITY (8): Overall mood graph (example) (Follow-up session)



ACTIVITY (9): Comparison of diaries

{Original diary and a later diary to appear for comparisons}

ACTIVITY (10): Looking at original goals and making new ones (follow-up session)


LIFE AREA 1: RELATIONSHIPS	
Goals I have reached	New goals
LIFE AREA 2: EDUCATION	
Goals I have reached	New goals
LIFE AREA 3: HOBBIES AND INTERESTS	
Goals I have reached	New goals
LIFE AREA 4: HEALTH	
Goals I have reached	New goals

Goals before the next session activities. Session 1: Activity monitoring


	<i>Example</i>	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
TIME	ACTIVITIES							
6-7AM	<i>Asleep (0)</i>							
7-8AM	<i>Had breakfast Watched TV (6)</i>							
8-9AM	<i>Went for a walk with my family (2)</i>							
9-10AM	<i>Did some studying (0)</i>							
10-11AM								
11-12AM								
12-1PM	<i>Lunch (3)</i>							
1-2PM	<i>Did some studying (0)</i>							
2-3PM								
3-4PM	<i>Skyped my friend (2)</i>							
4-5PM	<i>Had a sleep (3)</i>							
6-7PM	<i>Had tea (6)</i>							
7-8PM	<i>Watched TV (8)</i>							
8-9PM								

	<i>Did some homework</i>							
9-10PM	<i>Did nothing (0)</i>							
10-11PM	<i>Asleep (0)</i>							
11-12PM								
After Midnight								
The day's overall mood rating:	4							

Enjoyment Rating Scale:

1	2	3	4	5	6	7	8	9	10
Not enjoyable at all									Really enjoyable

Mood Rating Scale:

1	2	3	4	5	6	7	8	9	10
Feeling really low/negative									Feeling really happy/positive

Supplementary Materials

Supplementary 1: More help

LOCAL INFORMATION

YORK AND SELBY

Limetrees Child and Adolescent Mental Health Service (CAMHS)

Address: 31 Shipton Road, York, YO30 5RE

Tel: 01904 615300

Selby Cabin (Child and Adolescent Mental Health Service – CAMHS)

Address: Flaxley Road, Selby, YO8 4DL

Tel: 01904 615345

HUMBER AND EAST RIDING OF YORKSHIRE

West End (Child and Adolescent Mental Health Service – CAMHS)

Address: 2062-2068 Hessle Rd, Hull, Hessle HU13 9NW

Tel: 01482 303680

Crisis Service: 01482 301 701

NORTHALLERTON

Brompton House (Child and Adolescent Mental Health Service – CAMHS)

Address: 22 Brompton Road, Northallerton, DL6 1EA

Tel: 01609 718810

OTHER USEFUL CONTACTS

Young Minds	www.youngminds.org.uk
The NHS	www.nhs.uk (General website) www.nhs.uk/conditions/stress-anxiety-depression/ (Mood zone)
The Samaritans	www.samaritans.org/ Tel: 116 123 (free number) Email: jo@samaritans.org
Childline	www.childline.org.uk/ Tel: 0800 1111

Please remember if you feel you need urgent support call 999 immediately

Supplementary 2: Information for parents/guardians and friends

A brief guide to depression for parents/guardians

What is depression and what causes it?

Most teenagers (and indeed most people) have times when they are happy and times when they are sad or upset. This is very normal and is usually related to things that are going on in life, hormone changes and sometimes normal variability. We also know that some people seem to have a more positive outlook on life than others and this may be partly to do with genetics, temperament, personality, or life experiences. Feeling low or down comes and goes and is usually separated by long periods of time when people are content or happy.

Depression, by contrast, tends to be more severe, more long-lasting, and more persistent throughout the days, weeks or months. It can involve a lost ability to enjoy the things we used to enjoy, a lack of energy, lost motivation to do things and sometimes feelings of hopelessness or worthlessness. It also comes with appetite changes, sleep disturbance and reduced involvement with activities or other people. Sometimes people with depression feel that life is not worth living but rarely will try to take their own lives because they are feeling so desperate.

Whilst it is not always clear why some people develop depression and others do not, depression very rarely occurs out of the blue. It is usually in response to prolonged stress, trauma, a predicament where they feel trapped or significant experiences of loss. For this reason, it is important that the people around a person who is depressed think carefully about the numerous possible causes and ways of supporting the young person concerned.

Changes you may have noticed with your son/daughter

Depression can present in many different ways. You may notice that your son/daughter is often tearful or looking sad or down most of the time. They may smile or laugh infrequently. They may be less likely to go out and meet friends and do activities that they previously enjoyed. They may isolate themselves and avoid company. Sometimes sleep patterns can become very disrupted and they might lose their appetite or interest in food, although some people who are depressed may over-eat. They may find it difficult doing homework or concentrating on reading and they may lack energy.

Some of these things do not necessarily mean that your son or daughter is depressed, as it is common for teenagers to have disruptions in sleep patterns or mood swings. However, if any of these things are persistent and impact upon daily life then they should always be taken seriously.

Depression can affect different people in lots of different ways. Not everyone will feel the same but some of the things you might notice with your son or daughter if they are depressed are:

- Having a very sad mood
- Not being interested in or enjoying activities
- Feeling very tired
- Not taking part in activities as much
- Not being able to concentrate or pay attention as much
- Not having much energy
- Having less self-esteem and/or self-confidence
- Feeling guilty or worthless

- Feeling negative about the future
- Hurting themselves or thinking about it
- Thinking about suicide
- Having problems with sleeping (sleeping too much or not enough)
- Having problems with eating (eating too much or not enough)
- Feeling very sad or irritable
- Missing school a lot or not doing very well in their schoolwork
- Drinking alcohol or taking drugs
- Feeling angry or unfriendly
- Taking part in dangerous behaviours or activities

How can I best support my son or daughter if they are depressed?

The most important thing for your son or daughter is for them to know that you are there to listen to them and be supportive of them. Research suggests that parents/guardians who communicate well with their teenagers and who show warmth towards them are being helpful. Try and check in everyday with your son or daughter and create times to speak with them and spend time with them. Also try and find some fun activities to do with them from time to time.

It can be tempting to become angry or frustrated but try as hard as you can to stay calm when you are having any discussions or disputes. It is very difficult to help your young person with depression when you are in conflict with them. A few tips on conflict resolution may therefore be helpful.

- There may be occasions when you are frustrated or angry that your teenager is not doing the things they need to do for their own healthy development. Explaining this to them calmly and explaining that you are putting boundaries down for them in order to help them will make it much easier for them to hear what you are saying. When you become angry, then their focus becomes on the anger rather than the content of what you are saying.
- If you do have arguments with your teenager take some time to sit down with a friend or a partner to talk through how these disputes escalate. If you can understand this then it is often possible to prevent it happening in the future. For example, it is common for a teenager to storm out of the room and slam the door. If you chase after them and have an argument, then this often escalates because both of you want to have the last word. Think to yourself how important it is to have the last word. Is it helpful to chase after the teenager when they have stormed out of the room? Sometimes it is more helpful to let them go off and have some time to calm down, and then come back and have a calm discussion with them later.
- If arguments escalate and you say things that you later regret, then sometimes it is helpful for you to walk away and have some time on your own to reflect on the best way to explain things to your teenager. Some parents/guardians write down what they want to say to their teenager so that they can make sure what is expressed in a calm supportive language.
- Always remember that at some point your teenager will grow up to be an adult, and the vast majority of parents/guardians have good relationships with their adult children. Both of you have memories and both of you will look back on the conflicts that you had. So, don't forget that if you have stayed calm and thoughtful and generous in your interactions with your teenager, even when they are being very difficult, then their memory of you as a parent/guardian later on will be as a supportive and caring parent/guardian. This is a good aspiration to hold in mind.

- Warmth is also a help strategy. Even if teenagers do not want hugs, they will experience warmth as a positive thing from their parent/guardian.
- Finally, don't forget that a sense of humour is a very powerful tool for breaking negative ice. It can be difficult to use when both of you are angry, but it can be very helpful to laugh at yourselves and have a joke together.

How does BALM work?

BALM (Behavioural Activation for Low Mood) is based on a type of therapy called Behavioural Activation. Behavioural Activation is a practical treatment and involves those using it to make some small changes to their lives that might make them feel better. When people have low mood or depression, two things can happen – they can stop doing things that they used to enjoy, and they can start avoiding situations. This can lead to people getting stuck in a vicious cycle, where because they stop doing things or start avoiding situations, they find themselves even more down. Because they feel more down, they are then even less likely to take part in activities and more likely to avoid things. Behavioural Activation aims to break this vicious cycle in two ways. It aims to encourage people to start taking part in activities they used to enjoy even if they are feeling low and tries to help them to not avoid situations.

Through Behavioural Activation, a person who is depressed can get back in touch with the things that they used to enjoy doing. This can have numerous add on benefits such as helping them to make contact with other people, improving exercise and activity levels, giving them something to do which prevents them ruminating on the difficult things in their lives. Activities can also lead to achievements and this together with social contact can improve self-esteem.

Throughout their time using BALM your son or daughter will look at their current activity levels and make plans to take part in things that they used to do and enjoy before they became depressed. To do this they will be asked to set themselves some goals (both long-term and short-term) and think of activities that might help them to reach these goals. They will then be asked to try and take part in these activities by planning how and when they will do them. In total, by the end of BALM, we hope that they will have been able to take part in at least 12 activities. How your son or daughter uses the programme is up to them. They will be the ones picking the things that they will take part in so they will never be asked to do anything that they do not want to do. They will also be encouraged to plan all activities at convenient times to avoid any disruption.

Behavioural Activation has been around for a long time and has been tested with people with low mood or depression. A lot of this testing has been done with adults and it has been good at treating their low mood and depression. Less testing has been done with young people, but we think it can work. Everybody is different and what works for one person might not work for somebody else. Therefore, although we hope that BALM will help your son or daughter to feel better, we cannot be sure that it will.

How can I support my son/daughter when they are using BALM?

People who are depressed may lack motivation. This makes depression a vicious cycle in that it can be very difficult to motivate yourself to do the things that might help you get better. Your job as a parent/guardian therefore is to encourage them to do the activities that they have scheduled. Give them encouragement, rewards, praise and generally be positive about the approach. This will be a big help. Although BALM is designed to help your son or daughter to help themselves to feel better, it can be much easier for them if they have help from the people around them. This might include sitting with them when they are completing a session, talking to them about what they are doing on the programme or even helping them to plan or do activities. It might be that your son or

daughter would like to work through BALM on their own. This is completely fine, and we would like to respect their choice with this.

How can I tell if my son or daughter is having a relapse?

Sadly, it is fairly common for people who have had low mood or depression before to have a relapse and for their depression to come back after they have started to feel better. The good news is that relapses can be very temporary if they are dealt with as soon as possible. The main thing is to keep an eye out for the signs of low mood and depression mentioned above. A common sign of relapse is when young people reverse or stop the positive changes that they have made. For example, as treatment progresses, they may have got involved in more activities and arranged to talk to their friends more. If these begin to drop off, then this may be an early sign that they need support or someone to talk to about what is happening. We hope that BALM will give young people some tools to help them in the future if a relapse is to occur.

Links to additional support

Please see below some links to additional support that you might find useful. If you have any questions, please feel free to contact the research team (balm-study@york.ac.uk) and we will try to respond to you as soon as possible

<p>Young Minds: Supporting your child with depression</p>	<p>https://youngminds.org.uk/find-help/for-parents/parents-guide-to-support-a-z/parents-guide-to-support-depression/</p> <p>Parent helpline: 0808 802 5544</p>
<p>Relate: Parenting teenagers</p>	<p>https://www.relate.org.uk/relationship-help/help-family-life-and-parenting/parenting-teenagers?gclid=EAlaIQobChMlrYD9mba54wIVCLLtCh1WFAm3EAA YASAAEgLjPD BwE</p>
<p>NHS: Depression in children and teenagers</p>	<p>https://www.nhs.uk/conditions/stress-anxiety-depression/children-depressed-signs/</p>

A brief guide to Depression for friends

What is low mood and depression and why does it happen?

Everybody feels sad at times, and this might be for lots of reasons. Feeling sad is a normal part of life and it affects everybody. However, some people might feel sad a lot or all of the time even if nice things are happening around them. If this is really bad this is sometimes called depression. It does not matter who a person is, how old they are or where they are from...depression can affect anybody. Depression can also happen at any time. Your friend might have developed low mood or depression for lots of reasons. They might have had something bad happen to them, they might be under lots of stress, or they might have experienced a loss. Sometimes there are not always clear reasons why someone becomes depressed.

Changes you might have noticed with your friend

Low mood and depression can affect different people in different ways and so not everybody will feel the same when they have depression. There are some things that you might notice with your friend if they are feeling very low or depressed. These might be:

- Having a very sad mood
- Not being interested in or enjoying activities
- Feeling very tired
- Not taking part in activities as much
- Not being able to concentrate or pay attention as much
- Not having much energy
- Having less self-esteem and/or self-confidence
- Feeling guilty or worthless
- Feeling negative about the future
- Hurting themselves or thinking about it
- Thinking about suicide
- Having problems with sleeping (sleeping too much or not enough)
- Having problems with eating (eating too much or not enough)
- Feeling very sad or irritable
- Missing school a lot or not doing very well in their schoolwork
- Drinking alcohol or taking drugs
- Feeling angry or unfriendly
- Taking part in dangerous behaviours or activities

How can I support my friend if they have low mood or depression?

The most important thing that you can do for your friend is to let them know that you are there to talk to. Sometimes when people feel very down, they can stop wanting to see other people and they can start to avoid people. Let your friend know that you are there to support them. If you don't hear from them for a while, try and make some time to check in with them and see if they are OK. They might not want to talk and that is fine, but it is important that you let them know that you are there if they need you.

What is BALM and how does it work?

When people have low mood or depression, two things can happen – they can stop enjoying things that they used to enjoy, and they can start avoiding situations. This can make people feel even worse. BALM aims to help people feel better by helping them to start taking part in activities they used to enjoy even if they feel low and tries to stop them avoiding situations. This type of therapy is called Behavioural Activation. BALM, which stands for Behavioural Activation for Low Mood, is an online treatment for young people with low mood or depression.

When using BALM your friend will be asked to look at the things they are doing now and make plans to take part in things that they used to do and enjoy before they became down. They will be asked to set themselves some goals and think of activities that might help them to reach these goals. They will then be asked to try and take part in these activities by planning how they will do them and when. By the end of BALM, we hope that they will have been able to take part in at least 12 activities.

How can I help my friend when they are using BALM?

Even though BALM will hopefully help your friend to feel better it can be much easier for them if they have some help from the people closest to them. It might be that you could talk to them about what they have been doing on the programme or give them some ideas of activities that they could try. Your friend might also find it easier to do activities or find them more fun if you are there to do them with them. Your friend might want to do the programme on their own and not get help from others and that is fine. It is very important to respect their choice with this. Even if this is the case, you can let them know that you are there to help if they need you.

If you need any further information or have any questions, please feel free to contact the research team (balm-study@york.ac.uk) and we will try and get back to you as soon as possible

Supplementary 3: Communication and conflict resolution

As we have seen in BALM it can be really useful to get help from other people when you are feeling down. Sometimes this help might just be talking to someone (like a friend or a family member) about the way you are feeling. However, talking can sometimes be very difficult – it might be hard to tell people how you are feeling but also frustrating if you don't feel that they understand. Sometimes, if we don't communicate very well with other people this can lead to arguments. When you are feeling down, arguing with others will make you feel worse and will make it very hard for you to ask for their help. We have therefore put together some information below that you might find useful to help you to talk to people about the way you feel and avoid arguments.

- **Be honest about the way you feel:** Sometimes it can be hard to tell people exactly how you feel. This might be for lots of reasons – you might be embarrassed, worry about being judged or not want to upset someone else. Whatever the reason, the person you are talking to will find it much easier to help you if you are honest with them.
- **Tell people if you are finding it hard to talk:** If you are finding it hard to talk to someone – tell them. It might be that you are finding it hard to get the words out that you want to say. By being honest about this, the person you are talking to will be patient and might be able to help.
- **Be polite:** Even if you are feeling very upset it is important that you stay polite. This will make it much more likely that the person you are talking to will listen and try to help.
- **Try and see the other person's point of view:** Sometimes it can be very frustrating if you do not agree with what another person is saying. This can lead to an argument. Try and take some time to see things from their point of view. Let the other person explain to you why they think the way that they do. It might be that when you have heard their reasons that you agree with them. If you still do not agree with them, explain clearly to them why you feel the way that you do.
- **Try and look for alternatives:** It might be that you and the person you are talking to disagree on something. Can you find a different solution that suits both of you?
- **Be calm:** It will be a lot easier to explain your point of view to someone if you can do it calmly. If you find yourself getting angry or frustrated, give yourself some time to calm down and think things over. You are more likely to sort out an argument if you do it calmly.
- **Write things down:** Sometimes it can be very hard to talk to other people about the way that you feel. You might find it easier to write what you want to say down instead.

Supplementary 4: Problem Solving

This section gives you some information about problem solving. When using BALM, we hope you will find this useful if you are finding it hard to do an activity or reaching one of your goals. However, this information can be used for helping with lots of problems you may come across. In this section we will go through a useful step-by-step guide on how to look at the problem you have and find some ways to solve it. Work through all 6 of the steps to help you solve a problem. You can use this guide on your own or you might find it useful to ask someone like a family member or a friend to help.

STEP 1: Say what the problem is

What is the problem? In the space write down what the problem is. You might have more than one problem. If so, write down all of the problems that you have.

Problem 1:

.....

Problem 2:

.....

Problem 3:

.....

Have a look at your list. If you have written down more than one problem, pick the one you would like to work on first and move onto step 2. It is important to look at one problem at a time and so you can come back to your other problems later.

STEP 2: Decide what you would like from solving the problem

Now have a think about what it is that you would like to change. What is it that you would like to achieve by solving the problem? How is the problem stopping you from doing this? Are there any things that are getting in the way of you solving your problem? Remember there are no right or wrong answers here.

.....
.....
.....

STEP 3: Think about ways to solve the problem

Now that you have said what the problem is and how it is stopping you from doing something have a think of ways that you might solve the problem. Try and think of at least 3 different things you could do and write them down below. If you can think of more that is great.

1.
2.
3.
4.
5.

STEP 4: Decide which way is best to solve the problem

Look at the ideas you have come up with and decide which one you think will be the best to try and solve your problem. If you find it helpful you could list all of the good things (pros) and all of the bad things (cons) about each idea. You can use the table below to help you. In the table write down each of the ideas. Then write down all of the good things about each and all of the bad things about each.

	Idea	Good things (Pros)	Bad things (Cons)
1			
2			
3			
4			
5			

STEP 5: Give your idea a go

Look at the table and decide which of your ideas looks like the best one to help solve your problem. Now give this a go and see if it can help.

STEP 6: Review your progress

You might have been able to sort the problem you had using the idea you picked. If not, do not worry. It often takes time to find the best solution to a problem. Go back to the table and pick the next best idea you came up with and give this a go. Keep doing this until you have tried all of the ideas. If you have still not solved your problem when

you have tried all of your ideas go back to step 3 and see if you can think of some more ideas to help you. This time have a think about the following:

Can the problem be broken down?

Can you break down with the problem into smaller parts to make it easier?

Is the goal you are setting yourself too big?

It is important to try not to do too much at once. Have a think about what you want to get out of solving the problem. Can you break down your goal into smaller parts?

Can you ask someone to help you?

Maybe you would find the problem you have easier to deal with if you had some help. Can you talk to someone about it? Maybe a friend or a family member could help.

Are you giving yourself enough time to reach a goal?

Sometimes reaching a goal can take a long time. It might be that you are doing well to work towards a goal but have not reached it yet. For example, your goal might be to enjoy spending more time with your family. You might have started spending time with them more often but are finding it hard because you feel low. It might just take some time for you to start enjoying yourself again. It is important to keep trying if this happens.

Once you have solved your problem repeat each of the steps above for any other problems you have. You can use this method for lots of different problems that you might face both now and in the future.

Supplementary 5: Programme recap

- Feeling sad is a normal part of life but when it happens for a long time it might be called **depression**
- Low mood/**depression** can happen to anyone and is very **common**. This means that lots of people may have low mood or **depression**
- When you have low mood or **depression** you can get into a **vicious cycle** where you stop doing things because you feel down, and this makes you feel worse
- Sometimes avoiding situations can make us feel better in the **short-term** but in the **long-term** we will feel worse
- To help with making yourself feel better and break the low mood/**depression vicious cycle** it is important to start doing activities again and trying not to avoid situations
- It is important to make our behaviour **goal-directed** and not **mood-directed**. When we have low mood or **depression**, we can let our mood stop us from doing things (**mood-directed**) it is important to make our behaviour **goal-directed** and set ourselves goals to reach
- We need to set goals that are about things that are important to us. These might be our relationships, education, hobbies and interests and our health.
- Low mood and **depression** affect different areas of our lives and so when we set goals, we need them to be about different things in our lives and not just one area
- It is important to try not to avoid situations when we feel down. We can use **TRAP vs TRAC** to look for different ways to cope
- Having other people there to help us when we feel low can be really important
- It is important to pick activities to do that are enjoyable. If you don't enjoy them or pick things that will be too hard you are setting yourself up to fail
- Do things slowly – pick easy activities to do first and only move onto harder ones when you are ready
- Don't be upset if you don't notice differences in your mood straight away – when you have low mood or **depression** it takes time to start feeling better again. Don't give up!
- If you find activities hard try and look for ways to make them easier for yourself. Break them down or ask others who you trust for help
- **Relapse** is very **common** and can be **temporary** if you get help and start looking at ways, like the programme has shown you, to help improve your mood
- Remember what having low mood and **depression** is like for you (e.g. what symptoms you have) so you can see if you might be going to have a **relapse** or are having one and be able to do something about it

- If the programme has helped with your low mood or **depression** it is important to keep using what you have learned in it. This is important if you feel you might have a **relapse**

RISK MONITORING PROTOCOL

Current Version:	1
Effective Date	01.01.2020

Purpose and introduction

The purpose of this SOP is to ensure that an effective risk monitoring procedure is in place during completion of the BA feasibility study. The SOP outlines the procedures that need to be adhered to for the duration of the study.

Scope

The procedure describes the measures that are in place and will be adhered to by the study team for the duration of the feasibility study.

Responsibilities

It is the responsibility of all members of the study team to ensure the SOP is adhered to during completion of the BA feasibility study

Procedure

1. As per the study protocol, the responses young people have made to the Short Mood and Feelings Questionnaire (SMFQ) will be automatically sent to the study email address (balm-study@york.ac.uk).
2. The lead researcher (LT) will monitor responses to this email account on a daily basis (including weekends). In any instances where this is not possible (e.g. absence, illness) all members of the research team (BW, DM and AMW) will be notified and a named member of the research team, with availability to do so, will take over the role of monitoring the account for the necessary period of time. All members of the research team will have access to this email account for the duration of the BA study.
3. As per the study protocol, participants, their parent/guardian and the primary care provider will be contacted in any instances where risk is presumed (consent to this will be a requisite of study entry). Risk will be assumed where:
 - (a) A participant has responded 'true' to question 5: 'I thought about death and dying'

OR

 - (b) A participant has responded 'true' to question 10: 'I thought about killing myself'

OR

- (c) A participant has sent a message to the study email address suggesting they may be at risk
4. Parent/guardians and participants who take part in the consent process will be asked to provide a phone number and an email address and agree to monitor this at least every 24 hours. In the event that risk is presumed the lead researcher (LT) or nominated deputy will contact the young person and their parent/guardian informing them of the risk and request that they seek help from their general practitioner or the current child mental health provider (where appropriate) or from A&E if urgent. This contact will comprise a text and an email being sent to the parent/guardian and an email sent to the young person. They will be requested to seek help (with suggestions of sources of help provided). The primary care provider will be notified on the next working day.
 5. In any instances where risk is presumed out of hours (i.e. past 5pm on an evening, before 9am in a morning or at any point during a weekend) and therefore the primary care provider, their GP and other Child and Adolescent Mental Health Services (CAMHS) are unavailable, the young person and their parent or guardian will be advised to report to A&E or call 999 if this is deemed necessary.
 6. A further email will be sent to the young person, their parent/guardian and their care provider 24 hours after risk has been presumed to check the welfare of the young person.
 7. In any instances where the lead researcher (LT) or another member of the research team has any concerns about the wellbeing of a young person during completion of the BA study all members of the study team will be informed alongside information as to the actions taken.

HSRGC APPROVAL LETTER



DEPARTMENT OF HEALTH SCIENCES

c/o Department of Philosophy
Heslington
York YO10 5DD

Telephone (01904) 323253
Fax (01904) 321383
E-mail smh12@york.ac.uk

Dr Stephen Holland
Chair, Health Sciences Research
Governance Committee

www.york.ac.uk/healthsciences

24 October 2019

Miss L Tindall
University of York
Department of Health Sciences
York YO10 5DD

Dear Lucy

HSRGC/2019/355/C: Computerised Behavioural Activation Programme for the treatment of depression in young people: Feasibility Study

Thank you for your responses to the Health Sciences Research Governance Committee's review of your project, including meeting with me yesterday to discuss the changes, and sending your updated documents by email today.

I am writing to confirm by Chair's Action that the study can now go forward to the NHS REC for external review.

If you have need any further advice, please don't hesitate to get in touch. Also, if you make any substantial amendments to the study, you will need NHS REC approval; please send me approval of any substantial amendments, for our records. Finally if you intend to submit this letter or any other correspondence from the HSRGC as part of your assessed work (e.g., to demonstrate that your study has ethical approval) please make sure you edit the letter so as to maintain anonymity.

Yours sincerely

Stephen Holland
Chair: HSRGC

cc. Prof D McMillan, Prof B Wright

REC APPROVAL LETTER



Health Research Authority

Yorkshire & The Humber - Leeds West Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ
Telephone: 0207 1048 088

02 January 2020

Miss Lucy Tindall

The Department of Health Sciences

The University of York

York

YO10 5DD

Dear Miss Tindall

Study title: Computerised Behavioural Activation Programme
for the treatment of depression in young people:
Feasibility Study

REC reference: 19/YH/0426

Protocol number: N/A

IRAS project ID: 270172

The Research Ethics Committee reviewed the above application at the meeting held on 13 December 2019. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS

organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: <https://www.hra.nhs.uk/planning-andimproving-research/research-planning/research-registration-research-project-identifiers/>

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparencyresponsibilities/>

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/researchsummaries/>

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at

<https://www.hra.nhs.uk/approvalsamendments/managing-your-approval/>.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		

Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters [GP letter]	1	13 August 2019
GP/consultant information sheets or letters [GP contact form]	1	13 August 2019
IRAS Application Form [IRAS_Form_14112019]		14 November 2019
Letter from sponsor		
Non-validated questionnaire [Baseline Questionnaire]	1	13 August 2019
Non-validated questionnaire [Follow-up Questionnaire]	1	13 August 2019
Non-validated questionnaire [Short Evaluation Questionnaire]	1	22 August 2019
Non-validated questionnaire [Long Evaluation Questionnaire]	1	22 August 2019
Other [BALM Programme]	1	13 August 2019
Other [Participant preference form]	1	20 August 2019
Other [Expression of interest form]	1	10 October 2019
Other [GDPR Statement (Young People)]	1	03 October 2019
Other [GDPR Statement (Parents)]	1	03 October 2019
Other [University of York Lone Worker Policy]		
Participant consent form [Assent form young people (11 to 13 years)]	1	03 October 2019
Participant consent form [Consent form young people (14 to 16 years)]	1	03 October 2019
Participant consent form [Consent form parents (11 to 13 years)]	1	03 October 2019
Participant consent form [Consent form parents (14 to 16 years)]	1	03 October 2019
Participant information sheet (PIS) [Participant Information Leaflet (Young people aged 11 to 13 years)]	1	03 October 2019
Participant information sheet (PIS) [Participant Information Leaflet (Young People aged 14 to 16 years)]	1	03 October 2019
Participant information sheet (PIS) [Participant Information Leaflet (Parents where young person is aged 11 to 13 years)]	1	03 October 2019
Participant information sheet (PIS) [Participant information Leaflet (Parents where the young person is aged 14 to 16 years)]	1	03 October 2019
Research protocol or project proposal [Study Protocol]	1	10 October 2019
Summary CV for Chief Investigator (CI) [CV]		
Summary CV for supervisor (student research)		
Summary CV for supervisor (student research)		
Summary CV for supervisor (student research)		
Validated questionnaire [Screening Questionnaire - MFQ]	1	13 August 2019
Validated questionnaire [Session by Session Questionnaire - SMFQ]	1	13 August 2019

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-thehra/governance/quality-assurance/>

HRA Learning

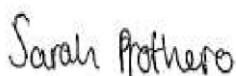
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improvingresearch/learning/>

19/YH/0426

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours
sincerely
pp



Mr Anthony Warnock-Smith

Vice Chair

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

“After ethical review – guidance for researchers”

Copy to: Dr Michael Barber

Lead Nation - England: HRA.Approval@nhs.net **Yorkshire & The Humber - Leeds West Research Ethics Committee**

Attendance at Committee meeting on 13 December 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Dr Rhona Bratt	Retired Multimedia Project Manager	Yes
Mr Jon Cohen	Partner (Pharmacist)	Yes
Mrs Kerrie Davies	Principal Clinical Scientist	Yes
Dr Martin Elliott	Consultant Paediatric Oncologist	Yes
Miss Aikaterini Katsouraki	Junior Associate	Yes
Ms Sarah Kirkland	Clinical Studies Officer	Yes
Dr Vera Neumann	Retired Consultant in Rehabilitation Medicine	Yes
Mrs Hannah-Claire Newman	Cardiology Research Nurse	Yes
Dr Bing-Chiu Pang	GP	No
Dr Susan Partridge	Teaching Fellow in Biomechanics	Yes
Dr Vishal Sharma	Research Fellow/PhD Student	No
Mr Anthony Warnock-Smith	Retired solicitor	Yes

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Sean O'Halloran	Observer
Miss Sarah Prothero	Approvals Officer
Mr Alex Thorpe	Approvals Manager

HRA APPROVAL LETTER



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales



Miss Lucy Tindall

The Department of Health Sciences

Email: hra.approval@nhs.net

HCRW.approvals@wales.nhs.uk

The University of York

York

YO10 5DD

03 January 2020

Dear Miss Tindall

HRA and Health and Care

Study title:	Computerised Behavioural Activation Programme for the treatment of depression in young people: Feasibility Study
IRAS project ID:	270172
Protocol number:	N/A
REC reference:	19/YH/0426
Sponsor	University of York

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the “Information to support study set up” section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "[After Ethical Review – guidance for sponsors and investigators](#)", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **270172**. Please quote this on all correspondence.

Yours sincerely,

Alex Thorpe

Approvals Manager

Email: hra.approval@nhs.net

Copy to: **Dr Michael Barber, Sponsor's Representative** **List of Documents**

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters [GP letter]	1	13 August 2019
GP/consultant information sheets or letters [GP contact form]	1	13 August 2019
IRAS Application Form [IRAS_Form_14112019]		14 November 2019
IRAS Application Form XML file [IRAS_Form_14112019]		14 November 2019
IRAS Checklist XML [Checklist_14112019]		14 November 2019
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Non-validated questionnaire [Short Evaluation Questionnaire]	1	22 August 2019
Non-validated questionnaire [Long Evaluation Questionnaire]	1	22 August 2019

Organisation Information Document		
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Schedule of Events or SoECAT [SoE]	1	04 December 2019
Summary CV for Chief Investigator (CI) [CV]		
Summary CV for supervisor (student research)		
Summary CV for supervisor (student research)		
Summary CV for supervisor (student research)		
Validated questionnaire [Screening Questionnaire - MFQ]	1	13 August 2019
Validated questionnaire [Session by Session Questionnaire - SMFQ]	1	13 August 2019

IRAS project ID	270172
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Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
<p>All sites will perform the same research activities therefore there is only one site type.</p>	<p>Organisations will not be required to formally confirm capacity and capability, and research procedures may begin after provision of the local information pack, provided the following conditions are met.</p> <ul style="list-style-type: none"> - You have contacted participating NHS organisations (see below for details). - HRA and HCRW Approval has been issued. - The NHS organisation has not provided a reason as to why they cannot participate. - The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. <p>You may now provide the local information pack for your study to your participating NHS organisations in England and/or Wales. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please do so when you are ready. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1</p>	<p>An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.</p>	<p>No study funding will be provided to sites as per the Organisational Information Document.</p>	<p>A Principal Investigator should be appointed at study sites.</p>	<p>No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on enhanced DBS checks and occupational health clearance.</p>

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

The majority of this study will be undertaken within schools or non-NHS premises. However, the applicant has explained that patients may be approached within NHS organisations and that study activities may take place there.

The applicant does not intend to apply for NIHR portfolio adoption.

Abbreviations

A-BAP	Adolescent Behavioural Activation Program
ACT	Acceptance and Commitment Therapy
ADIS-IV	Anxiety Disorders Interview Schedule for DSM-IV - child interview
AM	Activity Monitoring
AS	Activity Scheduling
BA	Behavioural Activation
BA	Behavioural Activation programme by Martell et al (2001)
BALM	Behavioural Activation for Low Mood
BDI-II	Beck Depression Inventory
BT	Behaviour Therapy
CAMHS	Child and Adolescent Mental Health Service
CBT	Cognitive Behavioural Therapy
CCBT	Computerised Cognitive Behavioural Therapy
CDI	Children's Depression Inventory
CDRS-R	Children's Depression Rating Scale – revised
CDS	Children's Depression Scale
CES-D	Center for Epidemiologic Studies Depression Scale
CGAS	Children's Global Assessment Scale
CQC	Care Quality Commission
CRD	Centre for Reviews and Dissemination
CS	Coping Skills
CYP-IAPT	Children and Young People's Improving Accessing to Psychological Therapy
DAWBA	Development and Well-Being Assessment
DfE	Department for Education
DHSC	Department of Health and Social Care
DoH	Department of Health
DSM	Diagnostic and Statistical Manual of Mental Disorders
FA	Fun Activities
FQOLS	The Family Quality of Life Scale–Family Interactions Subscale
GBAT	Group Behavioural Activation Therapy

GDPR	General Data Protection Regulations
GS	Goal Setting
HMIC	Health Management Information Consortium
HRA	Health Research Authority
HRQOL	Health Related Quality of Life
HSRGC	Health Sciences Research Governance Committee
ICD-10	International Classification of Diseases-10
IPT	Interpersonal Therapy
ITT	Intention to Treat
K-SADS	Kiddie Schedule for Affective Disorders
LYPFT	Leeds and York Partnership NHS Foundation Trust
MASC	Multi-Dimensional Anxiety Scale for Children
MDD	Major Depressive Disorder
MFQ	Mood and Feelings Questionnaire
MI	Motivational Interviewing
MINI-KID	Mini International Neuropsychiatric Interview for Children and Adolescents
MM	Mood Monitoring
MRC	Medical Research Council
NDT	Non-Directive Therapy
NHS	National Health Service
NICE	National Institute for Healthcare and Clinical Excellence
NIHR	National Institute for Health Research
PE	Psychoeducation
PI	Principal Investigator
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	Prospective Register of Systematic Reviews
PS	Problem-solving
QoL	Quality of Life
RCMAS	Revised Children's Manifest Anxiety Scale
RCADS	Revised Children's Anxiety and Depression Scale
RCT	Randomised Controlled Trial

REC	Research Ethics Committee
RP	Relapse Prevention
SCARED	Screen for Anxiety Related Emotional Disorders
SCED	Single Case Experimental Design Scale
SDQ	Strengths and Difficulties Questionnaire
SMFQ	Short Mood and Feelings Questionnaire
SPA	Single Point of Access
SWYFT	South West Yorkshire Partnership NHS Foundation Trust
TAU	Treatment as Usual
TEWV	Tees, Esk and Wear Valleys NHS Foundation Trust
UKCRN	United Kingdom Clinical Research Network
VBBA	Values Based Behavioural Activation
WHO	World Health Organisation

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