

Low Intensity Guided Self-Help Interventions: Understanding Change

By

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Declaration

I hereby declare that this work has not been, and will not be, submitted in whole or in part to another University or institution or for the award of any other degree at the University of Sheffield. I confirm that this is my original work and all other sources have been appropriately referenced.

Word Counts

Section One: Literature review	
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Lay summary

Low-intensity interventions (LIIs) aim to reduce mild-moderate distress associated with common mental health problems, such as anxiety and depression. To date, the vast majority of these interventions are based on the principles of Cognitive-Behavioural Therapy (CBT) and are delivered in guided self-help (GSH) or self-help (SH) format. Research shows that CBT based LIIs are effective at reducing anxiety and depression and in some cases are as effective as traditional face-to-face therapy. However, low intensity (LI) CBT does not always work for everyone and for some, the positive effects of LI CBT reduce over time. Offering clients choice about the intervention they receive is important for successful service delivery. Some research shows providing choice can improve therapy outcomes and satisfaction, however, there is currently a lack of choice for LIIs in primary care settings.

Whilst not currently available for use in clinical settings, LIIs that do not rely on the principles of CBT have been developed. The first section of this thesis reviews the literature on these alternative LIIs in the treatment of common mental health problems. Eleven relevant studies were included. Each was assessed for quality; the interventions were described; and findings related to feasibility, acceptability and effectiveness were examined. Largely, these studies were of good quality. Eight studies examined interventions based on psychodynamic therapy (PDT), two used interpersonal psychotherapy (IPT) and one used cognitive analytic therapy (CAT). Most interventions were delivered over the internet with varying levels of support. Except for one, all interventions reduced symptoms to the same extent as LI-CBT and all studies showed that their interventions reduced distress. Many participants did not complete their intervention and this was most common in interventions with lower levels of guidance or support. Where new interventions were examined, these were felt

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to be feasible for use by clinicians and participants. Further research using clinical samples is recommended.

Understanding how interventions lead to positive outcomes (mechanisms of change) is an important area of research which can help to improve interventions and service delivery. The second section of this thesis explored individual change across two different types of GSH interventions (CAT versus CBT). Seventeen individuals with successful outcomes following CAT-GSH and CBT-GSH were interviewed about the changes they had experienced. Results showed no differences in the types of change described, with both groups identifying emotional, behavioural, cognitive and relational changes as a result of their intervention. Using a method called thematic analysis, interviews were analysed and themes from both GSH intervention groups were compared. Regarding mechanisms of change, there were themes common to both groups, including the importance of offering tailored support, having a personal connection with the therapist and being personally committed to change. CAT-GSH completers uniquely reported on the importance of gaining insight to the origins of their anxiety as well as developing relational insight and change. CBT-GSH completers uniquely reported on the importance of understanding anxiety, learning new techniques to cope, and having supportive relationships. Limitations of this study are discussed alongside clinical implications and recommendations for future research.

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Section One

Low intensity interventions for common mental health problems; a systematic

review of approaches and outcomes

Abstract

Objectives. Despite the importance of offering choice in primary care settings, low intensity (LI) cognitive behavioural therapy (CBT) remains the dominant treatment option. This review aimed to explore alternative LI interventions and examine their feasibility, acceptability and effectiveness in treating common mental health disorders.

Methods. A systematic literature search of three databases (PsycINFO, Medline, Socpus) and a grey literature database was conducted. Eleven papers met the inclusion criteria. The Downs and Black (1998) checklist was used to appraise the quality of included papers. Data were extracted and grouped by therapy model.

Results. Eight studies used LI psychodynamic therapy (PDT), two used LI interpersonal psychotherapy and one used LI cognitive analytic therapy in the treatment of depression and anxiety disorders. Interventions were largely deemed comparable to LI-CBT and superior to waitlist control. Significant improvements were reported in all studies. Participant adherence to treatment varied and was highest in face-to-face interventions.

Conclusions. LI interventions, particularly LI-PDT appear effective at reducing mild-moderate distress associated with depression and anxiety disorders, however, the paucity of available studies limits stronger conclusions being drawn.

Practitioner points

- Alternative therapeutic models show promise in their applicability for GSH or SH format
- Alternative LI interventions remain an under researched area

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• Reliance on community samples limits generalizability into clinical populations

Limitations

- Included papers were not assessed for eligibility by an independent reviewer and are vulnerable to evidence selection bias
- The review may be influenced by publication bias
- Interpretation and synthesis of the findings may be subject to researcher bias

Key words: Guided self-help, self-help, low-intensity, systematic review

Introduction

Low intensity psychological interventions

Low-intensity interventions (LII) aim to provide effective and cost-effective care within primary care settings (Cuijpers & Schuurmans, 2007; Gellatly et al., 2007). Recommended by the National Institute for Clinical Excellence (NICE) for the treatment of common mental health problems (NICE, 2011), they are typically based on principles and theory of CBT due to the easily adaptable nature of the model to fit into an LII structure (Turpin, 2010). These 'least restrictive' interventions are widely utilised as part of a stepped care approach for the treatment of mild to moderate anxiety and depression, in which risk and need dictate more intensive interventions. An example of a stepped care approach is the Improving Access to Psychological Therapies (IAPT) programme which delivers LII through a range of methods, including one-to-one or group formats. Some are delivered via remote methods such as email or telephone while others rely on weekly face-to-face sessions. Some interventions are classed as 'guided' and provide access to a professional, a trained coach, or layperson, whereas self-guided interventions encourage the client to selfmanage their symptoms using a range of materials.

Guided Self-Help (GSH).

GSH interventions used within UK primary care services, are defined as selfadministered interventions involving CBT-based resources with limited support from a health care professional. They are delivered by trained clinicians, such as Psychological Wellbeing Practitioners (PWPs) who engage the client in the use of CBT self-help materials. Clinicians help to identify and manage barriers to treatment progress and administer sessional outcome measures to measure progress and outcomes over the course of treatment. GSH interventions are delivered face-to-face, over the telephone or via email (National Collaborating Centre for Mental Health, 2011). They are effective at addressing mild-moderate mental health problems in a primary care setting (Andrews et al., 2018; Cuijpers et al., 2008) and they are comparable in efficacy to face-to-face CBT (Andersson et al., 2013; Andersson et al., 2014; Cuijpers et al., 2010).

Computerised GSH interventions, also known as internet-delivered CBT (ICBT), deliver CBT materials over the internet. Clients log in regularly to a secure website where they can read online and download CBT self-help (SH) materials which have been arranged into a series of modules. Homework assignments are set at the end of each module and the expectation is that these are completed before the next module is available. Clinician contact varies across interventions but typically comprises weekly email contact following the submission of a homework task. Guided ICBT has been found to be effective in the treatment of mild to moderate depression and anxiety (Andersson & Cuijpers, 2009; Andrews et al., 2018; Cuijpers, et al., 2010) and comparable to face-to-face CBT (Andersson et al., 2014; Olthius et al., 2016; van Straten et al., 2008).

Self-Help

SH interventions typically utilise CBT based materials to facilitate symptom improvement and require clients to self-manage their treatment and complete tasks without significant support from a healthcare professional. Standardised materials are delivered in the form of a workbook or over the internet and enable clients to flexibly and independently help themselves. Examples of SH interventions include self-help books or SH resources alongside symptom monitoring where professional contact is brief with no focus on the therapeutic relationship or support. Although dropout rates are generally higher in SH interventions compared with GSH interventions; SH interventions are still effective at reducing distressing symptoms associated with common mental health problems (Spek et al., 2007), furthermore, SH treatment with minimal professional contact can be considered comparable to face-to-face therapies for the treatment of anxiety (Hirai & Clum, 2006).

In both SH and GSH interventions, reduced therapist contact results in the individual becoming the agent of change (Rogers et al., 2004), for some this role is misunderstood and ambivalence about this responsibility can be common, likely reflecting the dominant medical context where clients do not take a highly active role (Khan et al., 2007). Indeed, this may account for increased drop out rates seen in low-intensity interventions. The minimal therapeutic relationship in these formats also implies greater weight to the "scientific ingredients" of the therapeutic model as the mechanism of change. The learning of specific skills and techniques to tackle problems through therapy is thought to be a mechanism of change for individuals (Amos et al., 2019). LI formats such as those based on CBT, lend themselves well to the teaching of behavioural techniques and new ways of thinking to bring about change.

Limitations of low intensity CBT interventions

The use of LI-CBT in primary care services has vastly improved access to psychological therapies in the community (Martinez & Williams, 2010) however, there are limitations to its utility. There is mixed evidence regarding the durability of LI-CBT (Delgadillo et al., 2018) and whilst some studies report that treatment gains are maintained at follow-up (Andrews et al., 2010); a recent longitudinal study (Ali et al., 2017; Delgadillo et al., 2018) found high rates of relapse and symptom recurrence in LI-CBT completers after 12 and 24 months. This study identified that 53% of cases relapsed within one year, with the majority (79%) relapsing within the first six months. After two years, only 34% had maintained their remission status. High rates of dropout can be seen in primary care services offering LI-CBT; rates in IAPT for 2017-2018 were 45% (McInnes, 2018). There are also questions about acceptability for LI-CBT; in a systematic review examining the acceptability of ICBT, Kaltenthaler et al. (2008) found a mean dropout rate of 32% (range 0 to 75%) in studies evaluating ICBT interventions. Few studies recorded dropout reasons and acceptability and satisfaction data was only collected from intervention completers, making it hard to determine whether dropout was a true indicator of acceptability. A recent review by Cuijpers et al. (2019) determined that whilst CBT-GSH was as effective as individual or group CBT in the treatment of depression, it was significantly less acceptable when acceptability was measured using dropout rates. The authors also found CBT-GSH to be less acceptable than care-as-usual and waitlist control comparisons. However, it is not always possible to determine how many participants drop out of interventions or studies because of dissatisfaction or whether they chose to end therapy because they had improved enough to drop out.

Although the evidence for CBT in the treatment of anxiety and depression for many is strong, CBT is not always the most suitable treatment option for *all* (Lemma & Fonagy, 2013). For example, the focus in CBT on correcting "faulty thinking" may be viewed as being critical or disrespectful (Ryle, 2012), particularly in individuals sensitive to criticism due to harmful, previous interpersonal experiences. When examining participant perceptions of 'minimal' psychological therapies, Macdonald et al. (2007) identified that many participants were seeking insight into the cause and development of their current difficulties. Participants felt this was largely unaddressed within the CBT-based interventions they received, with their interventions focusing largely on symptom resolution.

Evidence for culturally adapted low-intensity interventions

Low-intensity interventions have largely been developed for and studied in highincome countries with participants from white, euro-centric populations i.e., UK and Europe, USA and Australia. Evidence suggests they are less effective for people with a differing cultural or ethnic background (Karyotaki et al., 2018). In recent years there have been increasing efforts to adapt low-intensity treatments making them culturally appropriate for a range of populations specifically those in low-middle income countries, for indigenous people, migrants, and refugees (Spanhel et al., 2021). There is encouraging evidence to suggest these adapted LIIs can be effective at manging psychological distress (Bryant et al., 2017; Rahman et al., 2016; Sijbrandij et al., 2017), particularly when the extent of cultural adaptation is greater (Soto et al., 2018).

Providing choice in low-intensity interventions

Healthcare providers are encouraged to offer people choice in their psychological treatment (Department of Health, 2005; NICE, 2018a). Using the UK as an example, clients can choose the time, location and delivery mode of therapy they receive (Irvine et al., 2021) but not always the intervention. Providing people with their preferred treatment has been found to improve the outcomes in some studies (Kocsis et al., 2009; Swift et al., 2018; Swift & Callahan, 2009; Williams et al., 2016).

There is a strong evidence base for therapies, such as psychodynamic psychotherapy (PDT), cognitive analytic therapy (CAT), interpersonal psychotherapy (IPT) in the treatment of common mental health disorders (Cuijpers et al., 2016; Hallam et al., 2021; Steinert et al., 2017). Therapies derived from CBT, often referred to as 'third wave' therapies i.e., compassion focussed therapy (CFT) and acceptance and commitment therapy (ACT) also have a strong evidence base in the treatment of a range of mental health difficulties (Craig et al., 2020; Gloster et al., 2020). However, very few LIIs utilise these psychological models in routine clinical practice. In recent years there has been emerging research into the development of LIIs using psychological models outside of CBT, however, none are currently available for use within primary care services in the UK.

What alternative low-intensity therapies have to offer

Mental health services struggle to meet increased demands and the number of people accessing mental health services in England has risen by a third over a five-year period (Trade Union Congress, 2018). An obvious advantages of offering alternative LIIs is their potential to create positive change for individuals experiencing common mental health problems whilst reducing demands services.

The availability of alternative, evidence-based therapies also helps to address the shortfalls of CBT. Brief interventions that consider developmental processes and causes of an individual's mental health difficulties, in addition to offering ways to reduce symptoms in the here and now could be very advantageous. Alternative interventions based on psychoanalytic principles such as CAT, IPT and PDT offer something different to CBT and third wave therapies, a key difference being the focus on past and present relationships in the cause and maintenance of mental health difficulties rather than cognitions and behaviour. As evidenced by Macdonald and colleagues (2007), clients may be looking for an LII that offers something deeper with more personal insight; perhaps this is what analytic based LIIs can help to provide.

Rationale

Analytic based interventions using therapeutic models such as CAT, PDT and IPT have been developed in LI format to improve a range of common mental health difficulties such as anxiety and depression, however at the time of writing, to the author's knowledge there are no systematic reviews exploring these studies. It is unclear whether these novel interventions offer a feasible or suitable alternative to CBT LIIs in primary care services. Considering evidence indicating questionable acceptability and high relapse rates in CBT-GSH in IAPT (Ali et al., 2017) it is important to determine whether other LIIs can offer an acceptable and effective alternative for use within a primary care setting. Having alternative LIIs that are comparable in effectiveness to CBT-based treatments would enable choice where CBT-based interventions are not suited or in line with clients' preference.

Objectives

This review had three objectives:

- 1. Provide an overview of LII treating common mental health disorders in an adult population, outside of those utilising CBT-based or third wave principles
- Review the quality of studies examining LII treating common mental health disorders in an adult population, outside of those utilising CBT-based or third wave principles
- Examine the feasibility, acceptability and effectiveness of LII treating common mental health disorders in an adult population, outside of those utilising CBTbased or third wave principles, compared to LI-CBT, where available.

Method

The synthesis without meta-analysis (SWiM, Campbell et al., 2020) reporting guidelines were used to inform this review.

Protocol

A predefined protocol was developed prior to the systematic review being conducted (Appendix A).

Information sources

A database search of peer-reviewed journals by title, abstract and key terms was completed using Scopus, Medline and PsycINFO. Grey literature was explored using OpenGrey, Searches took place during January 2021. Reference sections of relevant papers were examined, forward and backward citation searches were also conducted.

Search strategy

Search terms were organised using the PICO framework

(Population/Intervention/Comparator/Outcome; Methley et al., 2014). Boolean operators AND, OR and NOT were used to combine the elements "intervention", "comparator" and "outcome". Search terms included can be found in Table 1.

Table 1

Search Terms Used for Systematic Literature Search

Intervention	"self-help" "unguided self-help" "guided self-help" "low-
	intensity intervention" "analytic*" "psychodynamic"
	"psychodynamic therapy" "cognitive analytic* therapy" "CAT"
	"interpersonal psychotherapy" "IPT" "schema therapy"
Comparator	"CBT" "cognitive behavio* therapy"
Outcome	"depressi*" "anxiety" "anxiety disorder*" "common mental
	neatin disorder

Study selection

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; 2009) guidelines for systematic reviews were followed to support the systematic identification of papers for this review (Moher et al., 2009). All studies identified were imported into reference management software, Mendeley, and duplicates were removed. Study titles and abstracts were examined and those not reaching eligibility criteria were excluded. The full texts of the remaining articles were retrieved and screened for eligibility against inclusion and exclusion criteria (Table 2).

Table 2

Inclusion criteria	Exclusion criteria
Studies evaluating a self-help or guided	Studies evaluating a CBT or third-wave CBT
self-help intervention which was not	intervention
based on CBT or third-wave principles	
The intervention was aimed at common	The intervention was not based on a clear
mental health problems such as	theoretical model
depression or anxiety disorders	
The intervention involved a dedicated	The intervention was not clearly described
component encouraging the individual	
to partake in activities tailored towards	
positive change	
The study only contained data from	The intervention's focus was medication
adult participants.	adherence or education with no aim to reduce
	symptoms
	The intervention was aimed at something other
	than a common mental health disorder
	The study included child participants
	Review papers
	Theoretical or discussion pieces

Inclusion and Exclusion Criteria

Data extraction

Key data were extracted from the final sample of papers selected for the review. Extracted data included the study source (author, year of publication, and publication), study design, participant and recruitment details (country of recruitment, recruitment source, sample size, mental health problem), intervention (type, duration, follow-up period, therapeutic model, delivery method and comparison intervention), outcomes (primary and secondary outcome measures), and key findings including effect sizes where reported.

Risk of Bias

An adapted Downs & Black Checklist (1998) for assessing the quality of randomised and non-randomised studies of health care interventions was used to systematically assess the reliability of final papers selected for the review (Appendix B). The checklist assesses validity and confounding bias potentially present in randomised and non-randomised studies (including quasi-experimental studies) across 27 items. The items are divided into reporting quality (1-10), external validity (11-13), bias (14-20), confounding (21-26) and power (27). The checklist has good internal consistency (KR20 = .89), inter-rater reliability (r = .75) and test-retest reliability (r = .88) (Downs & Black,1998). The range of possible scores was 0-28, in line with previous studies, item 27 was modified with a score of '1' indicating that statistical power had been reported and '0' if not (Hooper, Jutai, Strong, & Russell-Minda, 2008). The majority of items are scored as 0 or 1 (0 indicating 'no' or 'unable to determine' and 1 indicating 'yes'). Question 5 is scored as 0, 1, or 2 (0 indicating 'no', 1'partially' and 2 'yes'). The total scores were categorised to indicate the level of quality for each study; excellent (26-28); good (20-25); fair (15-19) and poor (<14) (Hooper, Jutai, Strong, & Russell-Minda, 2008).

An independent rater with experience utilising the Downs and Black checklist and blind to the first author's ratings, quality assessed 20% (n = 3) of the studies selected at random. The intra-class correlation (ICC) was calculated using the statistical software package, SPSS version 25. Based on previous studies (Fleiss, 1986) an ICC of > 0.75 indicated excellent inter-rater reliability. Interrater reliability was found to be excellent, ICC = 0.91, 95% CI [0.87, 0.95], F (80,80) = 11.99, p <.001. Disagreements were discussed until an agreement was reached. Items causing disagreement were reviewed for the remaining studies and ratings were adjusted based on the consensus agreed with the second marker.

Results

Study selection

Databases were searched systematically using search terms listed above, resulting in 3759 identified papers. After duplicates were removed, titles and abstracts were examined to screen all remaining papers using the inclusion and exclusion criteria. Forward citation searches were conducted using Google Scholar and reference lists of eligible papers were examined resulting in four further papers being identified. Fifty full-text articles were assessed for eligibility. Of these, 12 did not utilise interventions with a clear theoretical model, seven evaluated a CBT-based intervention, nine evaluated third-wave low-intensity interventions and 11 were neither GSH nor SH resulting in n = 11 papers being included in the final synthesis. The selection process, from identification through to inclusion is represented in the PRISMA diagram in Figure 1.

Figure 1.

Literature and review process flow diagram (Moher et al., 2009)



Study characteristics

Study characteristics and interventions are described in Tables 3 and 4. Overall, 11 studies included 2424 participants accessing SH or GSH interventions for common mental health problems. Sample sizes ranged from 11 to 1843 participants with overlapping data found in two studies (Johansson et al., 2013a; Lindegaard et al., 2020). Studies examined interventions for depression (n=4), anxiety disorders (n=5), mixed anxiety and depression (n=1) and other mixed diagnoses (n=1). Most (n=8) used an RCT design, two explored a patient preference study design and one a small n design. Samples were largely recruited from a general population sample (n=9) with two studies utilising clinical samples. A range of outcome measures were used dependent on the aims of the study, country and mental health diagnosis.

Quality appraisal

Final quality ratings for each study can be found in Appendix C.

Most studies (n = 7) were of good quality, three were of fair quality (Johansson et al., 2013a; Lindegaard et al., 2020; Meadows & Kellett, 2017) and one study was deemed poor quality (Lemma & Fonagy, 2013). All studies with a good rating were RCTs. Reporting was a strength in most studies; all studies reported clear hypotheses, characteristics of outcome measures, interventions and inclusion criteria. All studies reported findings in sufficient detail including random variability estimates. Most studies described main confounding variables, with two exceptions (Lemma & Fonagy, 2013 and Meadows & Kellet, 2017) and all studies who included a follow-up within their study described the participant characteristics of those lost to follow-up. All but two studies reported the exact probability values of main outcome measures (exceptions were Johansson et al., 2012 and Johansson et al., 2013b). Two studies measured adverse events (Johansson et al., 2013a; Johansson et al., 2017).

External validity was poor overall with only one study scoring full points for these items (Zwerenz et al., 2017). One further study clearly demonstrated that their participants were representative of the population of interest (Donker et al., 2013) and in two studies the delivery of the intervention was representative of treatment that most clients would receive (Donker et al., 2013; Meadows & Kellett, 2017), it was not possible to determine these items in the remaining studies.

Table 3

Study Characteristics

Study (date) Country	Sample size (N)	Age range (years) % Female	Design	Population	Recruitment method	Primary and secondary outcome measure/s
Psychodynamic t	herapy					
Johansson et al. (2013a) Sweden	44	21-65 68%	PPT	Community	Waitlist control group from Johansson et al. (2012)	BDI-II Adherence, attrition, PHQ-9, MADRAS-S
Lemma & Fonagy (2013) United Kingdom	24	20-51+ 76%	RCT	Community	Online forum	PHQ-9, GAD-7
Andersson et al. (2012) Sweden	81	19-66 77%	RCT	Community	Website or national newspaper advert	PSWQ, GAD-Q-IV, STAI, BDI-II
Johansson et al. (2012) Sweden	92	21-73 75%	RCT	Community	National newspaper advert, depression treatment trial waitlist	BDI-II, PHQ-9, MADRAS-S, BAI, GAD- 7, QOLI

Study (date) Country	Sample size (N)	Age range (years) % Female	Design	Population	Recruitment method	Primary and secondary outcome measure/s
Lindegaard et al. (2020) Sweden	36	20-72 69%	PPT	Community	Waitlist control group from Johansson et al. (2017)	LSAS-SR PHQ-9, GAD-7, CGI-I, WAI-S, IIP-64
Johansson et al. (2017) Sweden	72	20-71 61%	RCT	Community	Newspaper and social media adverts	LSAS-SR CGI-I
Johansson et al. (2013b) Sweden	100	19-77 82%	RCT	Community	Internet and newspaper adverts	PHQ-9, GAD-7, EPS-25, FFMQ
Zwerenz et al. (2017) Germany	69	Missing 71%	RCT	Clinical	Inpatients and outpatients from Department of Psychosomatic Medicine and Psychotherapy	CSQ-8, ERSQ, GAD-7, PHQ-9, CDS-2, EUROHIS-QOL-8, RSW, SSS-8
Interpersonal Psychotherapy						
Donker et al. (2013) International	1843	18-55+ 72%	RCT	Community	Online recruitment via e-couch internet website	CES-D, CSQ-8, adherence

Study (date) Country	Sample size (N)	Age range (years) % Female	Design	Population	Recruitment method	Primary and secondary outcome measure/s	
Dagöö et al. (2014) Sweden	52	20-65 52%	RCT	Community	Internet and national newspaper advert	LSAS-SR, SPS, SAIS, BAI, MADRAS-S, QOLI	
Cognitive analyti	c therapy						
Meadows & Kellett (2017) United Kingdom	11	24-57 59%	Small <i>n</i>	Clinical	Patients receiving treatment at 'Step 2' IAPT	GAD-7, PHQ-9, WSAS, practitioner interviews	
Note: $BAI = Beck$	x Anxiety Inv	ventory, BAI = B	Beck Anxiety I	nventory, BDI-II = Be	eck Depression Inventory se	econd edition, CDS-2 = Cambridge	
Depersonalisation	n Scale, CE	S-D = Center for	r Epidemiolo	gical Studies Depress	on Scale, CGI-I = Clinical	Global Improvement, CSQ-8 =	
Client satisfaction questionnaire, EPS-25 = Emotional Processing Scale, ERSQ = Emotion Regulation Skills Questionnaire, EUROHIS-QOL-8							
= European Health Interview Survey Quality of Life 8-item index, FFMQ = Five Facets of Mindfulness Questionnaire, GAD-7 = Generalized							
Anxiety Disorder 7, GAD-Q-IV = General Anxiety Disorder Questionnaire IV, IIP-64 = Inventory of Interpersonal Problems, LSAS-SR =							
Liebowitz Social	Liebowitz Social Anxiety Scale-self report, MADRAS-S = Montgomery-Asberg Depression Rating Scale – Self Report, MDI = Major Depression						

Inventory, PHQ-9 = 9-item Patient Health Questionnaire, PPT = Patient Preference Trial, PSWQ = Penn State Worry Questionnaire, QOLI = Quality of Life Inventory, RCT = Randomised Control Trial, SIAS = Social Interaction Anxiety Scale, SPS = Social Phobia Scale, SSS-8 = Somatic Symptom Scale, STAI = State-trait Anxiety Inventory, WAI-S = Working Alliance Inventory, WSAS = Work and Social Adjustment Scale

Table 4

Description of interventions and comparators

Study (date)	Length (weeks)	Delivery and type	Guidance	Diagnosis	Intervention	Comparator
Psychodynamic therap	ру			U		i
Johansson et al. (2013a)	10	Online GSH	As original study (13.2 minutes per client per week)	Depression	PDT	ICBT
Lemma & Fonagy (2013)	8	Online group GSH	1 hour per week	Depression	DIT	a) Online group plus SH b) online well- being site
Andersson et al. (2012)	8	Online GSH	Weekly feedback totalling 113	Generalised Anxiety Disorder	PDT	a) ICBT b) WLC
Johansson et al. (2012)	10	Online GSH	Treatment group Average 13.2 minutes per week Active control group - basic weekly messages	Depression	PDT	a) Onlinepsychoeducationb) scheduledsupport
Lindegaard et al. (2020)	10	Online GSH	15 minutes per week	Social anxiety disorder	Affect- focussed PDT	ICBT

Study (date)	Length (weeks)	Delivery and type	Guidance	Diagnosis	Intervention	Comparator	
Johansson et al. (2017)	10	Online GSH	10-15 minutes per week via text messages.	Social anxiety disorder	Affect- focussed PDT	WLC	
Johansson et al. (2013b)	10	Online GSH	9.5 minutes per week	Depression or anxiety	Affect- focussed PDT	WLC with weekly therapist contact	
Zwerenz et al. (2017)	10	Online SH	Brief feedback via web- based platform	Mixed	PDT	WLC	
Interpersonal Psychot	therapy						
Donker et al. (2013)	4	Online SH	Automated. No therapist input.	Depression	IPT	a) e-couch b) active control (MoodGYM)	
Dagöö et al. (2014)	9	GSH via smart phone	15 minutes feedback per participant, per week	Social Anxiety Disorder	IPT	mCBT	
Cognitive analytic therapy							
Meadows & Kellett (2017)	6 weeks	Face to face GSH	35-minute weekly support.	Anxiety	CAT	None	

Note: CAT = Cognitive Analytic Therapy, DIT = Dynamic Interpersonal Therapy, GSH = Guided Self-Help, ICBT = Internet-based Cognitive Behavioral Therapy,IPT = Interpersonal Psychotherapy, mCBT = Cognitive Behavioral Therapy via mobile computer PDT = Psychodynamic Therapy, SH = Self-Help, WLC = Waitlist Control Participant blinding was not undertaken by any study and blinding of researchers measuring main outcomes was only demonstrated by one study (Andersson et al., 2012). All studies reported analyses clearly indicated from the outset and used appropriate statistical techniques. All studies with control groups who included a follow-up had the same follow-up period for participants. Most studies demonstrated that their outcome measures were reliable and valid, however in three studies this was not possible to determine (Johansson et al., 2013a; Johansson et al., 2012; and Lemma & Fonagy, 2013).

Regarding selection bias, besides Meadows & Kellet (2017) who had no control group, all studies recruited control groups from the same population at the same time. Of the eight studies that randomised participants into intervention groups, all studies clearly described the method of randomisation. Four studies demonstrated that the randomised intervention assignment was concealed from participants and health care staff until after recruitment was complete (Andersson et al., 2012; Johansson et al., 2012; Johansson et al., 2017 and Donker et al., 2013). All studies made adequate adjustment for confounders through use of intention-to-treat analysis and all studies that recorded follow-up data took losses into account. Just over half of the studies (n = 6) described their power analysis.

Delivery method

The delivery method of GSH and SH interventions varied across the studies. Most studies (n = 9) examined web-based interventions. One study examined an intervention delivered via mobile technology (Dagoo et al., 2014) and one study examined a face-to-face intervention (Meadows & Kellett, 2017).

Treatment comparators

Comparison groups varied; some included multiple comparison groups (n = 3), others used one (n = 7) or no comparison group (n = 1). Comparators included CBT interventions, i.e., i-CBT (n = 5), online support with general psychoeducation (n = 1), variations of the same treatment with less or no guidance (n = 1), or waitlist control with delayed treatment (n = 4).

Interventions

The eleven papers examined GSH and SH interventions based on psychodynamic or analytic therapy approaches. These included psychodynamic therapy (PDT; n = 8), interpersonal psychotherapy (IPT; n = 2) and cognitive analytic therapy (CAT; n = 1). The eight PDT studies based their interventions on three existing treatment protocols. Lemma and Fonagy (2013) utilised a similar protocol and structure to that of standard face-to-face dynamic interpersonal therapy (DIT) for their online group dynamic interpersonal therapy for depression. Their approach formulated distress as a response to interpersonal difficulties and perceived threats to attachments. The programme aimed to improve participants' capacity to tolerate and understand attachment related interpersonal threats by improving the capacity to reflect on their own thoughts and feelings. Self-help materials were sent weekly and participants were encouraged to take part in self-reflection and discuss reflections with group members online to meet therapeutic goals.

Three internet-based psychodynamic therapies (IPDT) for the treatment of anxiety (Andersson et al., 2012) and depression (Johansson et al., 2013b; Johansson et al., 2012) were based on a Swedish adaptation of the self-help book 'Make the Leap' (Silberberg, 2005). The programme consisted of eight modules however Johansson et al. (2012, 2013b) included a relapse prevention module. The treatment included a program called SUBGAP; (1) seeing unconscious patterns that contribute to emotional difficulties; (2) understanding these patterns; (3) breaking from unhelpful patterns; (4) guarding against patterns in the future.

Four further studies assessed the use of IPDT in samples with mixed anxiety and depression (Johansson et al., 2013a), social anxiety disorder (SAD) (Johansson et al., 2017; Lindegaard et al., 2020) and a sample with mixed diagnoses (Zwerenz et al., 2017). This intervention was based on the translated self-help book 'Live Like you Mean it' (Frederick, 2009) and was framed as "affect-focussed psychodynamic psychotherapy" under the overarching concept of "emotional mindfulness" (Frederick, 2009). The intervention taught participants to mindfully pay attention to their emotional experience through a range of "insight oriented" and skills-based exercises. The treatment held four therapeutic stages; (1) enhancing awareness to emotions and defences (2) regulating emerging anxiety related to feared emotions (3) fully experiencing one's feelings and (4) mindfully expressing feelings to others. The stages were presented online and included a variety of exercises and homework tasks. Both studies examining SAD (Johansson et al., 2017; Lindegaard et al., 2020) included an addition module focussed on self-compassion and working with shame.

Interpersonal Psychotherapy

Two RCTs explored the use of IPT. One used mobile technology to deliver IPT-GSH (mIPT) for SAD, over nine weeks (Dagoo et al., 2014) and another used the internet to deliver IPT- SH (i-IPT) for depression, over four weeks (Donker et al., 2013). Both interventions addressed the four problem areas of IPT treatment; grief, interpersonal disputes, role transitions and interpersonal sensitivity (Weissman et al., 2000) however, only IPT-SH was based on a clinician's manual of IPT (Weissman, et al., 2007).

Cognitive Analytic Therapy

One small *n*-design study (Meadows & Kellett, 2017) developed and piloted a CAT-GSH intervention for anxiety. The intervention mirrored the three phases of CAT; reformulation, recognition and revision (Ryle & Kerr, 2008) in a six-session framework. The modules included 'identifying the current patterns of your anxiety'; 'the roots of my anxiety'; 'linking my past to my present'; 'making a roadmap of my problems and how to make exits'; developing a new, healthy and more flexible you'; ending and preparing for the future.

Summary of main findings

Efficacy and effectiveness

Three of the studies (Andersson et al., 2012, Johansson et al., 2013a; Lindegaard et al., 2020) compared IPDT with ICBT and found their interventions to be comparable in respect to outcomes on their primary outcome measure, at posttreatment.

Comparing ICBT and IPDT for depression, Andersson et al. (2012) and Johansson et al. (2013a) noted small and insignificant between-group effect sizes at post treatment (d = 0.14; 95% CI: -0.50 to 0.78 and d = 0.33; 95% CI: -0.42 to 1.07 respectively). Johansson et al. (2013) found similar within-group effect sizes (ICBT: d= 1.04; 95% CI: 0.61 – 1.48, IPDT: d = 1.06; 95% CI:0.45 – 1.67) post treatment. Examining IPDT for SAD, Lindgaard et al. (2020) found small and insignificant between-group effect sizes (d = 0.22; 95% CI: -0.30 to 0.74) in favour of the ICBT group. ICBT and IPDT groups had comparable within-group effect sizes (d = 0.53; 95% CI:-0.29 to 1.31 and d = 0.40; 95% CI: -0.21 to 0.99 respectively) and their intention-to-treat analysis demonstrated no significant difference between the two treatment groups on any of the secondary outcome measures used at post-treatment or follow-up.

Comparing an internet-based IPT SH intervention with an equivalent ICBT intervention for depression; Donker et al. (2013), found i-IPT to have similar withingroup effect sizes post-treatment concluding that the interventions were comparable (ICBT: d = 0.87; 95% CI:0.65 to 1.09, i-IPT: d = 0.76; 95% CI:0.56 to 0.96). When comparing i-IPT with their CBT-based control treatment (MoodGYM) they found a non-significant and small effect in favour of MoodGYM (d = 0.14; 95% CI: -0.06 to 0.35).

When comparing mobile administered IPT (mIPT) to mobile phone administered CBT (mCBT) Dagoo et al. (2014) found mCBT resulted in better outcomes overall. Between-group effect size was moderate in favour of mCBT (d =0.64; 95% CI:0.06 to 1.22) however, the mIPT intervention was still considered effective at reducing anxiety with the treatment group showing a small yet significant effect (d = 0.43; 95% CI:0.09 to 0.77).

Two studies compared their treatment intervention with an active control group (Lemma & Fonagy, 2013; Johansson et al., 2012). Due to the small sample size (n =15), Lemma & Fonagy (2013) combined their control groups for comparison with their therapist-facilitated intervention group. They found a significant reduction on both anxiety and depression outcomes scores in their intervention group (depression: t = 2.04, df = 15, p = 0.03 and anxiety: t = 3.34, df = 15, p = 0.02). They also looked at percentage of participants scoring below the clinical cut off (recovery) and found the percentage of participants reaching recovery was slightly higher (depression) and substantially higher (anxiety) in the therapist facilitated group, however due to the small sample size, these were not significant.
Johansson et al., (2012) compared their IPDT treatment group for depression with an online supportive treatment programme. Between-group effect sizes were large (d = 1.11; 95% CI:0.67 to 1.56) in favour of the IPDT group. Within-group effect sizes were large for both treatment and active control groups (IPDT: d = 2.18; 95% CI: 1.49 to 2.86, active control: d = 0.84; 95% CI: 0.46 to 1.21).

Three studies compared their treatment group with waitlist control (WLC) (Johansson et al., 2013b; Johansson et al., 2017 and Zwerenz et al., 2017).

Johansson et al., (2013b) compared their IPDT intervention group for depression with a WLC group having weekly therapist contact for symptom monitoring and basic support. They found substantial within-group effects on depression at post treatment, for both IPDT and WLC groups (IPDT: d = 1.93; 95% CI: 1.31 to 2.55, WLC: d = 0.69; 95% CI: 0.40 to 0.97). The between-group effect size was significant and large (d = 0.77; 95% CI: 0.37 to 1.18) in favour of the IPDT group.

When compared with an inactive WLC group, Johansson et al. (2017) found a large, between-group effect size (d = 1.05; 95% CI: 0.62 to 1.53) in favour of an affect-focussed IPDT-GSH intervention on depression scores. Pre-post within-group effect size was also large in this intervention group (d = 1.45; 95% CI: 1.06 to 1.87).

Zwerenz et al. (2017) looked at patient satisfaction as their primary outcome and these results will be discussed in the feasibility section below. Significant effects were found for depression¹ (d = 0.60), emotional competence (d = 0.49) and quality of life (d = 0.53) compared with WLC.

¹ Confidence intervals were not provided by the authors

Maintenance of treatment gains at follow-up

Most studies included participant data obtained from follow-up (n = 9) with follow-up periods ranging from one month to 24 months. All studies reported that treatment gains were maintained and remained stable at follow-up, however in one study (Johansson, et al., 2013b) participants reported significant improvement in anxiety symptoms at 7-month follow-up compared to post-treatment (p < .05). Zwerenz et al., (2017), did not report their follow-up results possibly indicating unfavourable results, although this cannot be determined. Further details of maintenance of effects at follow-up can be found in Table 5.

Table 5

Summary of findings

Author (Date)	Adherence (definition)	Summary of outcomes	Maintenance of effects
Psychodynamic therapy			
Johansson at al. (2013a)	(Completed treatment modules) Mean ICBT= 62% (SD = 33.2%) IPDT = 73.8% (SD = 35.8%). This difference was not significant (<i>p</i> = 0.29).	No difference in efficacy between IPDT and ICBT post treatment, both showed improvements ($d = 1.0$). More ICBT participants showed improvement at follow- up. More people completed IPDT. More people chose ICBT however preference strength was not correlated with outcome.	No difference between IPDT compared with ICBT at 7MF-U (IPDT: $n = 5, 35.7\%$; ICBT: $n = 18, 60.0\%$), $\chi 2$ ($n = 44$, df = 1) = 2.25, p = 0.13.)
Lemma & Fonagy (2013)	 (Completed weekly questionnaires) Therapist facilitated group had significantly greater adherence rates 8/8 compared with no facilitation 5.6/8 (<i>p</i> <.03). 	Improvement superior in combined therapist facilitated groups compared to control. Statistically significant reductions in depression $p = 0.009$ and anxiety $p=0.007$ at post treatment. 62.5% were below clinical cut-off for depression post treatment and 75% for anxiety.	N/A
Andersson at al. (2012)	(Completed treatment modules) Average number of completed modules in IPDT was 5.9/8 (SD = 2.2) and in ICBT was 5.1/8 (SD = 2.5)	IPDT and ICBT comparable in outcomes compared to WLC. Difference between two treatment groups was small and insignificant ($d = 0.14$; 95% CI -0.50 to 0.78). ICBT and IPDT had moderate to large within group effects on anxiety at post treatment ($d = 0.87$ and $d = 1.16$ respectively).	At 3MF-U clinically significant change was seen in 29.6% (95% CI: 11.2–48.0%) in PDT group; 44.4% (95% CI: 24.4–64.5%) for the CBT group, and 7.4% (95% CI: – 0.3 to 17.9%) for the waiting list control group. This difference was significant $p =$ 0.009

Author (Date)	Adherence (definition)	Summary of outcomes	Maintenance of effects
Johansson et al. (2012)	(Completed treatment modules) 36/46 participants (78.3%) in the treatment group finished all the modules.	Large and superior pre-post improvements in IPDT compared with active control ($d =$ 1.11 [0.67-1.56]). Active control participants also showed improvement ($d =$ 0.84 [0.46-1.21]).	10MF-U 54.3% IPDT had recovered on the BDI-II. Large within group effect size for IPDT at 10M-FU ($d = 1.94$ [1.41-2.47]
Lindegaard et al. (2020)	 (Completed homework sent to therapist) IPDT 80% ICBT 59% Not significant (p = .08) 65.2% of IPDT completed <i>all</i> modules, 23.1% of ICBT completed <i>all</i> modules Significant (p = .02) 	Moderate within group effect sizes for both ICBT and IPDT ($d = 0.53$ and $d = 0.40$ respectively). 85% of ICBT and 74% IPDT improved but no significant differences between treatment groups on any outcome measure post treatment. Preference strength did not predict adherence, effectiveness or treatment completion.	At 6MF-U there were no differences between groups, 15% of ICBT and 35% of IPDT were recovered but this was not a statistically significant difference.
Johansson et al. (2017)	(Completed treatment modules)7.2/9 (80%)69% participants completed all modules.	Large between-group and within-group effect sizes post treatment ($d = 1.05$ and $d = 1.45$ respectively) on LSAS-SR. Remission rates post treatment were 27.8% for treatment group and 11.1% for WLC. At 24 M-FU remission rate for treatment group was 42.4% [CI 24.1, 60.8]	42% of the treatment group were in remission (30.4% at 6 months, 32.9% at 12 months). No change in PHQ9 at follow up. Continued improvements noted on GAD-7 and LSAS-AR.
Johansson et al. (2013b)	(Completed treatment modules) 42/50 (84%) of participants completed all modules.	Large between group effect-size ($d = 0.77$) on PHQ-9 and moderate ($d = 0.48$) on GAD-7. 52% recovered compared to 24% control.	At 7M-FU 50% of treatment group met threshold for clinical recovery (score of less than 10 on GAD-7 and PHQ-9).

Author (Date)	Adherence (definition)	Summary of outcomes	Maintenance of effects	
Zwerenz et al. (2017)	 (Not defined) Steady decline over time. 36% completed at least half the modules. Participants spent 5 hours per week on average on the program. 	At least 75% felt satisfied with the programme. Rate of completion was low. Moderate between group effect sizes for depression ($d = 0.60$) and QOL ($d = 0.53$	Not reported	
Interpersonal Psychot	herapy			
Donker et al. (2013)	 ((1) completion of post-test surveys, (2) number of treatment modules completed) 30% of all participants completed post-test assessments 49.5% completed at least half of the IPT intervention 27.3% completed all (compared to the CBT group - 37.7% and 	No significant differences between treatment groups on CES-D. Within group effect sizes were large for IPT completers at post and follow-up (d =0.76 and 1.02). IPT completers had significantly lower satisfaction scores compared to other treatments.	At 6M-FU large within-group effect size for i-IPT completers at follow up ($d = 1.02$). Between group effect-size (i-IPT vs active control) at FU: $d = 0.31$, 95% CI 0.02 to 0.60 in favour of i-IPT	
	14.4%).			
Dagöö et al. (2014)	(Completed treatment modules)	Within group effect sizes were small for mIPT (d =0.46). Results remained stable at 3-month follow-up. More participants reached clinically significant improvement in mCBT (55.6%) compared with mIPT (8%)	No significant difference in anxiety scores at follow-up compared to post-treatment for either mCBT or mIPT ($p = 0.47$ and $p = 0.23$ respectively)	
	17/27 (63%) completed all mCBT modules			
	13/25 (52) completed all mIPT modules			

Author (Date)	Adherence (definition)	Summary of outcomes	Maintenance of effects
Cognitive Analytic Therapy			
Meadows & Kellett (2017)	(Number of sessions attended) 10/11 (90%) participants	Significant decrease on GAD-7 at post treatment ($p = 0.009$)	Changes maintained at 4WF-U. Reliable recovery increased to 60% at follow up.
	completed the full six-session treatment	50% were in reliable recovery at post treatment. Intervention found to be feasible	The GAD-7 further reduced (p =0.005).
Note. $3MF-U = 3$ month follow-up, $6MF-U = 6$ month follow-up, $7MF-U = 7$ month follow-up, $12MF-U = 12$ month follow-up, $24MF-U = 24$ month			
follow-up. BDI-II = Beck Depression Inventory second edition, CBT = Cognitive Behavioral Therapy, , CES-D = Center for Epidemiological Studies			
Depression Scale, GAD-7 = Generalized Anxiety Disorder 7, ICBT = Internet-based Cognitive Behavioral Therapy, i-IPT = internet based			
$Interpersonal\ Psychotherapy,\ IPDT = internet-based\ Psychodynamic\ Treatment,\ LSAS-SR = Liebowitz\ Social\ Anxiety\ Scale-self\ report,\ mIPT - and and and and and and and and and and$			
Interpersonal Psychotherapy via mobile computer solutions, mCBT = Cognitive Behavioral Therapy via mobile computer solutions, PDT =			
Psychodynamic Treatment, PHQ-9 = 9-item Patient Health Questionnaire, SD = standard deviation			

Acceptability

Studies assessed acceptability of their intervention through the observation of participant adherence to treatment and dropout rates, this was examined and reported by all studies. Only one study (Lemma & Fonagy, 2013) reported 100% adherence to their intervention, a therapist facilitated online group intervention where eight out of eight weekly reports were submitted. Another intervention with a high adherence rate (10/11 completed all treatment sessions) also had a high level of therapist contact i.e. face-to-face GSH (Meadows & Kellett, 2017). Unsurprisingly, adherence was better in studies examining GSH interventions compared with interventions with no therapist feedback or guidance but there was still large variability across the studies. Further details of adherence rates for each study are reported in Table 3.

Levels of support

Only one study directly compared outcomes in treatment groups with varied levels of support (Lemma & Fonagy, 2013) Despite the small sample size, they were able to determine that participants with access to therapist facilitation showed greater improvement compared to those given access to the same self-help materials without therapist facilitation.

Feasibility

Four studies looked at the feasibility of their intervention, either as the focus of their study or as an additional aim. Overall, these novel interventions were largely found to be feasible as indicated by qualitative feedback from participants and therapists, uptake into treatment and satisfaction questionnaires.

Zwerenz et al. (2017) tested the feasibility of their intervention using the German translated Client Satisfaction Questionnaire (CSQ-8) and found that the majority were mostly (57%, 12/21) or very satisfied (38%, 8/21). More than half (57%, 12/21) said that they would 'definitely' do the program again if they needed help in the future. The authors report that the total mean score (26.33, SD 2.89) for the CSQ-8 was above the cut off (24.5) indicating high treatment satisfaction.

Using a small-scale qualitative design, Lemma and Fonagy (2013), reported that all participants (*n*=8) found their self-help material to be helpful, if not very helpful. Participants reported that the materials helped to provide a "calming" and "structured" way to think about their difficulties. Feedback regarding the therapist facilitated group was less consistent; many (66%) felt the therapist input was "very helpful" but 66% also felt that the self-help material would be useful without any therapist input.

Investigating the feasibility of their newly developed CAT-GSH intervention, Meadows & Kellett (2017) interviewed PWPs who delivered the new materials. Themes in the data indicated that materials were "useful clinical tools that could help patients better understand themselves and their problems" (Meadows & Kellett, 2017, p.14). Themes identified as "challenges/caution" and "feasibility" highlighted that the intervention could be feasibly delivered but most felt that they would need longer sessions to provide more emotional containment and some, initially, required more preparation time before hand, however this reduced with practice.

Donker et al. (2013) examined feasibility of their i-IPT intervention using the CSQ-8 and found randomised participants completing i-IPT had significantly lower satisfaction levels compared to those completing i-CBT (mean difference 2.71, SD 0.48, p < .001) or the CBT based active control (mean difference 2.26, SD 0.49, p < .001).

Discussion

This review set out with three objectives, each of which will be discussed in turn below. Firstly, the review aimed to provide an overview of the alternative LIIs available. A systematic search identified 11 studies evaluating LII for common mental health disorders drawing from a range of psychological models including PDT, IPT and CAT with most interventions being based on PDT. It was clear that these interventions were well grounded in theoretical principles of the psychological models used and all the interventions followed existing treatment protocols from self-help books or utilised adapted versions of the standard therapeutic model in question.

Most of the interventions utilised the internet as their main method of treatment with all psychodynamic based interventions using a web-based approach, despite historically, this delivery format being thought of as sceptical by the psychoanalytic community (Lemma & Fonagy, 2013). ICBT is widely used in primary care services and has a strong evidence base in the treatment of common mental health disorders (Salomonsson et al., 2020), the findings seen in this review seem to indicate that other psychological models have the potential to be used in a similar way. Web-based approaches can increase the coverage that health services provide, allowing access to treatment to those who would not be reached otherwise (Ebert et al., 2017). The availability of LIIs using different therapeutic models can further broaden the delivery of care.

Whilst web-based interventions provide flexible cost-effective access to treatment, there are limitations to this method of delivery. Such interventions rely on clients being computer literate and comfortable with technology, being able to understand complex written information and often having access to their own computer with the internet (Health Quality Ontario, 2019). This excludes individuals who fall outside of this category, who are often already considered disadvantaged. As we continue to develop LIIs, it is important that these barriers are addressed and services are accessible for all.

Is there an optimum level of guidance?

Therapist contact varied across the GSH studies and predictably, studies with a higher degree of contact resulted in improved adherence to treatment. Previous studies suggest better adherence leads to better outcomes however this was not found to be the case by Lindegaard et al. (2020). For a treatment to be both clinically effective and cost-effective there needs to be some consensus on the optimum level of therapist contact required to ensure adhere to treatment and receive positive outcomes. The literature does not seem to indicate a clear dose-response between support and outcome, and treatments with substantial support do not appear to differ from treatments with minimal support (e.g., 15 minutes or less per client and week) (Palmqvist et al., 2007). This finding has also been observed in other studies examining ACT as a low-intensity intervention, comparing extensive support and minimal support (Fledderus et al., 2012) and guided vs unguided ACT interventions (Ivanova et al., 2016). Understanding the optimal level of support in low-intensity interventions can help ensure that interventions remain cost effective in practice. The majority of studies within this review utilised psychology students trained for the purposes of the study as their "therapist". Intervention efficacy in these studies might indicate that people can be supported by supervised and trained individuals who are less qualified and ultimately less costly in clinical practice, however it also raises the question of whether better outcomes may have been observed using qualified therapists (Johansson et al., 2017).

Assessing the quality of the literature

The second objective of this review was to critically appraise studies examining LIIs for common mental health problems which do not use CBT or third-wave principles. There was some variability in the quality of the studies included however only one study was rated as being of poor quality. A common flaw across the studies related to external validity. Due to recruitment procedures within many of the studies, it was difficult to determine whether participants were representative of their population. Sampling bias was a key limiting factor due to most studies recruiting a self-selecting community sample. Although this recruitment approach is convenient it has limitations; self-selective participants may have been particularly motivated for treatment which may have affected the outcomes of the study. Despite the clinical levels of depression and anxiety within the samples used, community samples are not equivalent to a clinical sample. Indeed, individuals responding to trial recruitment adverts may never have considered accessing psychological support for their difficulties and may have had their difficulties for several years without seeking help (Andersson & Titov, 2014). This limitation was largely acknowledged by the authors; however, remains a factor when considering the quality of the research and ultimately the suitability and utility of these interventions in routine clinical settings.

Studies determining the feasibility of novel interventions were typically found to have lower quality ratings compared to RCT design studies. This was often due to methodological flaws related to the lack of a control group, no randomisation, small *n* designs and the absence of a power calculation. Given that GSH and SH interventions outside of a CBT treatment model are lacking, it was important to include feasibility studies examining new treatments in this review. Indeed, the methodological differences between these studies and larger RCTs was to be expected.

Are alternative LIIs feasible, acceptable and effective?

The third objective of this review was to consider whether these interventions were feasible, acceptable and effective in the treatment of common mental health disorders.

Acceptability was largely examined through the observation of dropout rates and participant adherence to treatment, however the operationalisation and reporting of adherence varied across the studies. Definitions of adherence included number of modules completed and number of homework tasks returned, sessions attended, or weekly questionnaires submitted. Despite the difficulty in making comparisons across the studies, it is possible to conclude that adherence rates were low in several studies. The low rates of adherence seen with these interventions could suggest that they are not as acceptable as we might believe, contradicting conclusions made by authors regarding the acceptability of their interventions. Reasons for non-adherence were only recorded by two studies included in this review (Zwerenz et al, 2017; Donker et al., 2013). Main reasons identified included interventions being "too time consuming" or "too demanding". Whilst this insight is useful, the lack of non-adherence information overall makes it difficult to identify suitable ways to address the high rates of attrition from low-intensity interventions. Poor adherence is common within web-based treatments, particularly self-guided interventions (Christensen et al., 2009; Karyotaki et al., 2015) which can lead to increased costs and demands on services in circumstances where clients do not recover and return for further treatment later, likely when their symptoms have exacerbated. Some suggest that providing clients with their preferred treatment can improve adherence and improve outcomes (Swift et al., 2011; Swift et al., 2018), however, neither of the studies examining patient preference (Johansson et al., 2013a; Lindegaard et al., 2020) found preference strength to be correlated with symptom reduction or adherence.

Studies examining novel interventions determined that these were feasible for use in clinical practice, except for an i-IPT intervention (Donker et al., 2013). Using participant satisfaction as a feasibility measure, Donker et al. found i-IPT to be less satisfactory when compared with i-CBT and an active control intervention. Participants reported lower levels of satisfaction with this intervention despite there being no significant difference in treatment preference prior to starting treatment. The authors believed that this could be due to IPT being less familiar to participants compared to CBT. This suggestion has implications for how alternative therapies may be received in routine care, however, Meadows and Kellett (2017) found slightly more participants opted for CAT-GSH (41%) compared to treatment as usual CBT-GSH (37%) suggesting that the familiarity of CBT does not always influence therapy uptake rates. Meadows and Kellett determined that the clinicians delivering the therapy did not require significant training or additional supervision to work in this new model, and they concluded that introducing CAT-GSH as an alternative to CBT-GSH at step 2 in IAPT was indeed feasible.

Efficacy and effectiveness findings demonstrated that LIIs are effective in the treatment of common mental health disorders. The interventions examined in this review were comparable to LI-CBT at reducing distress except for an IPT intervention using mobile technology (Dagoo et al., 2014). Compared with WLC, all interventions were superior. It is important to note, however, that many participants within the WLC groups, particularly active control groups, also demonstrated improvements over time. Regression to the mean should be held in mind when observing positive change in health care interventions (Linden, 2013), indeed, this phenomenon was observed in some of the studies who used a waitlist control. Johansson et al., (2017) found that nearly half of their waitlist control group demonstrated improvement on the Clinical Global Improvement Interview at post-treatment. In addition to regression to the mean,

Zwerenz et al. (2017) found that many participants accessed further therapy or medication during the trial period, making it difficult to determine whether the interventions in question were the cause for positive outcomes reported by the authors.

It is well known that researchers typically only publish when findings indicate a positive outcome, leading to publication bias (Song et al, 2013). An unfortunate biproduct of this is that data is not published when participants experience adverse reactions or harmful effects from psychological treatment and only two studies in this review monitored adverse effects.

Methodological considerations

Most of the studies in this review recruited non-clinical samples via web pages and online or newspaper adverts. These recruitment methods are particularly common in trials examining web-based and SH interventions; however, there are limitations to this approach. Firstly, recruitment of non-clinical populations tends to yield more favourable outcomes compared with those from clinical populations (Coull & Morris, 2011; Karyotaki et al., 2017). This method of recruitment tends to attract participants with a higher level of education (Andersson & Titov, 2014) whereas those accessing treatment in primary care settings have a range of educational experiences and include diverse personal characteristics such as cultural background and ethnicity which are not always reflected in trial participants. Additional methodological factors further limit the transferability of these findings, including the use of student therapists, the majority of samples originating from Sweden using majority female participants, therefore findings cannot be said to extend to wider and more diverse populations outside of these groups.

The majority of studies were RCTs and the limitations of this design should be considered, particularly their ability to adequately predict how a therapy will be received in routine practice (Gelman, et al., 2010). Typically, RCT designs exclude participants with comorbid symptoms, those deemed to be complex or those with suicidal ideation which are routinely seen in clinical practice and thus participants in RCTs are often not considered representative of most people accessing these services.

Limitations

The findings of this review must be interpreted in light of several limitations. As with all systematic reviews, this review is vulnerable to evidence selection bias (Drucker et al., 2016); whilst steps were taken to mitigate these types of bias through the use of PRISMA guidelines, it is possible that there are additional studies in the public domain which have not been accessed and included in this review. Furthermore, the papers selected by the author using the eligibility criteria were not assessed by an independent reviewer. Additionally, it is possible that the literature included in this review is subject to publication bias. Statistically significant findings are more likely to be published and are typically published earlier, on average, than studies with nonsignificant findings (Dwan et al., 2013; Hopewell et al., 2007). Whilst it is recommended that researchers include grey literature to minimise this bias, no grey literature met the inclusion criteria for this review. It is therefore unclear whether studies with contradictory findings exist. The search criteria used focused on specific therapies, i.e., psychodynamic, cognitive analytic which may have omitted the inclusion of studies examining other therapies adapted into a LI format.

The heterogeneity across the studies in methodological design, outcomes measures and dependent variables meant that no meta-analysis was conducted, the interpretation and synthesis of the findings may be subject to researcher bias. Whilst efforts were taken to minimise this bias, for example the implementation of inter-rater reliability assessment, the conclusions remain vulnerable to some degree of subjectivity. Future research would benefit from the use of additional researchers during quality appraisal, synthesis, and interpretation processes (Ioannidis et al., 2015).

Future research

Further high-quality research examining the efficacy of low intensity interventions using clinical samples is required before implementation within primary care settings. Future studies could incorporate more diverse and representative clinical samples to improve transferability of findings. Future research might seek to compare efficacy of these interventions to CBT LII. If an alternative low intensity therapy is to be provided for mild to moderate mental health problems, it must demonstrate equivalence to LI-CBT.

It would be advantageous if small scale feasibility studies were followed-up using a more robust RCT design or combine a feasibility study with RCT as Zwerenz et al. (2017). Given that RCTs are viewed as the 'gold standard' and the development of NICE guidelines rely on evidence from RCT studies, further research should utilise this methodological design to help expand the recommended options for low-intensity psychological interventions.

Future studies might also seek to prioritise capturing reasons for non-adherence and GSH drop out to further our understanding of why people choose to end interventions early and perhaps develop ways to reduce this.

Clinical implications

Services might consider replicating processes used within these studies; the use of community samples demonstrates a need for mental health care outside of clinical settings. Preventative mental health services may consider promoting web-based technology giving access to self-help mental health support. Services may also consider expanding their utility of student therapists for cost effective therapy provision.

Conclusions

This review has systematically identified and evaluated the available literature examining LIIs utilising a psychological model other than CBT or third-wave CBT. The results of this review demonstrate encouraging evidence for the use of alternative LIIs for mild to moderate mental health problems, specifically anxiety disorders and depression. However, given the lack of evidence from clinical populations and some methodological flaws, researchers are encouraged to further develop the evidence base of these novel interventions prior to their use in clinical settings.

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Appendix A: Systematic Review Protocol

Systematic Review Protocol

Working Review title: Low intensity interventions- a systematic review of non-

CBT interventions

1. Background

I. Relevance

Need for a choice of evidence-based interventions in primary care outside of CBT - based models. Addressing shortfalls of LI-CBT and giving patient choice

II. Specification

What are the PICO components of the review question / objective?

Participants/populatio n	Intervention	Comparison/contr ol	Outcome
• Participants with diagnoses of common mental health disorders (i.e. depression and anxiety disorders) accessing psychological interventions	• Self- help and guided self- help intervention s	• Treatment as usual, CBT, waitlist control	 Menta I health outcome Follow -up outcome if applicable

2. Methods

I. Search strategy

Which electronic databases will you search?

- Published literature: MEDLINE, PsycINFO, Scopus
- Grey/unpublished literature: OpenGrey,

What are your key search terms?

Search terms will include those relating to "self-help" "unguided self-help" "guided self-help" "low-intensity intervention" "analytic*" "psychodynamic" "psychodynamic therapy" "cognitive analytic* therapy" "CAT" "interpersonal psychotherapy" "IPT" "schema therapy"

NOT "CBT" "cognitive behavio* therapy" "ACT" "acceptance and commitment therapy" "CFT" "Compassion focused therapy"

"depressi*" "anxiety" "anxiety disorder*" "common mental health disorder"

What other sources will you search?

Manual searching of reference lists and recommendations sought from researchers, forward and reverse citation searches

II. Selection criteria

What are the inclusion / exclusion criteria?

Inclusion:

• Studies evaluating self-help or guided self-help interventions for common mental health problems

• Adult participants

Exclusion:

- Studies where intervention is not based on a clear theoretical model
- Interventions focussed on medication adherence or symptoms only
- Child participants (<15years)
- CBT self-help interventions
- Third-wave CBT interventions

How will study selection be performed?

Titles and abstracts of retrieved articles will be screened for suitability based on the listed inclusion and exclusion criteria. Those deemed suitable will progress to full text retrieval where full articles will be assessed for inclusion. Duplicates will be removed.

III. Quality assessment

What criteria will be used to assess methodological quality?

Downs and Black (1999) checklist

IV. Data extraction

What are the key data to be extracted?

- Study characteristics: study design
- Sample: size, demographics, mental health diagnosis
- Setting: mental health setting
- Intervention: type of psychological intervention offered and comparison intervention where applicable

• Outcome measures and psychometrics: primary outcome measures, any additional secondary outcome measures and personality psychometric tool

- Follow-up
- Summary of results

V. Data synthesis

The search terms for this review will be organised using the PICO framework

(Population/Intervention/Comparator/Outcome) (Methley et al., 2014). Synthesis

without meta-analysis (SWiM, Campbell et al., 2020) reporting guidelines will be used to inform the synthesis of data and structure of this review.
Appendix B: Downs and Black Checklist (1998)

Item	Criteria	Possible Answers
Report	ing	
1	Is the hypothesis/aim/objective of the study clearly described?	Yes = 1 No = 0
2	Are the main outcomes to be measured clearly described in the Introduction or Methods section? If the main outcomes are first mentioned in the Results section, the question should be answered no.	Yes = 1 No = 0
3	Are the characteristics of the patients included in the study clearly described? In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.	Yes = 1 No = 0
4	Are the interventions of interest clearly described? Treatments and placebo (where relevant) that are to be compared should be clearly described.	Yes = 1 No = 0
5	Are the distributions of principal confounders in each group of subjects to be compared clearly described? A list of principal confounders is provided.	Yes = 2 Partially = 1 No = 0
6	Are the main findings of the study clearly described? Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).	Yes = 1 No = 0
7	Does the study provide estimates of the random variability in the data for the main outcomes? In non-normally distributed data the interquartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.	Yes = 1 No = 0
8	Have all important adverse events that may be a consequence of the intervention been reported? This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).	Yes = 1 No = 0
9	Have the characteristics of patients lost to follow-up been described? This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.	Yes = 1 No = 0
10	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	Yes = 1 No = 0
Extern	al validity	-
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited? The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.	Yes = 1 No = 0 Unable to determine = 0

Appendix to: Trac MH, McArthur E, Jandoc R, et al. Macrolide antibiotics and the risk of ventricular arrhythmia in older adults. CMA/2016. DOI:10.1503/cmai.150901. Copyright @ 2016. 8872347 Capada Inc. or its licenters.

12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited? The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.	Yes = 1 No = 0 Unable to determine = 0
13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.	Yes = 1 No = 0 Unable to determine = 0
Interna	l validity - bias	
14	Was an attempt made to blind study subjects to the intervention they have received? For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.	Yes = 1 No = 0 Unable to determine = 0
15	Was an attempt made to blind those measuring the main outcomes of the intervention?	Yes = 1 No = 0 Unable to determine = 0
16	If any of the results of the study were based on "data dredging", was this made clear? Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.	Yes = 1 No = 0 Unable to determine = 0
17	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? Where follow-up was the same for all study patients the answer should be yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.	Yes = 1 No = 0 Unable to determine = 0
18	Were the statistical tests used to assess the main outcomes appropriate? The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.	Yes = 1 No = 0 Unable to determine = 0
19	Was compliance with the intervention/s reliable? Where there was non- compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.	$\begin{array}{l} Yes=1\\ No=0\\ Unable \text{ to determine}=0 \end{array}$
20	Were the main outcome measures used accurate (valid and reliable)? For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.	Yes = 1 No = 0 Unable to determine = 0
Interna	l validity - confounding (selection bias)	
21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information	Yes = 1 No = 0 Unable to determine = 0

Appendix to: Trac MH, McArthur E, Jandoc R, et al. Macrolide antibiotics and the risk of ventricular arrhythmia in older adults. CMAJ 2016. DOI:10.1503/cmaj.150901. Copyright © 2016. 8872147 Canada Inc. or its licensors

	concerning the source of patients included in the study.	
22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.	Yes = 1 No = 0 Unable to determine = 0
23	Were study subjects randomized to intervention groups? Studies which state that subjects were randomized should be answered yes except where method of randomization would not ensure random allocation. For example alternate allocation would score no because it is predictable.	Yes = 1 No = 0 Unable to determine = 0
24	Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? All non- randomized studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.	Yes = 1 No = 0 Unable to determine = 0
25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomized studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.	Yes = 1 No = 0 Unable to determine = 0
26	Were losses of patients to follow-up taken into account? If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.	Yes = 1 No = 0 Unable to determine = 0
Power		
27*	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Sample sizes have been calculated to detect a difference of x% and y%.	Yes = 1 No = 0 Unable to determine = 0

*Item has been modified.

Reference

 Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health* 1998;52:377-84.

Appendix C: Quality appraisal of included studies

Study															Item	L												Score and quality rating
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Johansson at al. (2013a)																												19/28 Fair
Lemma & Fonagy (2013)																												14/28 Poor
Andersson at al. (2012)																												23/28 Good
Johansson et al. (2012)																												20/28 Good
Lindegaard et al. (2020)																												19/28 Fair
Johansson et al. (2017)																												22/28 Good
Johansson, et al. (2013b)																												20/28 Good
Zwerenz et al. (2017)																												23/28 Good

Donker et al. (2013)																			24/28 Good
Dagöö et al. (2014)																			20/28 Good
Meadows & Kellett (2017)																			17/28 Fair
Note. Quality appraisal resu	Note. Quality appraisal results. = full points = no points. Items scored 1 when criteria was met (maximum score for item 5 was 2), 0 when criteria were not met or not																		
enough information to determine. Items 1-10 assessed reporting, 11-13 assessed external validity, 14-20 assessed bias, 21-26 assessed confounding and item 27 assessed																			
power.																			

Section Two: Research report

Comparing idiographic change in cognitive analytic and cognitive behavioural guided self-help: A qualitative study of successful outcomes

Abstract

Objectives: This study sought to identify types of idiographic change and to explore possible mechanisms of change through two forms of guided self-help (GSH); cognitive behavioural therapy guided self-help (CBT-GSH) and cognitive analytic therapy guided self-help (CAT-GSH).

Design and Methods: Seventeen individuals demonstrating reliable change after completing two different types of GSH for anxiety participated in semi-structured interviews. Participant reported changes were categorised from the Change Interview and then thematic analysis (TA) was used to extract themes.

Results: No differences were found between groups regarding types of change reported. Both intervention groups experienced cognitive, behavioural, emotional and relational change. Five overarching themes were found; *'Personal qualities of success'; 'Enlightenment through understanding'; 'Specific tools and techniques'; 'Relationships'; 'Tailoring support'*. Four themes maximally differentiated between the two treatment groups.

Conclusions: A combination of model specific and common factors across the models contributed to the process of change. Tailoring intervention structure to the needs of the client, connecting to the therapist and being committed to the change process were important for both groups. CAT-GSH completers uniquely reported relational insight and change while CBT-GSH completers uniquely reported on the importance of understanding anxiety, learning new techniques to cope and supportive relationships.

Practitioner points

 People may benefit from personalised approached to GSH interventions, including varying levels of scaffolding, intervention length and treatment type based on preference and treatment goals.

- Differing types of guided self-help produce similar and also different types of idiographic change.
- Supporting intervention choice is an important aspect of quality service delivery.

Keywords

Guided self-help; cognitive analytic therapy; cognitive behavioural therapy; qualitative; change mechanisms

Introduction

Common mental health disorders such as, anxiety and depression, pose significant economic and health care challenges in the UK, with one adult in six meeting criteria for a common mental health disorder (McManus et al., 2016). Low intensity (LI) therapies have been developed in response to the growing need for efficient and effective brief interventions to address increasing demand for mental health services (Shafran et al., 2021). These first-line treatments can be followed up with more intensive and therefore, more costly interventions for those who require ongoing care (Bower & Gilbody, 2005). This stepped-care approach is advocated by the National Institute for Health and Clinical Excellence (NICE) for the treatment of depression and anxiety disorders (NICE; 2009, 2011). The Improving Access to Psychological Therapies (IAPT) initiative (Layard, 2009) set out to nationally systematize stepped-care principles into the treatment of anxiety with the delivery of the most effective, least intensive and least restrictive treatments being a key feature.

What is guided self-help?

GSH is a type of LI treatment, typically based on CBT principles. Is it psychoeducational in nature and can be delivered over the phone, over the internet, in groups or in a one-to-one format (Wakefield et al., 2021). Clients are provided with information which helps them understand about the nature of their mental health difficulty and how to apply a range of change techniques to help reduce distressing symptoms; limited support is provided by a mental health professional throughout their treatment (Salomonsson et al., 2017). At Step 2 in IAPT GSH interventions consist of six to eight thirty-minute sessions facilitated by a Psychological Wellbeing Practitioner (PWP).

GSH interventions are recommended within NICE guidelines and proven to be an effective way to provide psychological help to those with mild-moderate mental health problems in a primary care setting (Andrews et al., 2018; Cuijpers et al., 2008) and they are comparable in efficacy to face-to-face CBT (Andersson et al., 2013; Andersson et al., 2014; Cuijpers et al., 2010). A study examining effectiveness durability of CBT-GSH in IAPT, however found 53% of clients relapsed within 12 months of completing treatment the majority of those who relapsed (79%), relapsed within the first 6-months post-treatment (Ali et al., 2017). In addition to high relapse rates, high dropout rates are also reported for PWP interventions (Chan & Adams, 2014). Low 'treatment acceptability' of CBT-GSH may be responsible for these high dropout rates (Milosevic et al., 2015) indicating that intervention and the client are a poor match. Service guidelines strongly advise offering a choice of treatments to people experiencing anxiety (CSIP, 2008), however choice of treatment at step 2 is not yet available. To address this lack of choice at step 2, Meadows and Kellett (2017) developed a manualized GSH version of cognitive analytic therapy (CAT) using Medical Research Council treatment development guidelines (MRC, 2008). CAT is a short-term, relational, researchable and integrative psychotherapy (Ryle, 1995) and has an established high quality evidence base (Hallam et al., 2021). CAT-GSH has been shown to be adherent to the philosophy of GSH, created low dropout rates, was easy for PWPs to deliver and was clinically effective with a durable short-term effect (Meadows & Kellett, 2017).

Examining client experience of change in therapy

Quantitative studies lack detail regarding the nature or mechanisms of change experienced by participants. Understanding the contexts and ways in which therapies are effective is crucial for effective clinical delivery (Campbell et al., 2000) and client perspectives should be integral to psychotherapy research (Macran et al., 1999). Qualitative outcome research helps contextualize findings from clinical trials and provides access to clients' views and reflections on what has brought about change. Identifying potential benefits or disadvantages to specific therapeutic techniques or approaches (Hjeltnes et al., 2016) can be used to optimize the effects of treatment and so be extended into clinical practice (Kazdin, 2007). Gaining insight into mechanisms of change within therapy can also increase our understanding of etiological factors responsible for mental health difficulties such as anxiety and depression (Mogoase et al., 2017).

What makes a therapy helpful or successful has been widely considered. It is thought by many that different psychological therapies are largely equivalent in their effectiveness and efficacy, i.e. the Dodo Bird Verdict (Budd & Hughes, 2009). This uniform efficacy is thought to be caused by a set of common factors, shared by all psychotherapies, which lead to beneficial outcomes. This idea dates back to Rosenzweig (1936) who proposed that common factors were, indeed, more important than the methods purposely employed. This concept has led researchers to examine what these shared mechanisms of change might be. The contextual model, described by Wampold (2015), outlines three pathways in which psychotherapy creates positive change: a) the real relationship, b) the creation of expectations through explanation of disorder and the treatment involved and c) the enactment of health promoting actions. The foundation of these pathways is thought to be the therapeutic relationship. Factors such as warmth, the therapeutic relationship, instillation of hope and the re-framing of past experiences, are thought, by some, to have a greater impact than 'specific' factors associated with individual therapy models (Lambert & Bergin, 1994). It has been proposed that 30% of improvement in psychotherapy can be said to be due to 'common factors' compared with 15% contribution attributed to specific techniques in therapeutic models (Lambert & Barley, 2001)

In contrast to the common factors theory, some believe that specific therapy factors are the cause of beneficial outcomes in therapy, whereby "scientific

ingredients" specific to each therapy are thought to be the driving force of change. Different treatments implement different and sometimes incompatible or contradictory techniques (Blagys & Hilsenroth, 2000). The implications of this theory suggest that specific therapies may be better suited to, and more effective for different diagnoses (Budd & Hughes, 2009).

Variation across therapy models

The client's experience of change through therapy has been studied in a range of therapy models including dynamic, CBT and integrative psychotherapy. When comparing therapies, Llewelyn et al. (1988) compared participant perceptions of what was helpful in two theoretically different therapies; prescriptive (CBT) and exploratory (psychodynamic). Participants reported few differences between the models, however, prescriptive participants identified 'problem solution' and 'reassurance' to be the most helpful compared with a process of 'awareness' and 'personal contact' by those having exploratory therapy. Nilsson et al., (2007) identified clear differences between those receiving CBT and those receiving psychodynamic therapy (PDT). When speaking about change, those receiving CBT spoke specifically about how they learnt to cope with their presenting problems, in contrast, PDT clients spoke more broadly about their experiences and changes involving their whole personality.

Using the Helpful Aspects of Therapy Questionnaire, Cahill et al. (2013) found only two factors that differentiated CBT and Psychodynamic Interpersonal Therapy (PIT) in terms of what clients found helpful. For PIT clients 'awareness' was a helpful factor, where clients described getting more in touch with feelings that had previously been warded off. Similar to Nilsson's findings, their CBT clients noted 'problem solution' as a helpful factor where ways of coping were worked out or rehearsed. Cahill and colleagues concluded that there were minimal differences in the helpful aspects found between two evidence-based models of therapy also noting the therapeutic relationship to be the most important factor from the participant's perspective.

A study exploring change during CAT as an integrative psychotherapy found the process of working in collaboration with the therapist to be the most prominent theme identified by participants (Rayner et al., 2010). When synthesizing research of service users' experience of receiving CAT therapy, Balmain et al., (2021) found service users described developing new knowledge, skills and strategies; they reported increased personal insight and awareness and an increased sense of trust which helped to facilitate positive change through therapy.

Experience of change in low intensity therapies

There is growing literature exploring change processes within low intensity therapy. When examining participant experiences of internet delivered CBT-GSH, Lillevoll et al. (2013) identifies three dimensions contributing to positive change after therapy; the active engagement of the patient, the guidance of the therapist and the content of the treatment program. Examining participants' experiences of internet delivered GSH for depression (Bendelin et al., 2011) found similar, distinct patterns of change related to the motivational experience of treatment; how they worked with the materials; attitude towards treatment and perception of skills and knowledge gained. Participants taking responsibility for change in treatment who attributed successes to themselves were more likely to have positive outcomes. Exploring expectations of guided self-help, Macdonald et al (2007) found gaps between the participants' expectations of therapy and actual experiences, namely, the amount of work that was required and surprise at required homework tasks. Perhaps this misunderstanding of the personal responsibility and effort required within GSH therapy accounts for why some experience less therapeutic change. Given that computerised GSH interventions, by definition, have minimal therapist contact, it makes sense that much of the reference to change processes are focused on client factors. However, when discussing change processes in traditional psychotherapy, Orlinsky, et al. (2003), also highlight the importance of client participation as being a key determinant in the outcome of therapy, more so than therapist factors or therapy related techniques. Therapist contribution is still important within low-intensity therapies, Amos et al., (2019) examined clients' experiences in face to face, low intensity therapy and identified four subordinate themes contributing to a positive therapeutic experience; benefits of talking, having sufficient time, a personal approach and the normalisation of their distress. Each of which relies on the therapist's presence and contribution.

Summary and rationale

Broadening our understanding of what works for whom and why, is essential to advancing and improving all forms of psychological therapies. Nomothetic measures provide insight into what works psychometrically but the goals that a person brings to therapy and their progression on these idiosyncratic measures provide equally important insight into mechanisms of change. By selecting a sample of participants demonstrating positive outcomes through a reliable index of change (Jacobson & Traux, 1991), this study hoped to contribute to the literature centred on guided-self help interventions and identify mechanisms of change in two distinct types of low intensity therapy. This study is the first study to examine change mechanisms in this novel CAT-GSH intervention. It is hoped that through this exploration we can better understand *how* this intervention is helpful in reducing anxiety and where this intervention differs and converges with treatment as usual. This exploration may also provide insight into ways to adapt and improve this new intervention for the future.

Research questions

This study set out to answer the following questions:

- 1) What are the similarities and differences in the types of idiographic change experienced during two differing GSH interventions?
- 2) What are the mechanisms of change during GSH interventions and do they differ across two GSH interventions?

Method

Design

Epistemological position

A critical realist position was adopted, assuming that whilst data is informative of reality, it requires interpretation to provide access to the underlying structures within it (Willig, 2013). Whilst participants within the study were asked about the changes they experienced throughout their therapy; we cannot assume that individual participants will understand the underlying mechanisms bringing about change. Adopting a critical realist stance through analysis allows for underlying structures to be interpreted. Furthermore, the current study assumes that the data reflects the individual's perspective, something that can be influenced by demand characteristics associated with interviews, and the researcher's interpretation is constructed based on their own experience, knowledge and understanding, therefore, the analysis is constructed by the lens through which the data is viewed.

Whilst several qualitative analysis methods were considered, thematic analysis was deemed the most appropriate for this study. Suitable for summarizing key features within large data sets (King, 2004) and useful for identifying and highlighting differences and similarities between participants (Braun and Clarke, 2006), the flexible approach of thematic analysis enabled the researcher to stay close to the data and examine the experiences of participants receiving two different therapies and identify patterns relating to how their experiences converged and diverged. Although the study did hope to explore personal experience of participants, the sole focus was not to develop a rich description of the individual's subjective experience, thus, interpretive phenomenological analysis was discounted. Similarly, the study did not aim to construct theory from the data, making methods such as grounded theory unsuitable.

Reflexivity

Understanding that the researcher acts as an active agent in the production of knowledge makes reflexivity an integral component within each stage of the research process (Trainor & Bundon, 2020). Transparency about the researcher's own perspectives, biases and assumptions provides context to the data and meaning that is constructed. Failure to do so can result in the participant's lived experiences being misunderstood and misrepresented.

The researcher kept a reflexive journal throughout the research process. Different types of reflexivity were reflected on including introspection reflexivity i.e., using self-understanding for interpretations and intersubjective reflection, i.e., reflecting on the researcher in relation to the participant (Finlay, 2002). A reflexive statement and excerpts of the researcher's journal can be found in Appendix A and B

Ethics and data protection

Ethical approval was obtained via the Integrated Research Application System (IRAS, 240751) following a full Research Ethics Committee review (Appendix C) and Health Research Authority approval (Appendix D). Scientific approval was gained from the University of Sheffield (Appendix E). The study was registered as a clinical trial (ClinicalTrials.gov Identifier: NCT03730532) and study protocol published (Kellett et al, 2021). Participants gave their informed consent to take part in both the clinical trial and the qualitative study (Appendix G). Confidentiality and anonymity were preserved through allocating participant numbers and removing identifying details.

Description of Partially Randomized Patient Preference Trial and Treatment

This qualitative study was nested within a partially randomized patient preference trial (PRPPT) examining the efficacy and clinical durability of two differing types of manualized GSH (CAT-GSH versus CBT-GSH) for anxiety disorders delivered at step 2 of an IAPT service (Kellett et al., 2021).

Suitability for participation into the clinical trial was determined during triage phone assessments as per routine clinical practice at the IAPT study site. Participants were offered participation into the trial and provided details of the study, where interest was indicated client details were shared with the PRPPT researcher who consented and conducted eligibility interviews using a shortened version of the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) to establish a diagnosis of an anxiety disorder. Table 1 provides details of the inclusion and exclusion criteria.

Table 1

Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria				
Client had self-referred, were referred by their general practitioner, other health or social care professional for the treatment of a common mental health problem	Client was engaged in another IAPT step 2 intervention.				
Client met criteria for an anxiety disorder based on the Mini International Neuropsychiatric Interview	Client did not currently meet criteria for an anxiety disorder,				
Client had clinically significant symptoms above the established cut-off on the Beck Anxiety Inventory	Client did not meet caseness on the Beck Anxiety Inventory				
Client was willing to engage in GSH to address their anxiety disorder.	Client met criteria for depression and a comorbid anxiety disorder, where the depression was more severe and was the main concern				
Client was motivated to engage in treatment and can attend six sessions of face-to-face GSH.	Client had a severe/chronic mental health problem and were already involved in psychiatric or secondary care mental health services				
	Client had a diagnosis of social phobia or PTSD (IAPT guidelines indicate that these disorders are treated at step 3)				
	The GSH sessions required an interpreter				
	Client was unable to read and write				

Note: GSH = Guided Self-Help, IAPT = Improving Access to Psychological Therapies, PTSD -

Post Traumatic Stress Disorder

Participants were provided with information about each treatment and asked to choose between randomization, CAT-GSH and CBT-GSH. Where no preference was stated, participants were randomized into either treatment group. GSH interventions were delivered by qualified Psychological Wellbeing Practitioners (PWPs). Participants were originally given the option of face-to-face or telephone therapy, however from March 2020 after service delivery changed due to COVID-19 restrictions, participants received their intervention by telephone or video call.

Participants completed outcome measures during the eligibility interview, each treatment session, 8-week follow-up and 24-week follow-up. These included the BAI and the IAPT minimum data set; consisting of Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006), Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001), Work and Social Adjustment Scale (WSAS; Mundt et al., 2002) and the IAPT Phobia Scale (Consort diagram can be found in Appendix I).

Treatment

CAT-GSH

The CAT-GSH delivery followed a structured 6-8 session treatment protocol supported by a detailed client workbook (Meadows & Kellett, 2017) 'Changing old and unhelpful patterns; creating stable steppingstones for change' uses a six session framework and includes the modules 'identifying the current patterns of your anxiety'; 'the roots of my anxiety'; 'linking my past to my present'; 'making a roadmap of my problems and how to make exits'; developing a new, healthy and more flexible you'; ending and preparing for the future.

CBT-GSH

CBT-GSH followed the treatment as usual (TAU) IAPT structured 6-8 session treatment protocol and associated client workbooks for anxiety (Richards & Whyte, 2011). PWPs use a range of materials depending on the client and their preference. CBT-GSH helps the client to identify and change unhelpful thought patterns about the self, others and the world around them; increase positive activity and teaches techniques and skills to cope with anxiety.

Intervention differentiation

Kellett et al. (2021) reported that CBT-GSH and CAT-GSH systematically differed in the following ways: (a) CBT-GSH works primarily with the here-and-now, (b) CAT-GSH works with the past and the here-and-now, (c) CBT-GSH does not make use of the therapeutic relationship, (d) CAT-GSH does work with the therapeutic relationship, (e) CAT-GSH is based on a dialogical and relational theoretical model, (f) CBT-SH is based on a cognitive-behavioural theoretical model.

Recruitment into qualitative study and procedure

A purposive sample of participants from the PRPPT was recruited for the current qualitative study. At eight-week follow-up, participants achieving 'reliable change' (i.e., a reduction of 4 points or more) on the pre-post GAD-7 score via the established IAPT criteria (National Collaborating Centre for Mental Health, 2021) were invited to interview by the trial researcher. Those who agreed were contacted by the current author and reminded of the participant information sheet and consenting information they had previously been given. They were provided with information about the interviews and verbal consent for interview was obtained. Interviews were arranged at a time that suited the participant. All participants were informed that they had a right to withdraw from the interview without giving any reason at any point.

Participants

Thematic saturation can be reached after six to twelve interviews when using thematic analysis to develop meaningful themes from a homogenous sample (Guest et al., 2006). Assuming heterogeneity when comparing two treatment groups, a larger sample was sought. The study aimed to include equal numbers of participants from each treatment arm however, several had previously received a CBT intervention and were more likely to choose the CAT-GSH treatment, resulting in unequal weighting across the treatment arms i.e., more CAT completers were interviewed (n = 10) compared to CBT completers (n = 7).

The final sample consisted of seventeen participants; ten who reached reliable improvement after completing CAT-GSH and seven from CBT-GSH; change scores ranged from five to 16. The number of sessions attended by participants ranged from four to eight, with an average of 5.76 sessions. The sample consisted of thirteen women and four men. The majority (n = 15) were white British, one participant was Pakistani, and one provided no ethnicity information. Table 2 outlines participant demographic information.

Table 2

Participant Demographic Information

ID	Gender	Age	Ethnicity	Guided self-help type	GAD-7 change score	Preference(P) /randomized (R)
1	Female	68	White- British	CBT	16	R
2	Female	39	White - British	CAT	9	R
3	Female	53	White - British	CAT	8	R
4	Male	33	White - British	CAT	11	R
5	Male	51	White - British	CBT	9	R
6	Female	19	White - British	CAT	7	R
7	Female	51	White - British	CAT	12	R
8	Female	19	White - British	CAT	9	R
9	Female	33	White - British	CBT	5	R
10	Female	19	Pakistani	CBT	14	R
11	Male	27	Not Stated	CBT	16	R
12	Male	35	White- British	CAT	9	R
13	Female	41	White - British	CAT	9	R
14	Female	56	White - British	CAT	12	R
15	Female	54	White - British	CBT	14	R
16	Female	53	White - British	CAT	19	Р
17	Female	35	White -British	CBT	9	R

Note. CAT = *Cognitive Analytic Therapy, CBT* = *Cognitive Behavioural Therapy*

Measures

Generalized Anxiety Disorder Scale (GAD-7; Spitzer et al., 2006); a 7-item, self-report anxiety scale used widely across mental health services that aims to assess GAD symptoms (Appendix J). Anxiety-related items (over the last two weeks) are rated from 0 (not at all) to 3 (nearly all the time). Change scores were calculated using GAD-7 scores obtained at screening and last treatment session.

Client Change Interview (Elliott, 2011) was adapted to make it more applicable for GSH and aims of the current study. The change interview is a 30–60-minute semistructured interview used to provide an overview of factors that the client found helpful from treatment. Questions focused on the changes that participants observed from GSH, what was helpful or unhelpful and what they believed caused any changes that occurred. Participants gave numerical ratings for how important these changes were, how likely it is that these changes would have occurred without the therapy and how much they expected these changes to occur (Appendix K). The schedule has been used to good effect in previous studies examining experiences of change in therapy (Hjeltnes et al., 2016; McElvaney & Timulak, 2013). The adapted schedule was shared with IAPT PWPs and changes were made based on feedback provided.

Data Collection

Before each interview the researcher explained the aims of the study and provided space to ask any questions, each participant was asked to confirm their consent to take part in the interview. Once the researcher was satisfied that the participant had no further questions and had consented, recording started and the interview began.

Analysis

Data analysis took part in two stages; first the analysis of change and rating data provided by the participants and secondly qualitative analysis using Thematic Analysis (Boyatzis, 1998).

Stage one

Participants were asked to list changes that had occurred during their GSH treatment and for each change identified they were asked to rate, between one and five, how important these changes were, how likely it is that these changes would have occurred without the therapy and how much they expected these changes to occur. Changes and rating scores were extracted from the interview data and compiled into tables split by therapy. Identified changes were categorized as cognitive, behavioural, emotional, or relational change, corresponding with the therapeutic models used and these were independently rated. Cohen's k was calculated and identified high levels of agreement (k = .942, p < .001). Associations between treatment type and changes reported were analysed using a Chi-Square test. Where assumptions of Chi-Square were violated (i.e. more than 20% of expected cells <5 for analyses greater than 2x2) the Likelihood Ratio statistic was reported (McHugh, 2013). Comparisons between CAT-GSH and CBT-GSH participants relating to rating scores were analysed using Mann Whitney-U tests.

Stage two

Interviews were digitally recorded and transcribed verbatim (n = 17). To maximize familiarisation with the data the author transcribed six randomly selected interviews. The remaining data were transcribed by a University approved transcriber (see Appendix L for confidentiality form). Interviews were analysed using a method of inductive thematic analysis described by Boyatzis (1998). This rigorous method of analysis was chosen because it allows for themes to be developed that differentiate between groups. Recordings were listened to multiple times whilst reading and rereading the transcripts; allowing the researcher to become familiar with the depth and breadth of the material (Braun & Clark, 2006).

The stages outlined by Boyatzis (1998) for developing codes inductively were adhered to, the nine-step criterion-driven analysis method is described in Table 3. The criterion variable of therapy type; CBT-GSH vs CAT-GSH was selected based on the aims of the study. To enhance reliability, a second researcher, experienced in TA, applied the code to 30% of the raw data (Boyatzis, 1998). Agreement on themes was calculated using Cohen's Kappa, codes were refined or dropped where agreement was low. Interrater agreement was assessed on six transcripts and was found to be 'strong' (k = .87) (McHugh, 2012).

Table 3

Stage	Description
1. Sampling	Defining the sampling unit Considering units of analysis and coding Identify criterion variable
2. Selection of subsamples	Subsamples selected based on criterion variable i.e., treatment type
3. Reducing raw data	Re-read and re-listen to interviews Summary of each piece of raw data within each interview
4. Summary of information	Outline developed for each subsample
5. Identification of themes within subsets	Compare summaries and identify similarities within each subset
6. Compare themes across subsets	List and compare similar items across subsets Develop a set of statements differentiating the subsets
7. Code creation	Develop usable codes, each containing a label, definition, indicators, exclusions and examples
8. Assessment of reliability	Second rater applies code to subsample of data Calculate intercoder reliability using Cohen's kappa and refine themes
9. Assessment of validity	Reliable code applied to remaining sample Further refinement of themes if required

Associations between treatment type and differentiating themes were analysed using a Chi-Square test. Where assumptions of Chi-Square were violated (i.e. more than 20% of expected cells <5 for analyses greater than 2x2) the Likelihood Ratio statistic was reported (McHugh, 2013).

Results

The results section contains two stages; stage one reports quantitative findings which answer the question of whether there are similarities and differences in types of change experienced in two GSH treatments . Stage two reports qualitative findings which identify different or similar mechanisms of change.

Stage one

Across the entire sample of participants, 73 changes were identified. Table 4 summarises the types of changes reported within each intervention and Appendix M details changes and ratings corresponding to each participant. There was no association between the intervention and type of change (X^2 (3, n = 73) = .94, p = .816).

Table 4

Changes Identified in each Intervention

	Intervention				
Type of Change	CBT-GSH	CAT-GSH			
Behavioural	13	13			
Emotional	3	5			
Relational	5	8			
Cognitive	10	16			
Total	31	42			

Note: CBT-GSH= Cognitive Behavioural Therapy Guided Self-Help; CAT-GSH = Cognitive Analytic Therapy Guided Self-Help

CAT-GSH completers were more likely to report being surprised by changes (Mdn = 5) compared to CBT-GSH completers (Mdn = 4) U(N=30, N=41) = 379.50, z = -2.88, p < .001. When comparing the groups in relation to how important the

changes were and how likely changes would have occurred without intervention, the Mann-Whitney-U homogeneity of variance assumption was violated due to differentially non-normally distributed data in the two intervention groups, and thus, these statistics cannot be interpreted.

Summary of quantitative findings

No differences were found between the two intervention groups in types of change or how change was experienced, with the exception of CAT-GSH participants who were more likely to express surprise about the changes that occurred.

Stage two

Qualitative analysis gave rise to five overarching themes across both treatment groups with four subthemes. Within these, four themes maximally differentiated the two groups. Table 6 outlines the themes and sub-themes, figure 1 presents these in a Venn diagram.

Table 6

Themes and Subthemes with Differentiating Statements

	Themes and subthemes	Differentiating statements
1	Personal qualities of success	
1a	The therapist as a relatable guide	
1b	The client as an active agent of change	
2	Enlightenment through understanding	Understanding why vs understanding what
3	Specific tools and techniques	Looking inwards to move forwards vs. using techniques
4	Relationships	
4a		Relational change and insight vs relational support
4b		Transformation of the self-self-relationship
5	Tailoring support	

Four subthemes maximally differentiated the mechanisms of change described by participants receiving CAT-GSH (n = 10) and those receiving CBT-GSH (n = 7). The association between differentiating themes and intervention type was significant (relational change/insight vs support X^2 (1, n = 49) = 23.07, p < .001); understanding why vs what X^2 (1, n = 28) = 28, p = <.001; looking inwards to move forwards vs using techniques X^2 (1, n = 75) = 26.13, p = <.001).

Figure 1

Venn Diagram Illustrating Common and Treatment Specific Themes



Table 7 Summary of sub-themes differentiating CAT-GSH completers from CBT-GSH completers

			Intervention								
		All participants $(n = 17)$		CAT-GSH (<i>n</i> = 10)		CBT-GSH (<i>n</i> = 7)					
Subtheme	Differentiating statements	No. of statements	% pts	No. of statements	% pts	No. of statements	% pts				
2	Understanding why vs. understanding what										
	Understanding why	16	47	16	80	0	0				
	Understanding what	12	29	0	0	12	71				
3	Looking inwards to move forwards vs. using new techniques	5									
	Looking inward to move forwards	35	70	33	100	2	29				
	Using new techniques	40	94	15	90	25	100				
4a	Relational insight and change vs. supportive relationships										
	Relational insight and change	35	65	30	80	5	42				
	Supportive relationships	14	35	2	10	12	71				
4b	Transformation of self-self relationship	16	41	16	70	0	0				

Note: CBT-GSH= Cognitive Behavioural Therapy Guided Self-Help; CAT-GSH = Cognitive Analytic Therapy Guided Self-Help

Themes

1. Personal qualities for success

This theme captures how the personal qualities of both the PWP and the client contributed to change through their GSH intervention. Conscious effort made by the client and a range of personal skills and qualities from both the client and the PWP contributed to success.

1a. The therapist as a relatable guide

Personal qualities, such as being warm, reassuring and empathic were said to be crucial in facilitating a safe place to explore difficult experiences. Many felt that the personal connection and similarities they shared with their therapist, helped to create an environment for positive change

P10: "I thought what was helpful was the fact that my therapist was from an ethnic minority, so that in itself i think was helpful because it was like, she comes from a background where she understands family circumstances and other family relationships that are harder for us to manage given that our family dynamics are a bit different"

P8: "because my therapist in this instance was younger, I felt less like I was being patronised. rather than talking to a therapist it felt like i was talking to a friend"

The therapist was referred to as a guide with authority and knowledge to help them reach their recovery, someone who was critical for change.

P16 " I couldn't quite connect the dots until I was speaking to the therapist and doing the exercises"

1b. The client as an active agent of change

Participants across both treatments talked about their personal efforts to recover. Participants worked hard to make therapy successful even when this had come at an emotional cost. Participants showed dedication in putting skills into practice, working on their recovery in between sessions and after therapy had ended.

P9 "I've set a reminder in my phone to remind me to sit down on my own in a quiet space with the material and go over the things"

P15 "I did read the modules which I've kept the link to, so if anything happens in the future I can go through the ABCs"

Participants were given the opportunity to put their skills to the test through challenging real-life events. Many made reference to COVID-19 and lockdown which had happened during their intervention and interviews. Participants spoke about the need to implement the skills learnt and some felt that the increased stress acted as a test that demonstrated how effective therapy had been in real life.

P16 "... the whole of society changed during that time and people's situations and that in itself helped me sit and evaluate certain things but definitely both of them coming together helped"

Several of the participants spoke of the emotional pain they experienced within treatment, this was spoken about as something essential and something they were willing to go through to overcome anxiety and see change.

P6 "The first three weeks were very hard. You know, having to go back over a lot of stuff that you've been through, it wasn't necessarily the nicest of times to have to talk about it again, but it had to be talked about. I recognise that it was something that had to be done..."

In addition to a willingness to experience pain, many participants needed to overcome preconceived beliefs and uncertainty about entering the GSH intervention.

P8 "When you think of counselling you think of cold, someone sat there with a clipboard and they're judging you"

Despite their apprehension, participants showed a commitment to persevere, a willingness to stay open-minded and give the intervention a chance. This personal quality of being open-minded and committed meant that, in all cases, the GSH they received surpassed their expectations.

P15 "I was a bit apprehensive because, you know, you don't want to root out something in a dark corner that you've hidden away or something... but it was totally different than what I thought it was going to be, a much better experience"

2. Enlightenment through understanding: "Understanding why vs. understanding what"

Both CBT-GSH and CAT-GSH participants felt that developing a better understanding of anxiety contributed to their recovery. CBT-GSH participants spoke about the importance of understanding what anxiety is, through psychoeducational content of the therapy, in the here and now.

P15 "I learnt some things that I was doing were completely typical of people with anxiety disorder and it made me feel less of a one off or less alone, I just had classic symptoms..."

CAT-GSH participants spoke about understanding anxiety in a different way, they learnt about the origins of their anxiety from specific past events, experiences, or relationships. Being able to understand why they experience anxiety in the first place, in addition to also learning more about anxiety through psychoeducation.

P3 "It was helpful, definitely, just knowing where this anxiety was stemming from and being able to pick different things out made it easier to know that it wasn't just happening without a reason..."

3. Specific tools and techniques: "Looking inward to move forwards vs. using new techniques"

Participants described how they were able to overcome anxiety. CBT-GSH participants spoke about the specific and active techniques they were given to manage worry, these included writing down worries, grounding, breathing or thought challenging.

P 10 "One was literally writing down what is it that's actually making me anxious and basically breaking it down into the options that it could have been,

or the options that did happen but then breaking those down into, say, how bad it could have been and kind of rating it"

CAT-GSH participants also discussed techniques, however these tended to come second to the participant going through an internal process of looking in at the origins of worry before being able to move forwards.

P16 "If I hadn't gone for low intense therapy I don't think I would have looked at my own analysis and how I process bad situations... I just think 'I can't cope'... that would be the first thing I would have said instead of stopping and thinking, you will cope with this, you have coped with this and what can I do about it?"

4. **Relationships**

4a. "Relational insight and relational change vs. relational support"

Both groups of participants reflected on relationships, however, those receiving CAT-GSH spoke of gaining insight into their relationships and how relationships contributed to the maintenance of their problems. Participants in CAT-GSH developed a better understanding of themselves and why others behave and relate in the way they do. As well as insight, CAT-GSH participants spoke more often about the changes that had occurred within their relationships as a result of GSH.

P12 "So now I understand the way she thinks or reacts to stuff I'm saying to her and what's coming back at me. A better understanding of that and I can deal with it appropriately, which hopefully makes her a bit happier without realizing it"
P14 "...with the therapy I was beginning to see that there's a relationship to how I've been brought up and the way you're taught things and how it carries as an adult...I was beginning to pick up on things that weren't quite right in the relationship with my mum..."

Relationships are still mentioned by CBT participants but the focus here was on how their relationships had helped alongside the therapy in being supportive or in facilitating change.

P1 "...he'd get ready and come with me, he didn't want me to go out walking alone so, he was very very much part of the recovery..."

4b. Transformation of the self-self relationship

Several of the CAT-GSH participants discussed changes that had taken place in relation to perceptions of themself, for example changes to their perceived identity. This was often associated with the re-processing of past experiences or re-framing adversity into personal growth. This theme was not present in the CBT-GSH sample.

P15 "By talking to somebody else about it I realized that yes, it's a horrible thing that happened to me but it wasn't my fault and the fact that I've been able to be strong enough to just pick myself up and carry on after, you know, is amazing. So rather than thinking 'oh my god why me?' I was thinking 'jeez, I managed to carry on'."

5. Tailoring support

There was a sense that by offering the 'correct' level of scaffolding, including the number of sessions, level of guidance or having future access to support; participants felt better able to succeed. Where this balance was not quite right, some participants experienced aspects of the intervention more negatively, for example some felt that they needed more support from the PWP.

P14 "I was questioning myself, am I doing this right?... I did get there but sometimes there were a few times where I was unsure if I was doing it correctly... I just needed that little bit more guidance"

Most participants expressed that they would have preferred more sessions but acknowledged that they had had 'enough' to make a difference.

P5 "if it's effective in a short period of time it doesn't need to be longer"

Some felt that more flexibility in how they received their sessions could have been helpful

P6"I feel like being able to spread your sessions out a little bit as well, I think when I was doing it there was that pressure of trying to do it every week, kind of thing, but still being able to have the opportunity to take a week or two break if you need to because you've got other stuff going on."

For many, the knowledge that they could access further support in the future was very helpful, it made them feel less alone at the end of their intervention and may have given them a sense that they were still being 'held' by the service. P14"she did say "if ever you get bad again, you can just ring up and we'll see you again", so that helps the fact that if things start going wrong I can go back. You know, that's there if I need it"

Discussion

This study explored the experience of change during two types of GSH. Two research questions were posed; 1) are there differences in the types of change experienced in two GSH interventions and 2) what are the mechanisms of change and how do they differ across two GSH interventions. The types of change experienced by participants did not differ between the two interventions, however, there were differences in how participants talked about the nature of change and how change came about. Inductive analysis yielded five overarching themes and four sub-themes. Four themes maximally differentiated between the two treatment groups. In line with previous research and theories of change, this study found there to be key differences in the mechanisms of change for those receiving CBT-GSH versus CAT-GSH as well as factors common to both.

Differentiating themes

Enlightenment through understanding: "understanding why vs

understanding what"

This distinction gives novel insight into the useful 'ingredients' of each intervention. Those in CAT-GSH found the exploratory process key to creating change. Increased personal insight and awareness of 'patterns' is a common experience for those receiving CAT (Balmain et al., 2021) and similar experiences are reported in other analytic based therapies (Nilsson et al., 2007). Discussions held by CAT-GSH participants emphasize the importance of the analytic and self-evaluative process in bringing about positive change for *these* participants. No less significant was the impact of psychoeducation for the CBT-GSH group; in line with cognitive-behavioural tradition where insight relates to understanding the role cognitions play in distress (Grosse-Holtforth et al., 2007 in Timulak & McElvaney, 2013). The results do not suggest that either method or model is superior to the other, rather, for these individuals, the intervention they received was right for them. This may suggest, although does not provide evidence for, the argument that some therapies are better suited for certain individuals, for example, CBT participant 15 who was worried that the therapy would "root out something in a dark corner" may not have seen the same improvements had she been in the CAT-GSH group with more focus on past experiences and relationships. Similarly, those participants who benefited from understanding how relational patterns contributed to their anxiety may not have benefited from CBT-GSH, a therapy model with less emphasis on relationships.

"Looking inwards to move forwards vs using techniques".

There are strong parallels here with previous literature, including Nilsson et al's (2007) study where CBT participants described change occurring as a result of the specific methods in which they had learnt to cope with their difficulties. This differentiation also shares similarities with findings from Llewelyn et al. (1988) where prescriptive therapy (CBT) participants identified 'problem solution' to be the most helpful impact compared with a process of 'awareness' by those having exploratory therapy. Behavioural change and problem solution is commonly identified by clients as being helpful in therapy (Timulak, 2007) and is key within CBT. It has been argued that the behavioural strategies within CBT as opposed to the cognitive elements lead to positive improvements for participants (Jacobson et al., 1996), perhaps indicating the importance of behavioural elements across all interventions regardless of the therapeutic model. Of note, however, CAT-GSH participants discussed techniques to a similar extent as CBT-GSH participants, however, these were dependent on an initial process of looking inwards and understanding why. This recognition that model-specific factors contribute to positive therapeutic change matches 'specific factors' theory and highlights the importance of distinctive factors held within different therapeutic models.

Relationships

The distinction between the two interventions regarding relationships gives insight into the critical role of relationships for creating change. For CAT-GSH participants the change mechanism seemed to be a process of insight into the self and others alongside relational change. Including a change within the self-self relationship. No equivalent theme was seen in CBT-GSH suggesting that something specific exists within CAT-GSH that allows for a reparative process of the self, leading to personal growth. Research into client experiences in traditional psychodynamic therapy also describe a wider experience of change involving their entire personality (Nilsson et al., 2007) however, to the author's knowledge, this finding has not been identified within the GSH literature.

The contribution of relationships differed in the CBT-GSH group; rather than reflecting on changes or insight, these participants reflected on the importance of having access to support from friends and family. This mechanism links with the 'client extra-therapeutic factors' outlined by Lambert (1992) and highlights the importance of social support in the context of recovery. The importance of supportive relationships is less commonly discussed in the change literature given its existence outside of the therapy room, however it is well evidenced that supportive relationships act as a protective factor for positive psychological health (Ozbay et al., 2007).

Common factors

In line with Wampold's (2015) contextual model, change was brought about through factors common to both interventions including positive therapeutic relationship, the development of an explanation of anxiety and positive behavioural change in the form of new techniques. Similarities seen in the themes from the current study and previous literature suggest that clients experience similar helpful elements in psychotherapy regardless of whether they are receiving high intensity therapy or manualised GSH.

Personal qualities of success

Despite GSH having minimal contact time with the PWP, the therapeutic relationship and influence of the therapist was significant for all participants. This was further minimised after COVID-19 restrictions stopped face-to-face contact. Nonetheless, participants spoke of the important role that the therapist played in their recovery, particularly when they were able to relate to the therapist on a more personal level i.e., similar age, being a parent, from similar cultural backgrounds. Relating to the therapist in a personal way was highlighted as something that made the therapy experience more positive and effective, in line with similar findings from therapeutic alliance literature where collaborative connections with the therapist influences outcomes (Orlinsky et al., 2003). This finding provides further support for the importance of therapeutic alliance for therapy outcomes and highlights the importance of developing therapeutic relationships despite the brief nature of the intervention. It also indicates the importance of "matching" the therapist to the patient, a luxury not often afforded in mental health services, however, something which might help improve outcomes. There was strong emphasis on the participant's own qualities in being open, willing and committed to their recovery, whether through making the decision to engage in the intervention despite apprehension or actively practicing techniques, similar to Lillevoll et al's (2013) finding that active engagement of the patient is key for creating positive change in GSH. Another quality seen in participants was their willingness to relive distressing past events. Participants, specifically those in CAT-GSH, tended to speak with depth about their emotional experiences, they re-evaluated past traumas and made sense of difficult personal events and relationships. It was clear that the emotional impact was great in some cases, matching findings by Balmain et al. (2021) where participants reported feeling strong emotional reactions during CAT therapy but felt the emotional costs were worth the therapeutic gains.

Some participants spoke of having negative beliefs or perceptions about therapy and some did not expect the therapy to work. Literature focussed on expectations of therapy indicates that positive expectations lead to good outcomes (Wampold & Kelly 2015; Rutherford et al., 2010), however the current findings suggest that having willingness to give therapy a chance despite apprehension is helpful and important for change.

Tailoring support

Personalizing the intervention experience by adjusting the level of support and intervention length appeared to be an important factor to the participants in this study. Participant disappointment tended to relate to a desire for more sessions, changing the focus of the work, thinking the model did not fit or feeling a lack of support. Where participants felt that the intervention was flexible to their needs and wishes this was thought to be beneficial, paralleling findings by Amos et al. (2019) who found that personalised approaches in LI therapy were considered more effective than those that were not. Offering sufficient scaffolding and suitably tailoring intervention length corresponds with the good-enough level literature suggesting that people respond differentially to psychotherapy (Bone et al., 2020). This further supports the well-established belief that psychotherapy should fit the person and effectiveness of psychotherapy can be improved by tailoring it to the needs of the patient (Norcross & Wampold, 2011).

Strengths and limitations

Results of this study should be seen in the context of its strengths and limitations. One strength of this study is the rigorous qualitative methodology used. Whilst thematic analysis can be thought of as less rigorous compared with grounded theory or IPA (Braun & Clarke 2006), this methodology allowed for a structured analysis with a validated code book. Further strengths come from the author's reflexivity to increase transparency and attempt to reduce bias, however as with all qualitative analysis, it is not possible to remove all bias. The study was sited within a trial and therefore the method benefitted from use of the MIMI and the certainty that participants met diagnostic criteria for the presence of an anxiety disorder. The use of the Change Interview was useful in eliciting quantitative change data to contextualise the qualitative analysis. An unexpected strength of this study was that, with the exception of one participant, the sample consisted of participants randomised into their intervention group which reduced any risk of preference effects or bias.

There were several limitations to this study; participants were mostly white British and female; given that mechanisms of change may vary across genders and cultures this limits the generalizability of the findings. PWP competence scores were not available for all participants in this sample, therefore it is not possible to say with certainty that each participant received the intervention as intended. The study only included those who had recovered based on the reliable change index score of 4 on the GAD-7, however, focusing on symptomatology reduction as an indication of recovery is not always in line with client-centred ideas of recovery, such as living alongside or with symptoms (Newbold et al., 2013). Those with a change scores lower than 4 may have qualitatively reported improvements from therapy that were not captured using the GAD-7 and the reliable change index. Additional positive change may have occurred and insight into their experiences would be valuable. Finally, more CAT-GSH participants were interviewed than CBT-GSH, possibly influencing the themes identified.

Future research

This study captures those accessing help for anxiety and is limited by the sample used; mechanisms of change may differ in the context of different diagnoses and cultures; further research might seek to replicate this study using different clinical populations as well as people considered to have unsuccessful outcomes.

Consistent with CBT and CAT therapeutic models, there were clear differences in how the therapies were helpful in reducing anxiety i.e., CAT-GSH participants spoke of the introspective process while CBT-GSH spoke of practicing techniques and strategies. Future research might seek to understand if we can identify and screen for preferences for inner exploratory work versus outer empirical strategies, in order to stratify clients to therapies that are the best fit for them. On a similar note, these findings seem to suggest something about outcomes being linked to clients' readiness for therapy where readiness is associated with a willingness to engage and commit to the process. Further research might seek to explore the relationship between clients' stages of change and outcomes in therapy.

Implications and recommendations for clinical practice

The participants in this study provide important insight into the utility of GSH interventions. This sample of participants demonstrated that alternative and novel interventions can have a significant impact on anxiety and overall wellbeing. The author was surprised by the impact described in relation to these brief interventions; this challenged a bias which stemmed, undoubtably, from the author's own clinical work, therapeutic preferences, and experience. The experiences described by participants gives important knowledge about low intensity therapies which can help to improve service provision to maximise psychological outcomes. Flexibility and personalization regarding session structure, length and therapist-patient matching was beneficial in improving the therapy experience for clients, therefore, services should adapt and attend to the personal needs and preferences of clients, where possible.

Those receiving CAT-GSH benefitted from the exploratory and analytic processes involved, indicating that this type of GSH would best suit those looking for this type of therapy experience, services may consider screening for this preference prior to treatment. Additional screening for readiness and motivation for therapy, specifically guided self-help where individuals are required to put in more personal effort, may prove useful to identify ambivalence or where readiness or motivation is low.

Conclusions

This study explored and compared types and mechanisms of change within two types of GSH for anxiety. It adds to the literature that tries to answer the question "what makes therapy helpful" and is the first study to identify mechanisms of change for CAT-GSH. This study shows that both common and specific factors facilitate positive outcomes; CAT-GSH enabled an exploration of internal processes and relationships whereas CBT-GSH provided better understanding of anxiety and offered techniques to cope. Common to both was a therapeutic environment where support was tailored, participants felt supported and connected to their therapist and participants were active in the change process. These findings suggest that change mechanisms are not either common factors or specific factors, rather, a collaborative integration of the two.

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Appendix A: Reflexive Statement

I am a white, cisgender, woman and mother in my mid-thirties. I am from a largely middle-class background. I have a genetic metabolic bone disease which causes chronic pain, and I am classified as having a disability under the equality act. I work in the field of paediatric mental health and use a range of psychological models in my work. I draw on attachment theory in a great deal of my thinking and I work therapeutically using models such as CBT, ACT, CFT, I also draw on psychoanalytic theory. I believe that language and the way we use language constructs our understanding of and interaction with the world around us. I would opt to use a relational therapeutic model overusing CBT in my clinical work but I understand the utility of CBT for a range of presentations.

Appendix B: Reflexive log excerpts

Interviews

My therapy background influences how I approach the way I ask questions and respond to answers given. I am noticing that I want to slip into "therapy mode" during my interview. I also think that my knowledge of the therapies may steer my thinking or the interview, despite the interview schedule.

I've been noticing some feelings of surprise at the impact of the therapy, I wonder if I have some bias about how impactful low intensity therapy can be - I wonder whether this is because I don't tend to see patients in my working life who would meet the criteria for mild-moderate anxiety or depression so it seems surprising that such a low "dose" therapy could have such life changing effects.

I find myself relating to the participants in varying ways, with other female participants I find myself making links to them and my own mother or indeed other older women I have worked with in my therapeutic work. I find myself relating in a more personal way to two young mothers being interviewed, after the birth of my own child I can appreciate the content of their distress in a different way to others and indeed, compared to how I might have related to them before becoming a mother.

Many of the interviews occurred after the pandemic started which brought in other similarities between myself and the participants - being able to relate to the impact of such a significant global event

Data Analysis

I have been reading theories relating to mechanisms of change, common factors and specific factors. This may be shaping the way that I look at the data so that I am looking for/more aware of these factors in the data.

My knowledge of the theory related to both CBT and CAT is allowing me to see how the changes relate to the theory of those therapeutic models - possibly this is also shaping the way I am interpreting the data

My own experience as a therapist using attachment based models and having received analytic therapy draws me to the significance of the changes participants refer to regarding changes in relationships and insight into how their childhood parental experiences link to their current relational patterns or mental health difficulties

I can't seem to help but jump ahead to the interpretation, I'm struggling to stay close to data!

I'm having lots of "doubt" thoughts - worrying if i'm doing it right or if what i'm doing is truly in line with the analysis method



East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel Royal Standard Place Nottingham NG1 6FS

10 July 2020

Miss Emma Beattie-Edwards Trainee Clinical Psychologist Sheffield Health and Social Care NHS Foundation Trust University of Sheffield, Clinical Psychology Unit Floor F, Cathedral Court, 1 Vicar Lane Sheffield S1 2LT

Dear Miss Beattie-Edwards

Study title:

REC reference: Protocol number: Amendment number: Amendment date: IRAS project ID: Cognitive-behavioural versus cognitive-analytic guided self-help for anxiety; a patient preference clinical trial 18/EM/0240 URMS 156722 9 29 January 2020

240751

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter from sponsor		29 January 2020
Notice of Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission]	9	29 January 2020
Other [Additional information (Statistics)]		29 January 2020
Research protocol or project proposal [CAT-SH Protocol]	9	29 January 2020
Research protocol or project proposal [CAT-SH Protocol (tracked changes)]	9	29 January 2020

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities- see details at: <u>https://www.hra.nhs.uk/planning-andimproving-research/learning/</u>

Yours sincerely

Mr Paul Hamilton Chair

E-mail: Nottingham1.rec@hra.nhs.uk

Enclosures:	List of names and professions of members who took part in the review	
Copy to:	Miss Emma Beattie-Edwards, Sheffield Health and Social Care NHS Foundation Trust	

East Midlands - Nottingham 1 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 July 2020

Committee Members:

Name	Profession	Present	Notes
Mr Paul Hamilton	Parish Administrator	Yes	
Dr Ursula Holdsworth	Retired Staff Grade Community Paediatrician	Yes	

Appendix D: Health Research Authority Approval



Miss Emma Beattie-Edwards Trainee Clinical Psychologist Sheffield Health and Social Care NHS Foundation Trust University of Sheffield, Clinical Psychology Unit Floor F, Cathedral Court, 1 Vicar Lane Sheffield S1 2LT Health Research Authority

Email: hra.approval@nhs.net Research-permissions@wales.nhs.uk

16 October 2018

Dear Miss Beattie-Edwards



Study title:

IRAS project ID: Protocol number: REC reference: Sponsor Cognitive-behavioural versus cognitive-analytic guided selfhelp for anxiety; a patient preference clinical trial 240751 URM S 156722 18/EM/0240 University of Sheffield

I am pleased to confirm that <u>HRA and Health and Care Research Wales (HCRW) Approval</u> 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.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "summary of assessment" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

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It is important 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 of the research management function for each organisation can be accessed <u>here</u>.

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 the devolved administrations of 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) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see <u>IRAS Help</u> 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 <u>obtain local agreement</u> in accordance with their procedures.

What are my notification responsibilities during the study?

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 <u>HRA website</u> also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Andrew Thompson Tel: 01142226637

Email: a.r.thompson@sheffield.ac.uk

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 240751. Please quote this on all correspondence.

Page 2 of 7

Yours sincerely

Chris Kitchen Assessor

Email: hra.approval@nhs.net

Copy to:

Dr Andrew Thompson, University of Sheffield (Sponsor Contact) Ms Brenda Pimlott , Pennine Care NHS Trust (R&D Contact)

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List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of indemnity]	V.1	05 September 2017
GP/consultant information sheets or letters [GP info letter]	I	06 July 2018
HRA Schedule of Events [SoE]	2	16 October 2018
HRA Statement of Activities [SoA]	2	16 October 2018
Interview schedules or topic guides for participants [Interview schedule]	2	02 June 2018
IRAS Application Form [IRAS_Form_16072018]		16 July 2018
Letter from funder [Letter confirmation]		
Letter from statistician [Scientific approval letter]	Ш	02 July 2018
Non-validated questionnaire [Secondary outcome measure]		
Other [Letter - response to provisional opinion]	1	03 September 2018
Other [Letter to REC 27.09.18]	1	27 September 2018
Other [Unfavourable opinion letter Rec Review]	I	24 May 2018
Other [Letter addressing REC review recommendations]	I	06 July 2018
Other [CAT-GSH workbook]		
Other [MINI]		
Other [preference support]	П	06 July 2018
Other [peer review feedback]	I	06 July 2018
Other [peer reivew letter]	I	06 July 2018
Other [Trust lone working policy]	I	06 July 2018
Other [PWP study invitation script]	V.1	28 August 2018
Participant consent form [consent form]	IV	27 September 2018
Participant information sheet (PIS) [participant info sheet]	IV	27 September 2018
Research protocol or project proposal [Research Protocol]	11	06 July 2018
Summary CV for Chief Investigator (CI) [Emma CV]	2	07 June 2018
Summary CV for Chief Investigator (CI) [CI CV]	1	03 September 2018
Summary CV for student [Student CV]	Ш	06 July 2018
Summary CV for supervisor (student research)		
Validated questionnaire [Beck Anxiety Inventory examplar]	1	06 January 2018

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Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	The applicant has confirmed that the Academic Supervisor will fulfil the role of Chief Investigator, rather than the Student as listed on the IRAS form.
2.1	Participant information/consent documents and consent process	Yes	No comments
0.4		N	N
3.1	Protocol assessment	Yes	No comments
		N	
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A Statement of Activities will form the agreement of the NHS organisation to participate. Updated since issue of Initial Assessment Letter: Both the Statement of Activities and Schedule of Events have been updated to version 2 (16/10/2018) following the issue of the Initial Assessment Letter.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	The study is funded by a grant from the Association of Cognitive Analytic Therapists. Updated since issue of Initial Assessment Letter: Schedule 1 of the Statement of Activities details funding to be provided to the participating organisation.

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Section	Assessment Criteria	Compliant with Standards	Comments
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	No comments
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

Participating NHS Organisations in England and Wales

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.

This is a non-commercial study with a single participating NHS organisation.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales 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. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at <u>hra.approval@nhs.net</u> or HCRW at <u>Research-permissions@wales.nhs.uk</u>. We will work with these organisations to achieve a consistent approach to information provision.

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 Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Principal Investigator is expected to be in place at the participating organisation.

As per the Statement of Activities, the sponsor will provide training on the use of the manual to support the CAT-GSH approach.

Updated since issue of Initial Assessment Letter: Top-up training will also be provided prior to commencing the study.

GCP training is <u>not</u> a generic training expectation, in line with the <u>HRA/HCRW/MHRA statement on</u> 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

For research team members that do not have existing contractual relationships with the participating organisation, Honorary Research Contracts should be in place if the activities undertaken at the NHS site impact upon patient care (e.g. randomising or helping to determine the treatment path), on the basis of Research passports (if University employed) or NHS to NHS confirmation of preengagement checks letters (if NHS employed). The pre-engagement checks should include enhanced DBS checks and Occupational Health Clearance.

For research team members that do not have existing contractual relationships with the participating organisation, and who will not engaged in activities impacting upon patient care, Letters of Access should be in place. The pre-engagement checks should include standard DBS checks and Occupational Health Clearance.

No specific pre-engagement checks are required to have taken place if the members of the research team are only accessing patients' data.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

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Appendix E: Scientific approval letter


Appendix F : Participant information sheet





Emma Beattie-Edwards Trainee Clinical Psychologist University of Sheffield Department of Psychology Floor F, Cathedral Court 1 Vicar Lane Sheffield S1 2LT UK Email: ebeattieedwards1@sheffield.ac.uk

Study Title: Cognitive-behavioural versus cognitive-analytic guided self-help for anxiety; a patient preference clinical trial (IRAS reference number: 240751 version VI)

PARTICPANT INFORMATION SHEET

You are being invited to take part in a research project. Before you decide, it is important to understand why the research is being done and what the research will involve for you. Please read the following information carefully, and please feel free ask any questions you may have.

Who is doing this research?

The University of Sheffield is organizing this research and the project has some funding from a charity. This project has been previously reviewed in terms of its scientific merit by the University of Sheffield Clinical Psychology department and has NHS ethics approval. This research is being undertaken in part fulfillment of an educational qualification.

Why have I been invited?

You have been invited to take part in this research project because you are going to complete a guided self-help intervention in the Improving Access to Psychological Therapies (IAPT) service. This treatment has the aim of helping you with the anxiety that you are currently experiencing. The treatment is delivered by Psychological Wellbeing Practitioners (PWPs) whom are well trained, experienced and supervised in delivering this type of treatment.

Do I have to take part?

It is completely up to you! If you decide to take part, you can keep this information sheet and will be asked to sign a consent form. You can withdraw

at any time without giving a reason. Getting help in the IAPT service for your anxiety is not dependent on being part of this research project.

What will happen if I take part?

You will be asked to take part in a screening appointment (an interview that asks you about your anxiety and you will be asked to complete a questionnaire that rates the severity of your anxiety; this is called the Beck Anxiety Inventory). The information that you give us in the interview and the total anxiety score from the questionnaire will tell us whether you are suitable for the research study.

If you are suitable for the study, you will be given information that helps you make a choice between the two differing types of guided self-help on offer. If you do not have a strong preference for either one of the treatments, you will be randomly allocated to a treatment by the research team. We really want you to have the opportunity to choose your treatment, but there is no pressure for you to choose. If you are really struggling to decide, the researcher cannot make you decide or make that decision for you. But, we can offer to allocate you to treatment at random, so that decision is taken out of your hands.

With your permission, we will inform your GP that you are taking part in a research study. You will also fill in measures of your levels of distress at each of the sessions with the Psychological Wellbeing Practitioner (PWP) who is helping you with your anxiety. This happens with all patients that are seen in the Improving Access to psychological therapies service. The research will also record how many sessions that you attend, whether you dropout and whether you need any more help after this treatment has finished.

One of your guided self-help treatment sessions will be recorded so that we can check that the intervention is being delivered correctly. This session will be selected at random and the recording will have you and the PWP talking on it. It will not have your name attached to it, but rather your study ID and therefore the information is anonymous. The content of the session will be checked for treatment fidelity (i.e. is the PWP doing their job well) by a member of the research team from Sheffield University. Once the session is scored in terms of its fidelity, then it will be deleted. At 8 and 24-weeks after completing your treatment, or if you have dropped out of treatment or have been allocated to another treatment you will be contacted via the telephone by a researcher. You will be asked to complete the Beck Anxiety Inventory on the telephone. You will also be contacted again at 24-week follow-up by telephone and this is the final follow-up for the study. Again, you will be asked to complete the Beck Anxiety Inventory on the telephone.

If you have really benefitted from the treatment (i.e. you no longer have symptoms that place you in a 'clinical' group) due to effect of the guided selfhelp, then you would also be asked if you want to take part in a 30-45 minute interview about the treatment you received. This will be conducted either on the telephone or in your home. This will take place at the time of the first follow-up at 8-weeks. In this interview, you will be asked questions about your experience of the guided self-help intervention, including what you found helpful or found unhelpful. These interviews will be audio-taped and then transcribed by a member of the research team at Sheffield University (i.e. they will be typed up to include everything that is said by a professional transcriber bound by a confidentiality agreement). Once transcribed the audio recording will be deleted and the transcribed record stored at Sheffield University. Below is a flow diagram that easily explains the process of participating in the study.



You will be allocated an anonymous study number if you choose to participate in the study and so no information can be attributed to you as a person. Interviews will therefore be attached to a study identification number (i.e. ID number) and not your individual name. Any direct quotes used in summary reports will only have a study ID number attached to them and your anonymity and confidentiality will therefore be protected. The quotes will be kept to a minimum and these direct quotes will be anonymized, but of course there is a small chance that you might recognize yourself in the final write-up if you can remember what you told us during the interview, but no one else really could.

Treatment choices

You are being offered one of two treatments. Both treatments are the same length (6 sessions that last 30-35 minutes each) and both use a guided selfhelp approach. This means that you will work through a workbook with the support of a PWP. One treatment is called 'cognitive-behavioural guided selfhelp' and one is called 'cognitive analytic guided self-help'. The key difference is that the cognitive behavioural self-help works in the 'here and now' with your anxiety, whilst the cognitive analytic self-help uses your past and how you grew up, as a way of understanding your anxiety, before moving onto making changes in the present day. You will be given an information sheet that describes the treatment choices and that will help you make the choice that suits you. If you have no strong preference and either treatment appeals to you, then please say and you will be allocated to a treatment by the research team. This allocation is done 'at random.' This means that a computer selects which treatment that you will receive based on a random sequence, to make sure that there is no bias. There is no pressure to choose or to be allocated; either are fine and are both part of the research.

What are the benefits of taking part?

You get the opportunity to share your experience of completing a guided selfhelp intervention in IAPT. This feedback is helpful for supporting the development and adaptation of guided self-help interventions in the IAPT service. We hope to improve the effectiveness of guided self-help for others through doing this research.

What if there is a problem?

If you feel that there is a problem at any time with participating in the research, you can let the research team know. If you experience any distress whilst sharing your experience, the researcher will be able to discuss this with you, and discuss what further support might be of help.

Will all the information be kept confidential?

Pennine Care NHS Foundation Trust IAPT service will collect information from you and your medical records for this research study in accordance with our instructions.

Pennine Care NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to The University

of Sheffield. Pennine Care NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from The University of Sheffield and regulatory organizations may look at your medical and research records to check the accuracy of the research study. The University of Sheffield will only receive information without any identifying information. The people who analyze the information will not be able to identify you and certainly will not be able to find out your name, NHS number or contact details.

You will also not be personally identifiable in any reports or publications. As stated, we will only use anonymized short quotes from the interview data. All the number results will be presented as group averages or percentages, and so no single person can be identified.

How long will the data be stored and how will it be handled?

The University of Sheffield is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep identifiable information about you for 6 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <u>https://www.hra.nhs.uk/planning-and-improving-research/policies-</u><u>standardslegislation/data-protection-and-information-governance/gdpr-guidance</u> or by contacting one of the researchers involved in this study.

The research data will be stored for 5 years. The data will be transferred between the IAPT service and the University. This will be via secure email and the files will also be password protected.

How many times will my data get used?

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What are the limits of confidentiality?

If during the research screening process or any of the follow-up meetings then you disclose an issue that has implications for your own safety (or the safety of others) or make a disclosure concerning criminal activities, then the research team have a duty of care to pass this information onto the relevant authorities. The researcher conducting the screening or the follow-ups will inform you of this is this is an outcome from that process.

Will I receive any reimbursement of expenses for taking part in this research?

No. There will be no reimbursement of expenses for this research, as we do not anticipate that any will be generated for you. You will not be paid for participating.

What will happen to the results of the study?

The results will be shared at national conferences and also in publications. You can obtain a copy of the results by contacting the researcher on <u>ebeattieedwards1@sheffield.ac.uk</u> or <u>s.kellett@sheffield.ac.uk</u>. Once the study has been published, you will be able to access it on the following University of Sheffield website <u>https://www.sheffield.ac.uk/clinicalpsychology/research/pubsgrants</u>

What if I wish to complain about the way the study has been carried out?

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact Andrew Thompson, Director of Research Training at the University of Sheffield who will investigate the matter <u>A.r.thompson@sheffield.ac.uk</u>. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

If you feel that your complaint has not been handled to your satisfaction following this, you can contact the University's Registrar and Secretary Dr Andrew West, Email: registrar@sheffield.ac.uk and Tel 0114 222 1051

Contact Information

This research is being conducted by **Emma Beattie Edwards** Trainee Clinical Psychologist under the supervision of the Chief Investigator Dr Stephen Kellett. This research will be used to write a thesis which fulfils part of their doctoral training. If you have any questions about the research, you can leave a telephone message with the Research Support Officer on: 0114 222 6650 and he will ask **Emma Beattie Edwards** to contact you.

Appendix G : Participant consent form



Pennine Care

Email: ebeattieedwards1@sheffield.ac.uk

Emma Beattie-Edwards Trainee Clinical Psychologist University of Sheffield Department of Psychology Floor F, Cathedral Court 1 Vicar Lane Sheffield S1 2LT UK

Study Title: Cognitive-behavioural versus cognitive-analytic guided self-help for anxiety; a patient preference clinical trial (IRAS reference number: 240751 version VII)

Name of Researcher: Emma Beattie Edwards Study participant ID number:

Please initial box if happy after reading

I confirm that I have read and understand the information sheet explaining the above research project and I have had the chance to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.

I understand that if I withdraw during the course of the study, any data I have provided until that point will still be used.

I understand that my responses will be kept confidential. I understand that I will not be identified or identifiable in the report or reports that result from the research.

I agree for any data collected from me to be stored anonymously.

I understand that I need to choose a treatment and if I am happy to receive either treatment, then the research team will randomly select a treatment for me.

I give consent for my GP to be contacted by letter and informed that I am participating in a research study whilst completing my routine treatment for my anxiety in the Improving Access to Psychological Therapies service.

I give my consent that one of my therapy sessions will be recorded and this recording will be listened to by a member of the research team to check that the treatment I am receiving is being delivered correctly.

I understand that if I have benefited from the treatment I will be asked to participate in

No

Yes

an interview and that this interview is voluntary and will be audio-recorded and then transcribed by a third party that has signed a confidentiality agreement. I understand that I will be followed-up at 8 and 24 weeks if I have completed the guided self-help, dropped out or been allocated to another intervention in the Trust. I understand that despite the efforts made to protect my anonymity relating to the interviews I might be able to recognize myself in any written reports in a direct quote by myself. I understand the limits of confidentiality explained to me in the information sheet, should I suggest that I am a risk to myself, to another person, I am at risk from another person or make a criminal disclosure then this will be shared with the relevant people I agree to take part in this research project. Name of Participant Date Signature Lead Researcher Date Signature

To be signed and dated in presence of the participant

Copies:

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form and the information sheet. A copy of the signed and dated consent form should be placed in the project's main record (e.g. a site file), which must be kept in a secure location.

Appendix H: Consort diagram

Not screened: Dropped out of DNA Screen = 2 Declined study =	service = 65 1 = 69		Agreed to take p	art = 470	Awaiting	research screen = 0	
Innapropriate =	5	י ו א	Screened =	310	Not E Witho Drop	Excluded: Sigible = 33 Irew at screening = ped out of service al	1 fter screen = 4
CAT = 180 CBT = 73 CBT = 73 CB							
In treatm	ent = 0 = 180	In treatm	eent= 0	In trea	tment= 0	In treat	ment= 0 MISED
				CAT	10	СВТ	= 8
Completed treat	ment: 83	Completed trea	tment: 33	Completed trea	tment: 2	Completed treat	ment: 4
8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	Attended: 2	Attended: 2
Allended, 40	Allended, 41	Allended, 20	Attended, 20	Allended, 1	Allended, 2	Missed: 1	Missed: 0
Withdrawn: 1	Withdrawn: 1	Withdrawn:0	Withdrawn: 2	Withdrawn: 0	Withdrawn: 0	Withdrawn: 1	Withdrawn: 1
Not due: 0	Not due: 17	Not due: 0	Not due: 5	Not due: 0	Not due: 0	Not due: 0	Not due: 1
Dropped out: 5	7 f/u: 29	Dropped out: 2	2 f/u: 14	Dropped out: 6	flu: A	Dropped out: 4	
8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U
Attended: 8	Attended: 5	Attended: 0	Attended: 0	Attended: 0	Attended: 0	Attended: 0	Attended: 0
Missed: 18	Missed: 17	Missed: 7	Missed: 7	Missed: 2	Missed: 2	Missed: 1	Missed: 1
Withdrawn: 2	Withdrawn: 4	Withdrawn: 1	Withdrawn: 1	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0
Not due: 0	Not due: 2	Not due: 0	Not due: 0	Not due: 0	Not due: 0	Not due: 0	Not due: 0
Stepped up: 40 Not eligible for	F/u: 3	Stepped up: 17 Not eligible for	F/u: 7	Stepped up: 2 Not eligible for	r F/u: 0	Stepped up: 0 Not eligible for	F/u: 0
8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U	8 WEEK F/U	24 WEEK F/U
Attended: 23	Attended: 12	Attended: 9	Attended: 5	Attended: 1	Attended: 2	Attended: 0	Attended: 0
Missed: 12	Missed: 19	Missed: 1	Missed: 0	Missed: 1	Missed: 0	Missed: 0	Missed: 0
Withdrawn: 2	Withdrawn: 3	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0	Withdrawn: 0
Not due: 0	Not due: 8	Not due: 0	Not due: 1	Not due: 0	Not due: 0	Not due: 0	Not due: 0

Appendix I: Generalised anxiety disorder -7

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Appendix J: Adapted Client Interview Schedule

Adapted Change Client Change Interview

Research ID:		
Self-help:	CAT-GSH	CBT-GSH
Number of sessions at	tended:	
GAD-7 pre and post sc	ores:	
Change:	clinical	non-clinical change

Interview schedule

After completing the GSH, clients are asked to park part in a semi-structured interview lasting approximately 30-45 minutes. The major topics of this interview are:

• any changes you might have noticed from your experience through guided selfhelp

- what you believe may have brought about these changes
- any helpful and unhelpful aspects of the intervention you received.

The main purpose of this interview is to allow you to tell us about your experience of guided self-help in your own words. This information will help us to understand better how the intervention works. This interview is tape-recorded for later transcription. Please provide as much detail as possible.

1. What <u>changes</u>, if any, have you noticed in yourself since you started the guided self-help? (For example, are you <u>doing</u>, feeling, or thinking differently from the way you did before or <u>has there been any change in your relationships</u>? What <u>specific ideas</u>, if any, have you gotten from the GSH, including ideas about how to better care for yourself and manage your anxiety? Have any changes in you been brought to your attention by other people?) [Interviewer: Jot changes down for later.]

2. Has anything changed for the <u>worse</u> for you since you started the guided selfhelp?

3. Is there anything that you <u>wanted</u> to change that hasn't since you started the guided self-help?

4. Have the changes (if any) been maintained since finishing the guided self-help and what has helped with keeping on track?

<u>Change Ratings</u>: (Go through each change and rate it on the following three scales:)

5. For each change, please rate how much you <u>expected</u> it vs. were <u>surprised</u> by it? (Use this rating scale:)

(1) Very much expected it

(2) Somewhat expected it

(3) Neither expected nor surprised by the change

(4) Somewhat surprised by it

(5) Very much surprised by it

6. For each change, please rate how <u>likely</u> you think it would have been if you <u>hadn't</u> completed the guided self-help? (Use this rating scale:)

(1) Very unlikely without GSH (clearly would not have happened)

(2) Somewhat unlikely without GSH (probably would not have happened)

(3) Neither likely nor unlikely (no way of telling)

(4) Somewhat likely without GSH (probably would have happened)

(5) Very likely without GSH (clearly would have happened anyway)

7. How <u>important</u> or <u>significant</u> to you personally do you consider this change to be? (Use this rating scale:)

- (1) Not at all important
- (2) Slightly important
- (3) Moderately important
- (4) Very important
- (5) Extremely important

<u>8. Attributions</u>: In general, what do you think has <u>caused</u> these various changes? In other words, what do you think might have brought them about? (Including things both <u>outside</u> of the GSH and <u>created by the GSH</u>)

<u>9. Helpful Aspects</u>: Can you sum up what has been <u>helpful</u> about your experience of guided self-help? Please give examples. (For example, general aspects, specific events, real life changes)

<u>10. Problematic Aspects</u>: What kinds of things about GSH were hindering, unhelpful, negative or disappointing for you? (For example, general aspects. specific events, specific technical aspects of the GSH like diary keeping or homework)

11. Please say what would have made your experience of the guided self-help that you received more effective or helpful?

Change	Change was:	Without GSH:	Importance:
_	1 - expected	1 - unlikely	1-not at all
	3 - neither	3 - neither	2-slightly
	5 - surprised by	5 - likely	3-moderately
			4-very
			5-extremely
1.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
2.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

3.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
4.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
5.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
6.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
7.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
8.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Thank you for your time

Appendix K: Transcribing confidentiality form

Doctorate in Clinical Psychology, University of Sheffield

Transcribing Confidentiality Form & Guidance Notes

Type of project: Clinical Skills Assessment / Research thesis

Project title _____

Researcher's name _____

The recording you are transcribing has been collected as part of a research project. Recordings may contain information of a very personal nature, which should be kept confidential and not disclosed to others. Maintaining this confidentiality is of utmost importance to the University.

We would like you to agree:

1. Not to disclose any information you may hear on the recording to others,

2. If transcribing digital recordings – only to accept files provided on an encrypted memory stick

3. To keep the tapes and/or encrypted memory stick in a secure locked place when not in use,

4. When transcribing a recording ensure it cannot be heard by other people,

5. To adhere to the Guidelines for Transcribers (appended to this document) in relation to the use of computers and encrypted digital recorders, and

6. To show your transcription only to the relevant individual who is involved in the research project.

7. If you find that anyone speaking on a recording is known to you, we would like you to stop transcription work on that recording immediately and inform the person who has commissioned the work.

Declaration

I have read the above information, as well as the Guidelines for Transcribers, and I understand that:

1. I will discuss the content of the recording only with the individual involved in the research project

2. If transcribing digital recordings – I will only accept files provided on an

encrypted memory stick

3. I will keep the tapes and/or encrypted memory stick in a secure place when not in use

4. When transcribing a recording I will ensure it cannot be heard by others

5. I will treat the transcription of the recording as confidential information

6. I will adhere to the requirements detailed in the Guidelines for transcribers in relation to transcribing recordings onto a computer and transcribing digital audio files

7. If the person being interviewed on the recordings is known to me I will undertake no further transcription work on the recording

I agree to act according to the above constraints

Your name ______

Signature _____

Date _____

Occasionally, the conversations on recordings can be distressing to hear. If you should find it upsetting, please stop the transcription and raise this with the researcher as soon as possible.

Appendix L: Change rating table

Changes Identified and Ratings

CBT	-GSH				
				Ratings	
ID	Changes identified	Change category	Change was unexpected (5 = completely unexpected)	Change would have occurred without therapy (5 = change would not have happened without therapy)	Change was important (5 = change was very important)
1	Better able to cope with stressful things	Cognitive	4	2	5
	Stopped worrying about what hasn't happened yet	Cognitive	5	2	5
	Calmer whilst driving	Emotional	4	2	5
	Using breathing techniques	Behavioural	4	2	5
5	Reduced feelings of panic	Emotional	4	1	4
	No longer putting things off	Behavioural	4	1	4
	Being able to see things from a different angle	Cognitive	4	2	4
	Improved concentration	Cognitive	1	1	4
9	Change in my negative thinking	Cognitive	2	1	4

	Reviewing the therapy workbook to keep in touch with thoughts and feelings	Behavioural	4	2	3
	More open with my partner	Relational	4	1	4
	More assertive in my relationships at work	Relational	3	2	5
	Better understanding and management of social anxiety	Behavioural	4	2	4
10	Taking a step back	Cognitive			
	Reduction in overworking	Behavioural	4	4	5
	Increased self-care	Behavioural	4	1	4
	Reduce caffeine intake	Behavioural	5	3	5
	Increased activities	Behavioural	4	1	3
11	Being more open with other people	Relational	5	1	5
	Better outlook on life/anxiety	Cognitive	2	3	3
	More active	Behavioural	4	1	4
	Better understanding of myself	Cognitive	2	1	4
15	Less clingy with my partner	Relational	3	3	4

	Being able to use the shower/bath	Behavioural		2	4	4
	Change in thoughts about being able to breathe	Cognitive		1	4	4
	Generally less panicky	Emotional		4	1	4
17	Writing down worries	Behavioural		2	4	5
	Grounding using senses	Behavioural		5	1	5
	New job	Behavioural		2	4	3
	More open with family members	Relational		3	2	5
	Recognizing unhelpful thinking patterns	Cognitive		4	2	5
CAT	-GSH					
Pt nun	Changes Identified iber		Change Category	Change was unexpected (5 = Completely unexpected)	Ratings Change would have occurred without therapy (5 = Change would not have happened without therapy)	Change was important (5 = Change was very important) ut
2	Less self-critical	Cognitive		3	3	4
	Taking time out for myself	Behavioural		4	1	4
	Listening to myself and acting on my own advice	Behavioural		2	2	5

3	Feeling like myself again	Emotional	5	1	5
	Taking a step back	Cognitive	5	1	5
	Improved relationships with son	Relational	5	1	5
	Having the desire to do things again	Emotional	3	1	5
	Not dissecting everything	Cognitive	5	1	5
	Not worrying all the time	Cognitive	5	1	5
	Separating work and personal life	Cognitive	5	1	5
4	Looking after myself better	Behavioural	2	1	5
	Improved self-awareness	Cognitive	3	1	5
	Overcoming negative thoughts	Cognitive	5	2	5
	Completing tasks and not napping	behavioural	5	1	5
6	Increased self-care	Behavioural	4	2	4
	Taking a step back	Cognitive	4	1	4
	Less self-critical	Cognitive	5	1	4
	More confident in myself	Emotional	4	1	5

7	Feeing more worthy	Emotional	5	1	5
	Starting a new job	Behavioural			
	Being more open in my relationship with my husband	Relational	5	2	5
	Better relationship with my kids	Relational	5	1	5
8	Change in outlook - focus on positive	Cognitive	4	1	5
	See myself as survivor not a victim	Cognitive	5	1	5
	Increased positive activity	Behavioural	3	2	5
	Less self-critical	Cognitive	5	1	5
12	Change in relationship with my wife	Relational	5	1	5
	Not overthinking things at work	Cognitive	1	1	4
13	More open and assertive	Relational	5	1	5
	Increased self-care	Behavioural	5	2	5
	Relaxing more	Behavioural	5	1	5
	Not getting caught up in other people's problems	Relational	5	1	5

Having insight into difficult relationship with mum, thinking about patterns between the past and present	Cognitive	3	2	5
Can better manage my relationship with my mum	Relational	3	1	5
More self-confident	Emotional	3	1	5
Taking a step back	Cognitive	4	1	5
No longer think everything is my fault	Cognitive	4	1	5
Positive change in relationship	Relational	5	2	5
Sharing my feelings at work	Behavioural	4	1	5
No longer avoid doing things	Behavioural	4	1	5
Being kinder to myself	Behavioural	5	2	5
Taking time to relax	Behavioural	4	2	5
	Having insight into difficult relationship with mum, thinking about patterns between the past and present Can better manage my relationship with my mum More self-confident Taking a step back No longer think everything is my fault Positive change in relationship Sharing my feelings at work No longer avoid doing things Being kinder to myself Taking time to relax	Having insight into difficult relationship with mum, thinking about patterns between the past and presentCognitiveCan better manage my relationship with my mum More self-confidentRelationalTaking a step backCognitiveNo longer think everything is my faultCognitivePositive change in relationshipRelationalSharing my feelings at workBehaviouralNo longer avoid doing thingsBehaviouralBeing kinder to myselfBehaviouralTaking time to relaxBehavioural	Having insight into difficult relationship with mum, thinking about patterns between the past and present Can better manage my relationship with my mum More self-confidentCognitive3Relational33Taking a step backCognitive4No longer think everything is my faultCognitive4Positive change in relationshipRelational5Sharing my feelings at workBehavioural4No longer avoid doing thingsBehavioural4Staring time to relaxBehavioural4	Having insight into difficult relationship with mum, thinking about patterns between the past and presentCognitive32Can better manage my relationship with my mum More self-confidentRelational31Taking a step backCognitive41No longer think everything is my faultCognitive41Positive change in relationshipRelational52Sharing my feelings at workBehavioural41No longer to myselfBehavioural41No longer to myselfBehavioural42

Note: CBT-GSH = Cognitive-Behavioural Therapy Guided Self-Help; CAT-GSH = Cognitive-Analytic Therapy Guided Self-Help; Pt = participant

Appendix M: Example of line-by-line coding to reduce raw data

These images have been removed by the author of this thesis for reasons related to confidentiality

Appendix N: Outline development

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mechanisms Personal Qualities Participatit therapist commitment. infuence auslines + qualities 2) Reionships CBT CAT Supportive change + insight relationships self reignonship transformation to the new self. 0 3 Enightenment CBT CAT inderstanding understanding Why what. 17 Tools Hechniques 14 UCBT CATL newtechnag Looking innords internal processes to cope before moving forward manago