Understanding common obstacles and solutions to deliver effective psychological treatment

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Declaration

I declare that this thesis has been submitted for the Doctorate of Clinical

Psychology at the University of Sheffield. This thesis has not been submitted for

the purpose of obtaining any other qualification or to any other institution.

Structure and word counts

Part I: Literature review

Excluding references and tables: 5,845 words

Including references and tables: 8,849 words

Part II: Research report

Excluding references and tables: 7,999 words

Including references and tables: 11,745 words

Total word counts (including lay summary)

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Lay Summary

There is substantial evidence suggesting that psychological therapies are largely effective for the treatment of mental health difficulties. However, the evidence-base has also demonstrated that some individuals do not improve after psychotherapy and others actually deteriorate. Therefore, there is a pressing need to understand how to improve outcomes in psychotherapy.

One approach to this is understanding the factors that predict good treatment response, so that therapists can make treatment decisions based on empirically based prognostic indicators. There is a well-documented literature highlighting social support as a relevant factor for mental health difficulties, especially for individuals with depression. However there remains considerable uncertainty about the extent to which social support may be associated with depression treatment outcomes.

Part I of this thesis is a systematic review and meta-analysis exploring associations between pre-treatment social support and psychotherapy outcomes for adults with depression. The results of 25 studies, including 7576 patients, were identified and synthesised and, of these, 12 studies were meta-analysed. Studies included randomised controlled trials and observational cohort studies. The quality of studies was assessed, ranging from low to high quality; however, the study quality did not influence the results. Higher levels of social support before psychotherapy were found to be significantly associated with lower depression severity following psychotherapy, especially in studies that used Cognitive Behavioural Therapy (CBT). This suggests that assessments of social support and early interventions aimed at increasing social support may be beneficial for improving depression outcomes, especially in CBT.

A second approach to improving outcomes in psychotherapy is the process of Outcome Feedback (OF). OF is a quality assurance system which relies on the tracking of patients' symptoms throughout therapy, using self-report questionnaires, to support therapists in identifying patients who may be at risk of a poor response to treatment. Numerous studies and reviews demonstrate that OF improves outcomes in psychotherapy; however, there is little research exploring why OF is beneficial.

Part II of this thesis is a research report exploring the processes underlying the effectiveness of OF. Therapists (n=28) who used OF in their routine practice were recruited from three psychotherapy services in England. Process data from 192 clinical case notes was collected, where therapists were asked to document the common obstacles to improvement and the common solutions (treatment strategies) with a cohort of patients (n=45) when they were identified by OF as being at risk of poor response to treatment. The large qualitative dataset was analysed using automatic topic modelling and content analysis. The results indicated several common obstacles to treatment progress – including the longstanding impact of patient's past experiences, the patient's attitudes and behaviours within therapy, the patient's social network, current stressors, and therapy factors – and several common solutions to these obstacles – including supporting the implementation of therapy tasks, ensuring focality of treatment', bridging between sessions, and developing a personalised formulation. The results could inform the foundations of a good practice guide for therapists utilising OF in routine practice.

Together, these studies provide useful insights into approaches to improving outcomes in psychotherapy.

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Part I

Literature Review

Understanding the role of social support in predicting effective

psychological treatment for depression

Abstract

Objectives

There remains considerable uncertainty about the extent to which social support is associated with depression treatment outcomes. Therefore, this systematic review and meta-analysis aimed to explore the associations between pre-treatment social support and psychotherapy outcomes for adults with depression.

Method

A systematic review and meta-analysis (PROSPERO registration: CRD42019155178) was conducted. Electronic databases (PsycINFO, MEDLINE and Scopus) were searched using a comprehensive systematic search strategy. Inclusion and exclusion criteria were applied. Included papers were assessed for quality and narratively synthesised. A subsample of studies was quantitatively synthesised using a random-effects meta-analysis.

Results

A total of 25 studies were included in the narrative synthesis and 12 studies were meta-analysed. Higher levels of social support before psychotherapy were found to be significantly associated with lower depression severity following psychotherapy ($r = -0.12$). This relationship was particularly relevant in the context of Cognitive Behavioural Therapy (CBT). Quality varied between studies; however, this did not influence the results.

Conclusions

This review demonstrated that social support can be considered as a significant prognostic indicator in psychotherapy for depression, albeit with a small effect.

Practitioner Points

- Having good social support at the beginning of psychotherapy may make a favourable difference to the outcome, especially in CBT.

- It might be important to attend to the quality of social support in cases where suicidal risk is assessed.

Limitations

- Four studies were assessed as having a high risk of bias.

- Non-English studies and grey literature were excluded, potentially reducing inclusivity.

Introduction

There is substantial evidence to suggest that psychological interventions are effective for the treatment of depression; however, it is also evident that many patients do not respond well to treatment, as shown in practice-based studies (Lambert, 2013; Lambert & Ogles, 2004). Large-scale studies of psychotherapy in routine care demonstrate that approximately 30% of clients do not show statistically reliable improvement and around 10% of clients show deterioration following therapy for a range of mental health difficulties (Hansen, Lambert & Forman, 2002; NHS Digital, 2016). For the treatment of depression specifically, it is estimated that more than half of patients relapse within 2 years of treatment (Vittengl et al., 2007). Therefore, there has been a pressing need to explore ways to improve outcomes in psychotherapy, particularly for the treatment of depression.

There is a well-documented literature highlighting social support as a relevant factor for psychotherapy outcome, especially for individuals with depression. Several studies have demonstrated the negative association between lower levels of social support and high levels of depressive symptoms, and systematic reviews have concluded that clients consider social support to be among the most important factors influencing their mood and outcomes from treatment (Bagby et al., 2002; Smith et al., 2015). Despite this, the only meta-analysis to date that has specifically explored the association between social support and psychotherapy outcomes found only a small correlation, suggesting that this variable may not be as critical in psychotherapy as initially considered (Roehrle & Strouse, 2008). However, the authors recommended that their findings should be interpreted with caution – due to the wide range of different

studies included in their review, and a risk of publication bias – and concluded that at that time insufficient research had been conducted to robustly answer their research questions, despite the well-recognised concept that social support is a relevant factor for psychotherapy outcome.

Since this review, a recent meta-analysis investigating the association between pre-treatment social support and prognosis for adults seeking treatment for depression in primary care reported significant associations (Buckman et al., 2021). However, the authors concluded that after adjusting for routinely assessed clinical characteristics, the prognostic value of social support was unlikely to be of a clinically important magnitude. Additionally, the review inclusion criteria specified that studies were required to explore treatments delivered by a General Practitioner or Family Physician and, of the 6 randomised controlled trials (RCTs) included, only two involved psychotherapy and the remainder involved treatment as usual or pharmacological treatments. Consequently, general conclusions about the predictive ability of baseline social support in psychotherapy for depression specifically cannot be drawn.

To date, there remains considerable uncertainty about the extent to which the quantity and quality of social support may be associated with depression treatment outcomes after psychotherapy. On this basis, the present study aimed to update the literature and conduct a more specific systematic review and meta-analysis of studies investigating associations between pre-treatment social support and psychotherapy outcomes for adults with depression. The primary objective of the study was to further the understanding about the association between pre-treatment social support and post-treatment depression outcomes, in order to inform clinical practice and support therapists to make treatment decisions based on empirically based prognostic indicators. The secondary

objective was to explore the associations between social support and depression outcomes across multiple measurements, in order to further inform clinical practice.

Method

Study protocol

The review protocol was pre-registered in the international prospective register of systematic reviews (PROSPERO) database prior to the search being conducted (registration number: CRD42019155178).

Inclusion criteria

The inclusion and exclusion criteria for the present review were informed by an earlier review of the literature (Roehrle & Strouse, 2008), with adjustments to ensure a specific focus on samples with depression. The review included studies meeting the following criteria: (1) studies published in English; (2) studies involving psychological interventions, including controlled trials and observational studies for adults with clinical depression; (3) studies that reported associations between social support measured before treatment and the post-treatment outcomes of psychological interventions for depression; (4) studies that included standardised and validated measures of both social support and depression. Only peer-reviewed papers published in scientific journals were included; grey literature – such as non-peer-reviewed papers, posters, and dissertations – were excluded. No restrictions were imposed on the study publication dates.

Search strategy

A comprehensive systematic search strategy was developed using best practice guidelines (Centre for Reviews and Dissemination, 2009). Three

databases (PsycINFO, MEDLINE and Scopus) were searched for relevant articles published with no date restrictions, using compound search strings of terms indicative of depression, psychotherapy, and social support. Specifically, search terms included variations of the key words: 'depression', 'psychotherapy', 'cognitive behaviour therapy', 'behaviour therapy', 'interpersonal therapy', 'counselling' and 'social support'. The full search strategy can be found in the Appendix (Appendix A). Titles and abstracts of all articles were screened by the author, and full text articles of potentially eligible studies were retrieved. In the instance of uncertainty over study eligibility, discussions with a supervisor were carried out to resolve ambiguity. Reverse-citations and reference list searches were conducted by hand on eligible studies to identify any further relevant studies.

Quality assessment

The quality and risk of bias for all eligible studies was assessed using the CASP checklists for cohort studies and RCTs (Critical Appraisal Skills Programme, 2018). Eligible studies were rated independently by two reviewers who subsequently compared their assessments. The reviewers arrived at a consensus without the need for moderation by a third reviewer for all studies. Detailed quality assessment tables can be found in the Appendix (Appendix B).

Primary outcomes

The primary outcomes of interest were post-treatment depression outcomes, as determined by diagnostic interview or validated self- or clinician-rated depression symptom measures, and pre-treatment social support, as determined by validated self-rated measures of social support. Whilst this review primarily focused on studies that examined the influence of pre-treatment social

support on depression outcomes, studies that included measures of social support and depression at different time points were included for the purposes of the secondary objective.

Data extraction and synthesis

A standardised extraction form was used for evidence synthesis, based on the Cochrane Collaboration's data collection form (Higgins & Green, 2011). Extracted information included: author; year of publication; study design; country published; sample size (total N and analysed N); study population; details of intervention and control conditions; outcomes; statistics; and information for the assessment of risk of bias.

A narrative synthesis was conducted to summarise the characteristics, methods and results of the included studies. This included evidence concerning variables that were not examined in the meta-analysis, including the impact of social support throughout the course of treatment. Statistical tests of the correlations between the measures of baseline social support and depression treatment outcomes were quantitatively synthesised using a random-effects meta-analysis for available studies that examined the influence of pre-treatment social support on depression outcomes and provided sufficient statistical information. For the primary omnibus analysis, the relevant inferential statistics were transformed into correlation coefficients (r) to attain standardization, and heterogeneity was examined using the I^2 and the Q statistics (Borenstein et al., 2009; Cochran, 1952; Higgins et al., 2003). In addition, funnel plots, a weight function model and fail-safe N calculation using Rosenthal's method were employed to investigate publication bias (Orwin, 1983). For the sensitivity analyses, subgroup analyses were conducted to examine methodological

sources of heterogeneity, according to therapy models, outcome measures, study design and risk of bias ratings.

Results

Study selection

A total of 25 studies met the inclusion criteria and were eligible for inclusion in the review. Figure 1 shows the PRISMA diagram (Moher et al., 2009) for the systematic selection of articles. Studies that were screened but excluded from the review can be found in the Appendix (Appendix C).

Figure 1

PRISMA flow diagram of the systematic study selection
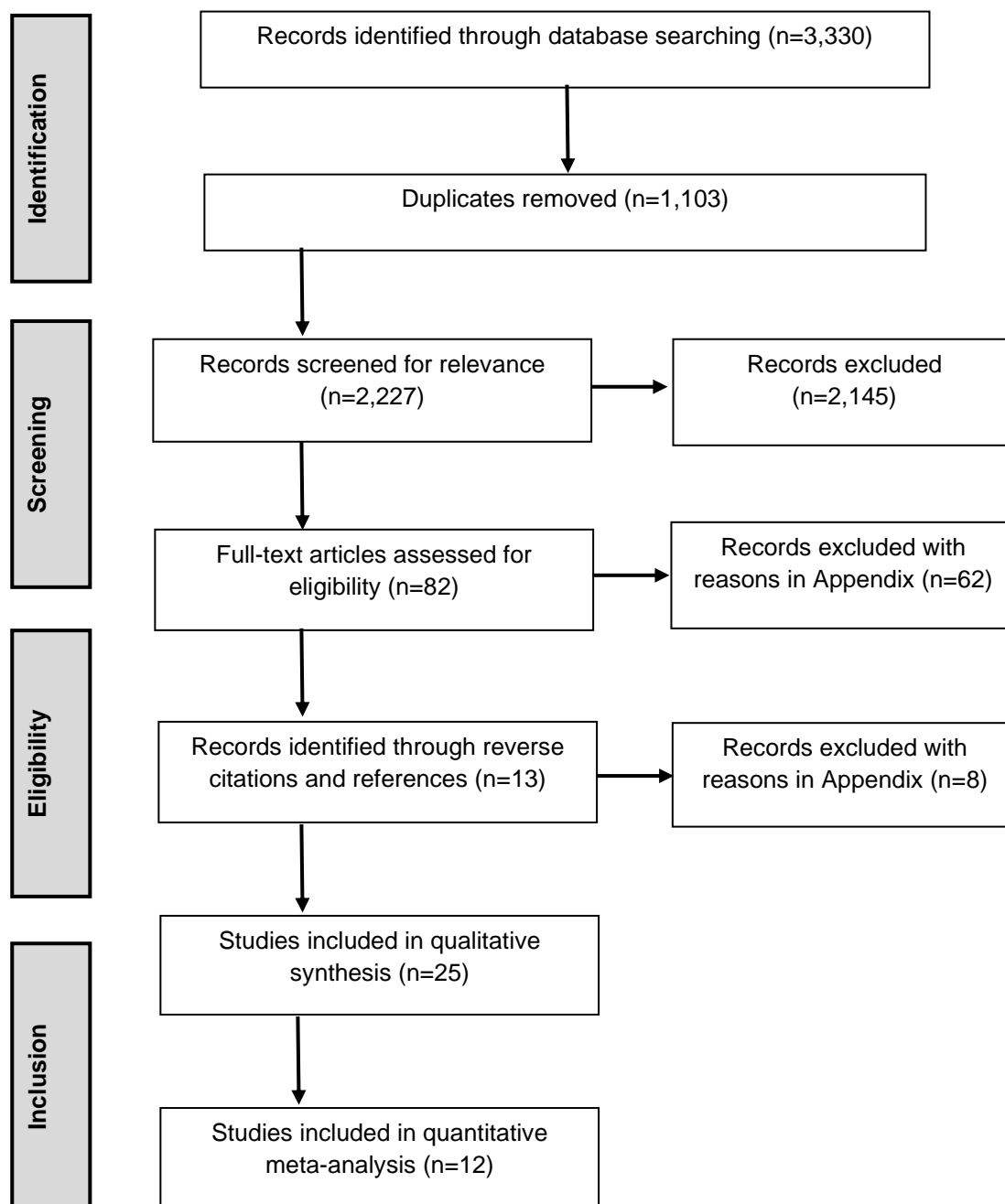
Study characteristics

The study characteristics of included studies are described in Table 1. Nine studies were RCTs and 16 were observational cohort studies (OCS). Studies were conducted between 1983 and 2019. Most studies were based in

North America (N = 17 in the USA; N = 1 in Canada), a number of studies were based in Europe (N = 2 in the Netherlands; N = 2 in Finland; N = 1 in Sweden; N = 1 in Norway) and one study was based in Asia (N = 1 in China). Across the studies, participants' ages ranged from 18 to 88 years old. Most studies included adults in general; however, 5 studies included exclusively older adults. There were a considerably higher proportion of female participants in all samples, excluding Kohen et al. (2011) where the majority of the sample were male. The ethnicity of participants was reported in approximately half of the studies (N = 12), where the majority of participants were reported to be white, with the exception of Toth et al., (2013) where a higher proportion of participants were reported to be black. Rates of employment were reported in 11 studies, where the proportion of employment within the samples ranged from approximately 15% to over 90%. The total pooled sample size across included studies was 7576; however, the total analysed sample size was 5206.

In terms of clinical characteristics, the majority of studies included clinically depressed samples (N = 16). Of these, four samples included participants with comorbid physical health conditions – including MS, cancer, and stroke – and one sample included participants with mild to moderate dementia. Of the nine remaining studies, three samples included participants with mild depression or dysthymia, and four samples included general mental health diagnoses with sub-samples of depression. One sample included participants with both depression and anxiety, and one sample included an anxiety sample with depressive symptomology. All studies included analyses for depression outcomes.

In terms of the psychological intervention examined, nine studies explored one psychological intervention, two studies explored usual care, seven studies included two or more psychological treatments and six studies included

psychological treatments, usual care and/or medication. The most widely used psychological intervention was Cognitive Behaviour Therapy (CBT; N = 9), followed by behaviour therapy (N = 5), Interpersonal Therapy (IPT; N = 4), Problem Solving Therapy (PST; N = 3) and Psychoeducation (N = 3). Of the psychological interventions, a large proportion were direct individual therapies; however, four were in a group format, and three were delivered via the telephone or the internet. The number of sessions ranged from three to 300, although sessions were described as "open" in five studies. A high proportion of samples included participants who were receiving concurrent antidepressant medication (N = 16).

Table 1

Study characteristics of included studies

First Author and Year.	Study Design.	Country.	*N.*	Analysed *N.*	Population.	Intervention.	Number of Sessions.	Outcome.	Social Support (SS) Measure.	Depression (Dep) Measure.	Timing of Measures (weeks/months since baseline)	Relationship Between SS & Depression.	Risk of Bias.
Beckner, 2010	RCT	USA	127	127	Adults; MS & depression	T-CBT or T-EFT	16	Patient- rated depression	UCLA-Social Support Inventory	BDI-II & HAM-D	Dep: Baseline & 16-weeks (pre/post) SS: Baseline	Interaction & moderation effect between baseline SS and treatment condition on Dep outcomes	Mod
Bernecker. 2014	OCS	Canada	95	95	Adults; major depression	IPT	16	Patient- & clinician-rated depression & global functioning	SSQ-B	BDI-II & HRSD	Baseline & 16-weeks (pre/post)	Associations between change in SS and Dep outcomes	High
Bosworth, 2002	OCS	USA	166	166	Older adults (60+ years); depression	Guideline-based treatment	Open	Clinician-rated depression	DSSI	MADRS	Dep: Baseline and annually SS: Baseline	Bivariate and multivariate associations between Dep outcome and baseline SS	Mod
Dew, 1997	OCS	USA	104	95	Older adults (60+years); recurrence of major depression	Antidepressant & IPT	12+	Patient-rated depression (response patterns)	Interpersonal Support Evaluation List - adapted	HAM-D	Dep: Weekly (12 weeks) then bi-weekly SS: Baseline	Baseline SS as a predictor of categorical Dep recovery patterns	High
Dour, 2014	RCT	USA	1004	804	Adults; panic disorder, GAD, social anxiety and/or PTSD	Medication and/or CBT or usual care.	Not specified	Patient-rated anxiety & depression	MOS-SSS – Abbreviated	PHQ-9	Baseline, 6-, 12-, & 18-months	Effect of intervention on 18-month SS via Dep, and effect of intervention on 18-month Dep via SS	Low
Eidelman, 2019	OCS	USA	74	74	Adults; any DSM-IV disorder	Case formulation-based CBT	3-30	Patient-rated depression & anxiety	MOS-SSS	DASS	Dep: Weekly SS: Baseline	Relationship between baseline SS and baseline negative social exchange, and the slope of change in Dep symptoms	Mod
Eurelings-Bontekoe, 1995	OCS	The Netherlands	131	120	Adults; primary care	Behaviour Therapy	Open	Psychological distress	Utrechtse Coping List "seeking social support" subscale, Social Network Questionnaire &	SCL-90	Baseline & 6-months	Relationship between baseline SS and Dep, and SS as a predictor of Dep outcome	Mod

									number of social contacts				
Eurelings-Bontekoe, 1996	OCS	The Netherlands	131	112	Adults; primary care	Behaviour Therapy	Open	Psychological distress	Utrechtse Coping List "seeking social support" subscale, Social Network Questionnaire & number of social contacts	SCL-90	Baseline, 6- & 18-months	Relationship between baseline SS and Dep, and SS as a predictor of Dep outcome	Mod
Hallgren, 2017	OCS	Sweden	945	722	Adults; mild to moderate depression	I-CBT, Exercise or usual care	12	Clinician-rated depression	ISSI (short version)	MADRS	Dep: Baseline & 3-months (pre/post) Ss: Baseline	Association between the availability of SS at baseline and change in Dep outcome	Low
Hoberman, 1988	OCS	USA	63	40	Adults; depression	Psychoeducation group intervention	12	Patient-rated depression	Perceived Social Support Questionnaire	BDI	Dep: Baseline, 3- (post), 4- & 9-months SS: Baseline	Predictive validity of SS on Dep outcome	High
Hopko, 2008	OCS	USA	43	32	Adults; cancer & major depression	BA	9	Clinician-rated depression (responders & non-responders)	MSPSS	HRSD	Baseline & 9-weeks (pre/post)	Association between baseline SS and Dep outcome	Mod
Hopko, 2015	OCS	USA	80	80	Adults (women); breast cancer & major depression	BA or PST	8	Patient-rated depression (response and remission)	MSPSS	BDI-II	Dep: Baseline & 8-weeks (pre/post) SS: Baseline	Baseline SS as a predictor of categorical Dep recovery patterns	Mod
Kiosses, 2015	RCT	USA	74	39	Older adults (65+years); mild to moderate dementia & major depression	PATH or ST-CI	12	Clinician-rated depression & suicidal ideation	MAI Social Support domain	CSDD	Dep: Baseline, 4-, 8- & 12-weeks SS: Baseline	Predicting or moderating effect of baseline SS on the course of Dep	High
Knapstad, 2018	OCS	Norway	2512	1059	Adults; PMHC	Low intensity and high intensity CBT	Open	Patent-rated depression & anxiety	OSS-3	PHQ-9	Dep: Weekly & follow-up SS: Baseline	The predictive value of baseline SS for treatment response.	Mod
Kohen, 2011	RCT	USA	101	101	Adults; stroke & depression	PST & antidepressants or usual care & antidepressants	9 (PST)	Patient-rated depression	ESSI	HAM-D	Dep: Baseline & 9-weeks (pre/post) SS: Baseline	The interaction of treatment group and SS on percent change of Dep	Low
Leskela, 2006	OCS	Finland	269	193	Adults; depression	Usual care	Open	Patient-rated depression	IMSR & PSSS-R	HAM-D	6- & 18-months	The impact of SS on later outcome of three groups of Dep patients (fully remitted, partially remitted	Mod

												and non-remitted)	
Lindfors, 2014	RCT	Finland	326	326	Adults; anxiety & depression	Solution-focused therapy, short-term psychodynamic psychotherapy or long-term psychodynamic psychotherapy	12, 20, 300+	Patient-rated psychological distress & depression	BISSI	SCL & BDI	Dep: Baseline, 7-, 12-, 24- & 36-months SS: Baseline	The prediction of SS on Dep outcome	Mod
Marquett, 2013	OCS	USA	60	60	Older adults (60+ years); depression	CBT	12	Patient-rated depression	DSSI	BDI-II	Baseline & 12-weeks (pre/post)	SS as a predictor of Dep outcome	Mod
Oxman, 2001	RCT	USA	307	104 (PST)	Older adults (60+ years); mild depression or dysthymia	Placebo, antidepressants or PST	6 (PST)	Patient-rated depression	Social Network Questionnaire & MSPSS	HAM-D	Baseline, 6- (post) & 12-weeks	The relationship of SS to Dep outcome in treatment for dysthymia or minor Dep	Low
Steinmetz, 1983	OCS	USA	112	75	Adults; depression	Psychoeducation group intervention	12	Patient-rated depression	Perceived Social Support Inventory	BDI	Dep: Baseline, 3- (post), 4- & 9-months SS: Baseline	Baseline SS as a predictor of Dep outcome	Mod
Stiles-Shields, 2015	RCT	USA	325	325	Adults; depression.	T-CBT or CBT	18	Patient- and clinician-rated depression	SPS	PHQ-9 & HAM-D	Dep: Baseline & 18-weeks (pre/post) SS: Baseline	Baseline SS as a predictor of response to CBT for Dep. Differences between predictive ability of SS between treatment delivery method.	Mod
Teri, 1986	RCT	USA	90	66	Adults; depression	Group social learning or individual behaviour therapy	12	Patient-rated depression	Perceived Social Support Inventory	BDI	Baseline, 3- (post), 4- & 9-months	The impact of SS on Dep outcome	Low
Toth, 2013	RCT	USA	128	99 (IPT)	Adults (ethnic minority women); depression	IPT or ECS	14 (IPT)	Patient-rated depression	SSB	BDI-II, HRSD-R	Baseline, 14-weeks (post) and 11.5-months	Mediating effect of increase in SS on sustained Dep outcome	Mod
Wang, 2019	OCS	China	102	100	Adults; mild depression or dysthymia	G-CBT	12	Clinician-rated depression	MSPSS	HRSD-17	Baseline, 4-, 8-, 12- (post), 24-, 36- & 48-weeks & 2 years	The influence of categorical perceived SS at baseline on Dep outcome	Mod
Zuroff, 2002	OCS	USA	207	187-192	Adults; depression	IPT, CBT, antidepressants & placebo (including non-specific supportive therapy)	>12	Clinician-rated depression	The Social Network Form	HRSD-17	Dep: Baseline, 6-, 12- & 18-months post intervention SS: 6-, 12- & 18-months post intervention	Post treatment SS as a predictor of Dep outcome	Mod

Note: RCT = randomised control trial; MS = Multiple Sclerosis; T-CBT = Telephone administered Cognitive Behavioural Therapy; T-EFT = Telephone administered Emotion-Focused Therapy; BDI II = Beck Depression Inventory-II; HAM-D = Hamilton Depression Rating Scale; OCS = observational cohort studies; IPT = Interpersonal Therapy; SSQ-B = Social Support Questionnaire-Brief; HRSD = Hamilton Rating Scale for Depression; DSSI = Duke Social Support Index; MADRS = The Montgomery–Åsberg Depression Rating Scale; GAD = generalised anxiety disorder; PTSD = post-traumatic stress disorder; MOS-SSS = The Medical Outcomes Social Support Survey; PHQ-9 = Patient Health Questionnaire-9; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition; DASS = Depression Anxiety Stress Scales; SCL = Symptom Checklist; I-CBT = Internet-based cognitive behavioural therapy; ISSI = Interview Schedule for Social Interaction; BA = Behavioural Activation; MSPSS = Multidimensional Scale of Perceived Social Support; PST = Problem Solving Treatment; PATH = Problem Adaptation Therapy; ST-CI = Supportive Therapy for Cognitively Impaired Older Adults; MAI Social Support = Philadelphia Multiphasic Assessment Instrument Social Support Domain; CSDD = Cornell Scale for Depression in Dementia; PMHC = Prompt Mental Health Care; OSS – 3 = Oslo 3-items social support scale; ESSI = ENRICHD Social Support Inventory; IMSR = Interview Measure of Social Relationships; PSSS-R = Perceived Social Support Scale – Revised; BISSI = Brief Inventory of Social Support and Integration; ECT = Electroconvulsive therapy; G-CBT = Group Cognitive Behavioural Therapy; SPS = Social Provisions Scale; ECS = enhanced community standard; SSB = Social Support Behaviors Scale

The primary outcome in the majority of studies was patient-rated depression. The most utilised patient-rated depression measures were the Beck Depression Inventories (BDI; Beck et al., 1961; BDI-II; Beck et al., 1996; N = 9), followed by the Hamilton Depression Rating Scale (HAM-D; Hamilton, 1960; N = 6). Clinician-rated depression was used as the primary outcome in eight studies, where the most frequently used measure was the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960; N = 4). Psychological distress was used as the primary outcome measure in two studies; however, individual analyses were reported for the depression subscales. Follow-ups ranged from four weeks to 36 months; however, one study had no depression follow-up due to having a pre-post design. A total of 19 social support measures were used across the studies. The most frequently used was the Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al., 1988; N = 4). Two studies did not include measures of social support at baseline. The majority of studies (N = 17) reported on baseline social support as a predictor of depression outcome. The remaining studies reported on a variety of investigations, including post treatment social support as a predictor of depression outcome, the interaction between social support and treatment on depression outcome, and the association between changes in social support and changes in depression outcome.

Quality assessment

The majority (84%) of the studies were rated as being at moderate risk of bias. Of the RCTs, four studies were rated as having low risk of bias, four studies were rated as having moderate risk of bias and one study was rated as having high risk of bias. The main sources of bias were due to generalisability and differences in baseline characteristics between groups. Of the observational cohort studies (OCSs), one study was rated as having low risk of bias, 17 studies

were rated as having moderate risk of bias and three studies were rated as having high risk of bias. The main sources of bias were methods of recruitment (such as using financial incentives), including only completer samples, lack of follow-up and reporting on interventions that were not controlled. See Table 1 for the individual ratings of bias for each study.

Narrative synthesis

Studies evaluating the predictive value of baseline social support on depression outcome

A narrative summary of study results is presented below, grouped according to psychotherapy models. See Appendix D for the table of key findings, which includes statistical methods and data, where this information was provided.

CBT. A total of four OCSs and one RCT included CBT interventions. Of the OCSs, two studies reported results in line with the hypothesis that baseline social support significantly predicts depression outcomes, and two studies reported results indicating the contrary. Hallgren et al. (2017) reported a significant association between high levels of available social support at baseline and post-treatment depression outcomes in a sample of 722 participants receiving I-CBT, exercise, or usual care for mild-moderate depression. Additionally, Wang et al. (2019) reported that higher social support at baseline led to significantly more and faster improvements in depression than low social support at baseline for 100 participants receiving G-CBT for mild depression. However, Knapstad et al. (2018) reported that level of social support at baseline did not predict change in latent depression scores for 1059 participants receiving both low and high intensity CBT for a range of mental health diagnoses. Additionally, Marquett et al. (2013) reported that level of social support at baseline

did not predict depression outcomes for 60 older adults receiving CBT for depression. The RCT reported conflicting results for different measures of depression. Stiles-Shields et al. (2015) reported that social support predicted response on the HAM-D, but did not predict response on the PHQ-9 for 325 participants receiving T-CBT or CBT for depression.

Behavioural Interventions. A total of four OCSs and one RCT included behavioural interventions. Of the OCSs, one study reported results in line with the hypothesis that baseline social support significantly predicts depression outcomes and three studies reported results indicating the contrary. Hopko et al. (2015) reported that perceived social support at baseline was associated with better post-treatment outcomes for 80 women with breast cancer receiving BA or PST for depression, when treatments were collapsed into a single group. However, Hopko et al. (2008) reported that levels of perceived social support at baseline did not significantly differ between treatment responders and non-responders in 32 adults with cancer receiving behavioural activation (BA) for major depression. Additionally, Eurelings-Brontekoe et al. (1995) reported that social support variables at baseline and 6 months post initiation of therapy did not significantly predict depression outcomes at 6 months for a group of 120 participants receiving behaviour therapy in primary care. In a follow-up study, Eurelings-Brontekoe et al. (1996) reported that the social support variables continued to have insignificant predictive power for depression outcomes at 18 months in 112 of the original 120 participants. In the RCT, Teri and Lewinsohn (1986) reported that perceived social support did not predict treatment outcome in 66 adults receiving group social learning or individual behaviour therapy for depression, when treatments were collapsed into a single group.

PST. A total of one OCS and two RCTs included PST interventions. The results of the OCS (Hopko et al., 2015) have been discussed previously and will, therefore, not be reported here. Of the RCTs, Kiosses et al. (2015) explored a PST alongside a supportive therapy for older adults with dementia and depression. They reported that PST was associated with a greater reduction in depression in those with high levels of social support than the supportive therapy in a sample of 39 older adults with dementia and depression; nonetheless, baseline social support had a significant effect on the course of depression across treatments. In contrast, Oxman and Hull (2001) reported that perceived adequacy of support at baseline was not predictive of decreased depression following PST in 104 older adults with mild depression.

Psychoeducation. A total of two OCSs included group psychoeducation interventions. Hoberman et al. (1988) reported that perceived social support from family at baseline was significantly correlated with post-treatment depression outcomes for 40 adults with depression; however, after pre-treatment depression scores were partialled out, this was no longer significant. Steinmetz et al. (1983) reported that after controlling for participants' initial level of depression, significantly better treatment outcome resulted for those with more perceived family support at baseline in 75 adults with depression. However, perceived support from friends could not account for a significant proportion of outcome variance beyond that explained by pre-treatment depression scores.

Other. A further two OCSs and one RCT included other interventions. Of the OCSs, Bosworth et al. (2002) reported that lower levels of baseline social support predicted poorer depression outcomes one year later in a sample of 166 adults receiving guideline-based treatments for depression. Dew et al. (1997) explored the impact of social support on categorical depression recovery patterns

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in 95 older adults receiving antidepressants and IPT for depression. They reported that high perceived social support at baseline was not strongly linked to subsequent rapidity of sustained response but did predict greater likelihood of partial or mixed response to treatment (Cluster analysis revealed 4 depression recovery patterns: none response, partial response, delayed response, and rapid response). Finally, Lindfors et al. (2014) reported that patients with anxiety and depression and low initial level of social support had a faster symptom reduction in short-term therapy with no additional benefit from long-term psychotherapy during the 3-year follow-up. Conversely, patients with a high level of support benefited more from long-term therapy than short-term therapy at the 3-year follow-up.

Studies evaluating post treatment social support as a predictor of depression outcome

One OCS evaluated the impact of post-treatment social support. Zuroff and Blatt (2002) reported that depression was significantly negatively correlated with levels of social support at termination and at 6-, 12- and 18-months follow-up in 192 adults receiving IPT, CBT antidepressants or placebo treatment for depression. The between-subjects effect of social support was almost twice the size of the within-subjects effect which is argued by the authors to suggest that the level of depression was more strongly determined by stable personality components of social support rather than fluctuations in the supportiveness of the social network.

Studies evaluating the interaction between social support and treatment on depression outcome

One OCS and two RCTs explored the interaction between social support and treatment on depression outcome. The OCS (Dour et al., 2014) reported that CBT led to changes in perceived social support, that in turn lead to subsequent changes in depression in 804 participants with anxiety disorders and depressive symptoms. Of the RCTs, Beckner et al. (2010) reported that received social support and satisfaction with social support was found to moderate outcome as a function of T-CBT but not T-EFT in 127 adults with MS and depression. Kohen et al. (2011) reported that there were no significant main effects or interactions with treatment group for baseline level of social support on treatment outcomes for 101 adults with stroke and depression receiving either PST and antidepressants or usual care and antidepressants.

Studies evaluating the association between changes in social support and changes in depression outcome

Three OCSs and one RCT explored changes in social support and changes in depression outcome. Of the OCSs, Bernecker et al. (2014) reported no significant associations between change in number of social support and satisfaction with social support on post-IPT depression outcomes in 95 adults with depression. Additionally, Eidelman et al. (2019) reported that social support was not associated with change in depression, symptoms over the course of treatment in 74 adults with a range of mental health diagnoses receiving case-formulation based-CBT. Leskela et al. (2006) reported that poor perceived social support influenced the medium-term prospective outcome of 193 adults with depression receiving usual care, but their impact varied somewhat depending on

the level of depressive symptoms at onset. In the RCT, Toth et al. (2013) reported that family social support was a statistically significant mediator of the effect of IPT on depression in 99 ethnic minority women with depression. However, social support from friends did not mediate sustained treatment outcome.

Meta-analysis

A total of 12 studies (N = 1,719) provided sufficient data for inclusion in the primary meta-analysis, which examined the correlations between pre-treatment levels of social support and post-treatment severity of depression. The primary meta-analysis yielded a weighted mean effect size of r = -0.12 [95% CI: -0.18, -0.66], p = 0.0001, indicating that a higher level of social support at baseline was significantly associated with lower depression severity post-treatment (see Figure 2).

Figure 2

Random effects meta-analysis: Effect (Pearson's r) of level of social support at baseline

Beckner_2010	-0.11 [-0.28, 0.06]
Bosworth_2002	-0.05 [-0.20, 0.10]
Eurelings-Bontekoe_1996	-0.18 [-0.35, 0.00]
Hallgren_2017	-0.21 [-0.27, -0.14]
Hoberman_1988	-0.26 [-0.51, 0.02]
Hopko_2008	0.29 [-0.02, 0.55]
Hopko_2015	-0.01 [-0.23, 0.21]
Kohen_2011	-0.02 [-0.21, 0.17]
Marquett_2013	-0.11 [-0.35, 0.14]
Oxman_2001	-0.12 [-0.30, 0.07]
Steinmetz_1983	-0.18 [-0.38, 0.04]
Wang_2019	-0.21 [-0.38, -0.02]
RE Model	-0.12 [-0.18, -0.06]

Transformed Correlation Coefficient
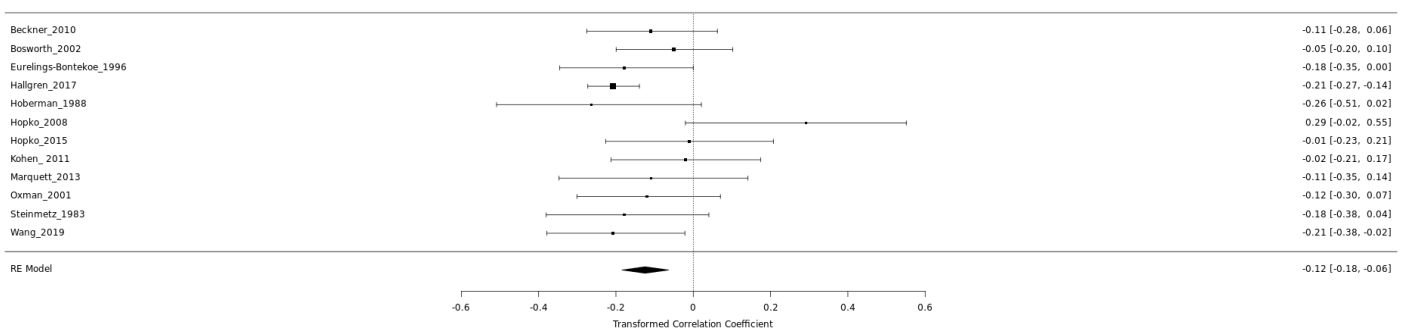
The I² statistic (28.2%) indicated a small index of heterogeneity; however, this was not significant according to Cochran's Q-test statistic (Q[11] = 15.32, p = 0.17). There was some discrepancy between tests for publication bias: whilst the regression for funnel plot asymmetry was marginally statistically significant (t[10] = 2.30, p = 0.044), indicating some evidence for publication bias, Kendall's

tau indicated no evidence of publication bias (Kendall's τ = 0.15, *p* =0.545).

Additionally, the Fail-safe N calculation indicated that 82 non-significant studies

would be necessary to contradict (i.e., nullify) the primary finding. A funnel plot is

presented in Figure 3.

Figure 3

Random effects meta-analysis: Funnel Plot
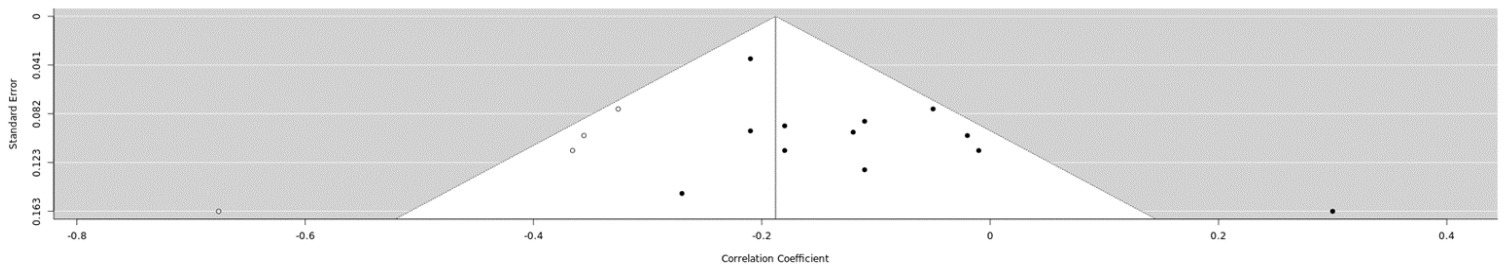
Sub-group analyses were conducted to examine the potential influence of

a number of pre-registered methodological and clinical features. In terms of the

specific therapeutic model provided, removing samples from four studies that

involved CBT interventions resulted in a small reduction in heterogeneity (Q[7] =

8.75, *p* = 0.27; I² = 20.0%) and reduced the magnitude and statistical significance

of the effect size (*r* = -0.08 [95% CI: -0.17, 0.00], *p* = 0.058) in the remaining

sample (k = 8). It is important to note that, due to limitations in the provision of

detailed statistics, one of the samples that was removed (Beckner et al., 2010)

also included individuals receiving T-EFT. Removing samples from three studies

that involved PST interventions resulted in a slight increase in heterogeneity (Q[8]

= 11.62, *p* = 0.17; I² = 31.1%) and magnitude of the effect size (*r* = -0.15 [95% CI:

-0.22, -0.07], *p* = 0.0001) in the remaining sample (k = 9). It is important to note

that, due to treatment groups being collapsed into a single group, one of the

samples that was removed (Hopko et al., 2015) also included participants

receiving BA. Removing samples from three studies that involved behavioural

interventions resulted in a considerable decrease in heterogeneity (Q[8] = 7.32, $p = 0.50$; $I^2 = 0.00\%$) and a slight increase in the magnitude of the effect size ($r = -0.16$ [95% CI: -0.21, -0.11], $p = <0.0001$) in the remaining sample (k = 9). Once again, it is important to note that, due to treatment groups being collapsed into a single group, one of the samples that was removed (Hopko et al., 2015) also included participants receiving PST.

In terms of outcome measures, removing five samples including the Beck measures (BDI and BDI-II) resulted in a substantial increase in heterogeneity (Q[7] = 13.04, $p = 0.07$; $I^2 = 46.3\%$) and a comparable effect size ($r = -0.12$ [95% CI: -0.20, -0.04], $p = 0.0046$) in the remaining samples (k = 8). Removing three samples including the HAM-D resulted in a slight increase in heterogeneity (Q[9] = 13.33, $p = 0.14$; $I^2 = 33.0\%$) and a comparable magnitude of effect size ($r = -0.13$ [95% CI: -0.21, -0.06], $p = 0.0003$) in the remaining samples (k = 10). Removing two samples including the HRSD resulted in a considerable reduction in heterogeneity (Q[9] = 8.79, $p = 0.46$; $I^2 = 0.0\%$) and a slightly larger magnitude of effect size ($r = -0.15$ [95% CI: -0.20, -0.10], $p < 0.0001$) in the remaining samples (k = 10). Removing two samples including the Montgomery–Åsberg Depression Rating Scale (MADRS; Svanborg & Asberg, 2001) also resulted in a considerable reduction in heterogeneity (Q[9] = 9.68, $p = 0.38$; $I^2 = 7.0\%$) and a comparable magnitude of effect size ($r = -0.11$ [95% CI: -0.18, -0.04], $p = 0.0025$) in the remaining samples (k = 10).

In terms of the design of the study, removing samples from three RCTs resulted in a slight increase in heterogeneity (Q[8] = 13.11, $p = 0.11$; $I^2 = 39.0\%$) and a comparable effect size ($r = -0.13$ [95% CI: -0.21, -0.05], $p = 0.0013$) in the remaining sample (k = 9). Finally, in terms of methodological quality, including only samples that were rated as "high quality" (k = 11) resulted in a slight increase

in heterogeneity (Q[10] = 14.71, p = 0.17; I² = 32.0%) and the same effect size (r = -0.12 [95% CI: -0.18, -0.05], p = 0.0004). Including samples that were only rated as "low quality" (k = 9) resulted in a decrease in heterogeneity (Q[8] = 9.46, p = 0.30; I² = 15.4%) and a comparable magnitude of effect size (r = -0.11 [95% CI: -0.19, -0.04], p = 0.0024). The corresponding forest and funnel plots for these subgroup analyses are available in the Appendix (Appendix E).

Discussion

This systematic review and meta-analysis found that higher levels of social support before psychotherapy was significantly associated with lower depression severity following psychotherapy. The effect size was small (r = -0.12) but robust, given that the failsafe N calculation suggested that 82 non-significant studies would be necessary to nullify the primary result. Subgroup analyses revealed that social support was associated with depression prognosis independent of the depression measure and study design, and the results were not unduly influenced by methodological quality. Additionally, heterogeneity was consistently low across analyses, further indicating that the results are stable and robust.

The only subgroup analysis that noticeably changed the results was the modality of psychotherapy delivered. Specifically, the effects of social support on depression outcome were considerably reduced and no longer significant when samples who received CBT were excluded from the analyses. Removing samples receiving other models of psychotherapy did not have a considerable impact on the results. This indicates that the relationship between baseline social support and depression outcome is particularly relevant in the context of CBT for depression and implies that social support may be a moderator of treatment outcomes in CBT.

It is interesting to note that of the studies included in this review, only one specifically investigated the moderating effect of social support on CBT for depression. Beckner et al. (2010) reported that social support moderated depression outcome as a function of psychotherapy model, where high levels of social support at baseline predicted post-treatment depression outcomes for T-CBT but not T-EFT. They concluded that depression outcomes vary depending on baseline levels of social support and the treatment modality.

One potential explanation for this is that the theoretical approaches that underpin therapeutic models place emphasis on different aspects of psychotherapy, and, consequently, the underlying mechanisms of change may be more or less influenced by social support. For example, Helgeson et al (2000) found that following a peer support group, individuals with high levels of baseline social support had poorer outcomes than those with low levels of baseline social support. Beckner et al. (2010) hypothesised that those with low social support benefitted more from the group because the treatment offered what they lacked – group members' support. They subsequently argued that in their study, those with high levels of social support may have been better placed to take on the more practical, skill-building tasks used in CBT, by utilising their support network to complete homework and test out new behaviours and skills.

This hypothesis has implications for clinical practice, where appraisals of social support before psychotherapy for depression could be incorporated into initial assessments to inform collaborative decisions about the most appropriate psychotherapy model for an individual. For example, if an individual has particularly low social support, one might argue that models that concentrate on the therapeutic relationship, such as IPT, may be more beneficial when compared with approaches that might be moderated by high social support, such as CBT.

This pragmatic method in determining the most appropriate therapeutic approach could lead to improvements in psychotherapy outcomes.

However, it is important to highlight that, with the exception of CBT, the subgroup analyses and qualitative synthesis did not reveal any notable differences between any other therapeutic model, including more practical and skills-based approaches – such as BA and PST – and approaches with a more relational focus – such as IPT and psychodynamic psychotherapy. Therefore, further research is required to further understand and draw conclusions about the hypothesis that social support moderates outcome in CBT.

Another potential clinical implication is that efforts to increase social support in the early stages of psychotherapy for depression might improve outcomes, especially in CBT. This is particularly relevant for suicide prevention, where lack of social support has been repeatedly shown to be one of the main risk factors associated with suicidal outcomes. A recent narrative review reported that the main social constructs associated with suicidal outcomes were marital status, living alone, social isolation, loneliness, alienation and belongingness (Calati et al., 2019). The interpersonal theory of suicide (ITS) explains that suicidal ideation occurs when individuals have a thwarted sense of belonginess and consider themselves burdensome to others (Joiner, 2005). Several meta-analyses have emphasised the protective role of social support in depression, and the ITS suggests that feelings of belonging to loved ones and, in a broader sense, society might safeguard individuals from suicide ideation (Joiner, 2005; Gariepy et al., 2016; Rueger et al., 2016). Therefore, it may be especially helpful to assess and, if necessary, seek to improve an individual's' social support where risk of suicide is identified during psychotherapy for depression.

A number of limitations are worth considering in relation to the studies involved in this review. In particular, four studies were rated as having a high risk of bias due to: having a small sample size and issues with generalisability, such as excluding participants who did not complete a full course of therapy; issues with methods of recruitment – such as using financial incentives – or lack of clarity over recruitment methods; differences in baseline characteristics between groups; reporting on interventions that were not controlled or appropriately measured, increasing the potential for confounding variables; and lack of complete follow-up. Additionally, the range of social support measures used in studies was extensive, raising questions over construct validity and the ability to compare measures meaningfully. Together these shortcomings may offer future directions for research, where particular care is taken to address these issues in the design of study methodology in order to minimise the potential for bias. Additionally, whilst the reported limitations may suggest that the results should be interpreted with some caution, it is important to highlight the finding that the methodological quality did not unduly influence the meta-analytic results.

There are also number of strengths and limitations of the review methodology that should also be considered when interpreting the result. To our understanding, this is the first and most comprehensive review to specifically assess the influence of baseline social support on depression psychotherapy outcomes. The review methodology demonstrates numerous qualities of good practice in systematic reviews; including pre-registration of the study protocol, a comprehensive search strategy applied across multiple databases, double-rated risk of bias assessment, and a quantitative synthesis and meta-analysis. Whilst non-English studies and grey literature were excluded, potentially reducing inclusivity, the quantitative evidence for publication bias was not strong. The

review question was specific to depression samples; however, examining a range of interventions aimed at depression samples with a range of comorbidities impacts the specificity of the conclusions drawn. In view of this, along with the preliminary review findings, it is recommended that future research narrows the breath of subsequent reviews by exploring the role of social support in predicting outcomes for specific therapeutic models, especially CBT.

Conclusion

In conclusion, the results from this systematic review and meta-analysis suggest that social support can be considered as a significant prognostic indicator in psychotherapy for depression, albeit with a small effect. This suggests that having good social support at the beginning of psychotherapy can make a favourable difference to the outcome, especially in CBT; however, the small effect size suggests that psychotherapy can still be effective if individuals have low social support at baseline. Therefore, assessments of social support and early interventions aimed at increasing social support may be beneficial for depression outcomes. It might be especially important to pay attention to the quality of social support in cases where suicidal risk is assessed. Overall, social support is an important factor in psychotherapy for depression and it is important that research continues to explore and understand the relevance of this extra therapeutic factor.

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Appendices

Appendix A: Search strategy

Appendix B. Risk of bias assessments

Appendix C: Studies that were screened but excluded from the review

Appendix D: Table of key findings

Appendix E: Forest and funnel plots for subgroup analyses

Appendix A: Search Strategy

PSYCHINFO

21: limit 20 to adulthood <18+ years>

20: 1 and 18 and 19 - 1365

19: 16 or 17

18: 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17: depress*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

16: exp Major Depression/ or depression.mp.

15: Counselling.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

14: ITP.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

13: Interpersonal Therap*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

12: CBT.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

11: Cognitive Behavio* Therap*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

10: Cognitive Therap*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

9: Behavio* therap*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

8: Psychotherap*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

7: exp Counseling/ or counselling.mp.

6: exp Behavior Therapy/ or behaviour therapy.mp.

5: cognitive therapy.mp. or exp Cognitive Therapy/

4: interpersonal therapy.mp. or exp Interpersonal Psychotherapy/

3: exp Cognitive Behavior Therapy/ or cbt.mp.

2: psychotherapy.mp. or exp Psychotherapy/

1: social support.mp. or exp Social Support/

MEDLINE

1: social support.mp. or Social Support/

2: psychotherapy.mp. or Psychotherapy/

3: Cognitive Behavioral Therapy/ or cbt.mp.

4: interpersonal therapy.mp.

5: cognitive therapy.mp. or Cognitive Behavioral Therapy/

6: behaviour therapy.mp. or Behavior Therapy/

7: Counseling/ or counselling.mp.

8: Psychotherap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

9: Behavio* therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

10: Cognitive Therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

11: Cognitive Behavio* Therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

12: cbt.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

13: Interpersonal Therap*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

14: ITP.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

15: counselling.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

16: Depressive Disorder, Major/ or major depression.mp.

17: depress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol

supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

18: 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

19: 16 or 17

20: 1 and 18 and 19

SCOPUS

Title abstract keyword

("Psychotherap*" OR "Behavio* therap*" OR "Cognitive Therap*" OR "Cognitive Behavio* Therap*" OR "Interpersonal Therap*") AND (depress*) AND ("social support") AND (adult*)

Appendix B: Risk of bias assessments

Randomised Controlled Trials

First Author (Year)	Clearly focused question?	Assignment randomised?	Participants accounted for at conclusion?	Participants, investigators, assessors blind?	Study groups similar at start and end?	Groups receive same level of care?	Effects reported comprehensively?	Precision of effects reported?	Benefits outweigh harms/costs?	Results Applicable to Intended Population?	Great value than existing intervention?	Overall rating?
Beckner, 2010	Low	Low	Low	Low	Low	Low	Low	Mod	Mod	Mod	Low	Mod risk
Dour, 2014	Low	Low	Low	Low	Low	Low	Mod	Low	Low	Mod	Low	Low risk
Kiosses, 2015	Low	Mod	Low	Mod	Low	Low	Low	Mod	Low	High	Low	High risk
Kohen, 2011	Low	Low	Low	Mod	Low	Mod	Mod	Mod	Low	Low	Low	Low risk
Lindfors, 2014	Low	Mod	Low	Mod	High	Low	Low	Low	Low	Mod	Low	Mod risk
Oxman, 2001	Low	Low	Mod	Low	Low	Low	Low	Mod	Low	Low	Low	Low risk
Stiles-Shields, 2015	Low	Low	Mod	Low	Low	Low	Mod	Mod	Low	Low	Low	Mod risk
Teri, 1986	Low	Mod	Mod	Mod	Low	Low	Mod	Mod	Low	Low	Low	Low risk
Toth, 2013	Low	Low	Low	Mod	Low	Mod	Low	Low	Low	High	Low	Mod risk

Cohort Studies

First Author (Year)	Clearly focused issue?	Recruited in an acceptable way?	ER Accurately Measured to Minimise Bias?	Depression accurately measured to minimise bias?	Identified all important confounding factors?	Accounted for confounding factors in design or analysis?	Follow up of subjects complete enough?	Follow up of subjects long enough?	Precision of effects reported?	Believe results?	Results Applicable to Intended Population?	Fit with other available evidence?	Implications considered?	Overall Rating
Bernecker. 2014	Low	High	Mod	Low	Low	Low	Low	High	Mod	Low	Mod	Low	Mod	High risk
Bosworth, 2002	Low	Mod	High	Low	Low	Low	Mod	Low	Low	Low	Mod	Low	Mod	Mod risk
Dew, 1997	Low	High	Mod	Low	Low	Low	High	Mod	Mod	Mod	Mod	Low	Low	High risk
Eidelman, 2019	Mod	Mod	Mod	Low	Low	Low	Mod	Mod	Low	Mod	Mod	Low	Low	Mod risk
Eurelings-Bontekoe, 1995	Mod	Low	High	Mod	Mod	Mod	Mod	Low	Mod	Mod	Mod	Low	Low	Mod risk
Eurelings-Bontekoe, 1996	Mod	Low	High	Mod	Mod	Mod	Mod	Low	Mod	Mod	Mod	Low	Low	Mod risk
Hallgren, 2017	Low	Low	Low	Low	Low	Low	Mod	Mod	Low	Low	Low	Low	Low	Low risk
Hoberman (1988)	Low	High	Low	Low	Low	Mod	Low	Low	Mod	Mod	High	Low	Low	High risk
Hopko, 2008	Low	Low	Low	Low	Low	Low	Low	High	Mod	Low	Mod	Low	Low	Mod risk
Hopko, 2015	Low	Mod	Low	Low	Low	Low	Low	High	Low	Low	Mod	Low	Low	Mod risk
Knapstad, 2018	Low	Low	Mod	Low	Low	Low	Low	Mod	High	Low	Low	Low	Mod	Mod risk
Leskela, 2006	Mod	Low	Mod	Mod	Mod	Mod	Mod	Low	Mod	Mod	Mod	Low	Mod	Mod risk
Marquett, 2013	Low	Low	Low	Low	Low	Low	Mod	High	Mod	Mod	Mod	Low	Low	Mod risk
Steffens, 2005	Mod	Mod	High	Low	Low	Low	Mod	Low	Mod	Mod	Mod	Low	Low	High risk
Steinmetz, 1983	Low	High	Low	Low	Low	Low	Mod	Low	Mod	Mod	Mod	Low	Low	Mod risk
Wang, 2019	Low	Mod	Low	Low	Mod	Mod	Low	Low	Mod	Mod	Mod	Low	Low	Mod risk
Zuroff, 2002	Low	Mod	Low	Low	Low	Low	Mod	Low	Mod	Mod	Low	Low	Low	Mod risk

Appendix C: Studies that were screened but excluded from the review

Original search

Not written in the English language (n=2)

Not a clinical sample (n=15)

Not a psychological intervention (n=7)

No full access (n=3)

Do not include a social support measure (n=8)

Do not report findings of correlation/associations of social support and depression outcomes (n=27)

Forward and backward tracking

No mention of psychotherapy (n=5)

Long-term observation of course of depression, where participants do not remain treatment seeking (n=3)

Appendix D: Table of key findings

First Author and Year.	Population (Analysed N)	Psychological Intervention	Reported findings relating to social support and depression
Beckner, 2010	Adults; MS & depression (127)	T-CBT or T-EFT	Hierarchical multiple linear regression techniques revealed no significant main effects for baseline levels of received social support and baseline levels of satisfaction with social support on post-treatment BDI-II scores (b= 0.17, p=0.25; b=0.23, p=0.24, respectively) or HAM-D scores (b=0.05, p=0.21; b=0.12, p=0.13, respectively), after adjusting for baseline depression severity, baseline social support, treatment assignment, and the cross-product of treatment condition and social support at baseline. However, received social support and satisfaction with social support was found to moderate outcome as a function of treatment. Separate regression analyses demonstrated that levels of received social support and satisfaction with social support predicted post-treatment BDI-II scores (b=-0.33; b=-0.42, respectively) and post-treatment HAM-D scores (b=-0.35; b=-0.44, respectively) as a function of T-CBT. This relationship was not significant for those assigned to T-EFT. Detailed statistics were not reported, including b values for T-EFT and exact p values for both T-CBT and T-EFT.
Bernecker, 2014	Adults; depression (95)	IPT	Hierarchical linear modelling techniques revealed no significant associations between change in number of social support and satisfaction with social support on post-treatment BDI-II (b=0.56, SE=0.722, p=0.473; b=-0.1423, SE=0.792, p=0.081, respectively) and HRSD outcomes (b=0.286, SE=0.645, p=0.659; b=-0.153, SE= 0.652, p=0.816, respectively) when adjusting for baseline depression outcomes, change in a number of interpersonal and cognitive characteristics, gender and medication use.
Bosworth, 2002	Older adults; depression (166)	Guideline-based	Bivariate analysis revealed that lower levels of baseline subjective social support predicted poorer depression outcomes one year later (p=0.0001). Instrumental social support and social network size did not predict outcome (p=0.49 and p=0.33, respectively). Detailed statistics were not reported. Multivariate analyses revealed that lower levels of social support at baseline predicted poor recovery (OR=1.21; CI=1.09-1.35; p<0.001).
Dew, 1997	Older adults (60+years); depression (95)	Antidepressant & IPT	Cluster analysis revealed 4 depression recovery patterns: none response, partial response, delayed response and rapid response. Univariate analysis revealed that levels of perceived social support significantly differed between recovery patterns (F=4.42, p<0.05). Multivariate discriminant function analyses extracted 2 underlying dimensions of (1) rapidity of sustained improvement and (2) partial or mixed response. High perceived social support at baseline was not

			strongly linked to subsequent rapidity of sustained response (loading=0.18) but did predict greater likelihood of partial or mixed response (loading = -0.3842).
Dour, 2014	Adults; panic disorder, GAD, social anxiety and/or PTSD (804)	Medication and/or CBT or usual care.	All pathways between depression and perceived social support were significant. Relative to usual care, the evidence-based intervention led to changes in perceived social support, that in turn lead to subsequent changes in depression (b=-0.16; CI=-0.28, -0.08, P<0.05, ratio=10.51%). Similarly, the intervention led to changes in depression that in turn led to changes in perceived social support (b=0.13; CI=0.04, 0.25, P<0.05, ratio=16.27%).
Eidelman, 2019	Adults; any DSM-IV disorder (74)	Case formulation-based CBT	Baseline level of overall social support was associated with baseline depression (b=0−2.63; CI=-4.66 – -0.61; p=0.01). Social support was not associated with change in depression, anxiety, or stress symptoms over the course of treatment, b's=−0.06 – 0.03, p's = 0.25 – 0.92 It is not possible to disentangle between outcomes as individual p and b coefficients were not reported.
Eurelings-Bontekoe, 1995	Adults; primary care (120)	Behaviour Therapy	Canonical correlation analyses revealed the number of contacts correlated negatively with depression at baseline (b=-0.29, p<0.01) but at 6 months this association disappeared (b=-0.12, p>0.05). Social support seeking was not associated with depression at baseline or 6 months (b=-0.01, p>0.05; b=-0.03, p>0.05). Stepwise multiple regression analyses revealed that social support did not predict change in depression symptoms over the course of treatment. Detailed statistics were not reported.
Eurelings-Bontekoe, 1996	Adults; primary care (112)	Behaviour Therapy	Canonical correlation analyses revealed a significantly negative association between perceived quality of social relationships and depressive symptoms (r=-0.21; p<0.05) and no significant association between number of social contacts and depressive symptoms (r=-0.15) 18 months after the beginning of therapy. Stepwise multiple regression analysis revealed that social support variables at baseline and 6 months after beginning therapy did not significantly predict depression outcomes at 18 months. Detailed statistics were not reported.
Hallgren, 2017	Adults; mild to moderate depression (722)	I-CBT, Exercise or usual care	Multiple linear regression models revealed a significant association between high levels of available social support at baseline and post-treatment depression outcomes (low vs high: b=-3.95, 95% CI = −5.49, −2.41, p<0.01) after adjusting for age, gender, treatment group, anti-depressant use, baseline depression and employment status. A binary outcome variable (<50% reduction in post-treatment depression severity) also revealed that high levels of available social support was associated with significantly better treatment response than low levels of available social support (low vs high: OR = 2.17, CI = 1.40, 3.36, p< 0.01).

Hoberman (1988)	Adults; depression (40)	Psychoeducation group intervention	Univariate correlations revealed that perceived social support from family at baseline was significantly correlated with post-BDI scores (r=-0.31; p<0.05). A change in social support showed no significant correlations with post-BDI scores (r=0.14). However, after pre-treatment BDI scores were partialled out, perceived social support from family was no longer significant (r=-0.27) and changes in social support were significantly related to post-BDI scores (coefficient=-0.31; p<0.05). Multiple regression analyses revealed that significantly better depression outcomes resulted for individuals who were less likely to have had an increase in social support in the 6 months prior to treatment F(6, 13)=5.35, p<0.001).
Hopko, 2008	Adults; cancer & major depression (32)	BA	Reliable change indices were used to determine treatment responders and non-responders. Levels of perceived social support did not significantly differ between treatment responders and non-responders (t=0.19, p=0.85).
Hopko, 2015	Adults (women); breast cancer & depression (80)	BA or PST	Treatments were collapsed into a single group. Reliable change indices were used to determine remission. Binary logistic regression analyses revealed that perceived social support was associated with better post-treatment outcomes on the BDI-II and remission (b=0.03, SE=0.02, p<0.05, OR=1.08; b=0.03, SE=0.02, p<0.05, OR=1.03 respectively).
Kiosses, 2015	Older adults (65+years); dementia & depression (39)	PATH or ST-CI	PATH was associated with a greater reduction in depression in patients with high levels of social support than ST-CI (Social Support × treatment interaction: F[1,30.9] = 5.12, p = 0.0308; Social Support × treatment interaction × time: F[1,32.2] = 5.14, p = 0.0303). There was no significant difference between PATH and ST-CI in those with low social support. Baseline social support had a significant effect on the course of depression. Patients with high social support had greater reduction in depression in both treatments than those with low social support. Detailed statistics were not provided.
Knapstad, 2018	Adults; PMHC (1059)	Low intensity and high intensity CBT	Level of social support at baseline did not predict change in latent depression scores. Accordingly, the lower socially supported showed similar degree of improvement as the higher socially supported, though notably reporting lower depression symptom severity both at pre and post treatment (ES baseline score depression − 0.47). Detailed statistics were not provided.
Kohen, 2011	Adults; stroke & depression (101)	PST & antidepressants or usual care & antidepressants	Analysis of covariance revealed that there were no significant main effects (p=0.858) or interactions (p=0.566) with treatment group for level of social support. Detailed statistics were not provided.
Leskela, 2006	Adults; depression (193)	Usual care	Poor perceived social support influenced the medium-term prospective outcome of psychiatric MDD patients, but their impact varied somewhat depending on the level of depressive symptoms at the onset. At the 6-month follow-up, those in major depressive episodes (MDE) perceived significantly

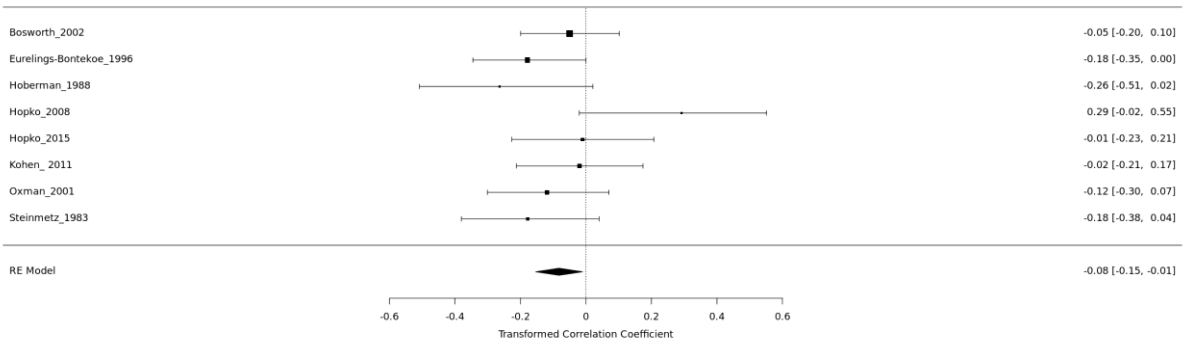|			less social support (sd =13.8, p<0.001), had a significantly smaller network (sd=2.8, p<0.01), and had fewer contacts within 2 weeks (sd=2.3, p<0.01) compared with those in remission and those in partial remission. In the overall linear regression, perceived social support at 6 months predicted the 18-month HAMD significantly in original zero-order correlation and within-group standardized correlations (r=-0.352, p<0.05). Perceived social support had the strongest predictive roles in the subgroup of patients currently in full remission (r=-0.411, p=0.000).
Lindfors, 2014	Adults; anxiety & depression (326)	Solution-focused therapy, short-term psychodynamic psychotherapy or long-term psychodynamic psychotherapy	Linear mixed models revealed that patients with low initial level of social support had a faster symptom reduction in short-term therapy with no additional benefit from long-term psychotherapy during the entire 3-year follow-up. Conversely, patients with a high level of support benefited more from long-term therapy than short-term therapy at the 3-year follow-up, and in short-term therapy their faster symptom reduction in comparison to patients in long-term therapy was more limited.
Marquett, 2013	Older adults (60+ years); depression (60)	CBT	Use of logistic regression to predict responders versus non-responders indicated that social support did not predict depression outcomes (b=0.255, SE=0.287, t=0.889, p=0.379).
Oxman, 2001	Older adults (60+ years); mild depression or dysthymia (104)	PST	Covariance structure models revealed that in the PST group perceived adequacy of support at baseline was not predictive of decreased depression at 6 weeks (r=-0.07, p>0.05) or 11 weeks (r=-.012, p>0.05). Perceived adequacy of support at 6 weeks was not predictive of decreased depression at 6 weeks (r=-0.18, p>0.05) or 11 weeks (r=-0.16, p>0.05). Perceived adequacy of support at 11 weeks was predictive of decreased depression at 11 weeks (r=-0.24, p<0.01).
Steinmetz, 1983	Adults; depression (75)	Psychoeducation group intervention	Stepwise multiple regression revealed that after controlling for participants' initial level of depression, significantly better treatment outcome resulted for those with more perceived family support F(1, 64)=4.37, p=0.041, b=-0.19. Perceived support from friends could not account for a significant proportion of outcome variance beyond that explained by pre-treatment BDI scores. Detailed statistics were not provided.
Stiles-Shields, 2015	Adults; depression (325)	T-CBT or CBT	Perceived social support (score < 65) predicted response on the HAMD. Scores of less than 65 predicted non-response on the HAMD. Perceived social support did not predict response or non-response on the PHQ-9. Treatment delivery method did not impact the prediction of outcome. Detailed statistics were not provided.

Teri, 1986	Adults; depression (66)	Group social learning or individual behaviour therapy	Data for all subjects were grouped and analysed together. Perceived social support did not predict treatment outcome. Detailed statistics were not provided.
Toth, 2013	Adults (ethnic minority women); depression (99)	IPT	Family social support was found to be a statistically significant mediator of the effect of IPT on depression. Specifically, changes in family social support predicted depression at the 8-month follow-up ("a" path = 0.169 (0.088), t = 1.925, p = 0.054, d = 0.45; "b" path =–25.55 (11.44), t = –2.233, p = 0.026, d = 0.407. The correlation between the "a" path and "b" path was 0.618. Social support from friends did not mediate sustained treatment outcome, although detailed statistics were not provided.
Wang, 2019	Adults; mild depression or dysthymia (100)	G-CBT	In patients with high perceived social support at baseline, the total depression scores decreased significantly more and faster than those with low perceived social support at baseline through G-CBT (F=4.968, p=0.036).
Zuroff, 2002	Adults; depression (187-192)	IPT, CBT, antidepressants & placebo (including non-specific supportive therapy)	Depression was significantly negatively correlated with levels of social support at termination and at 6, 12 and 18 months follow-up (r=-0.20, p<0.05; r=-0.25, p<0.001; r=-0.33, p<0.001; r=-0.32, p<0.001, respectively). Increases and decreases in social support were predictive of lower and higher depression scores, only when patient had high stress levels (b=-0.53). The between-subjects effect of social support was almost twice the size of the within-subjects effect (b=-0.62, -0.35, respectively), suggesting that the level of depression was more strongly determined by stable personality components of social support rather than fluctuations in the supportiveness of the participants social network.

Appendix E: Forest and funnel plots for subgroup analyses

<u>Therapeutic model</u>

Removing samples from studies using CBT

Forest Plot

Funnel Plot
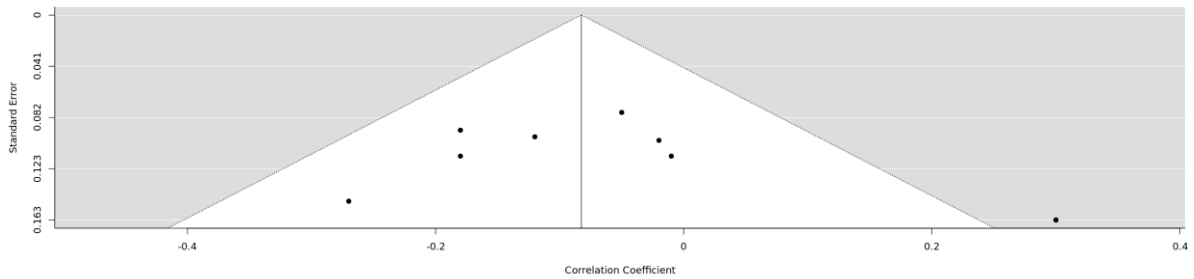
Removing samples from studies using PST

Forest Plot

Beckner_2010		-0.11 [-0.28, 0.06]
Bosworth_2002		-0.05 [-0.20, 0.10]
Eurelings-Bontekoe_1996		-0.18 [-0.35, 0.00]
Hallgren_2017		-0.21 [-0.27, -0.14]
Hoberman_1988		-0.26 [-0.51, 0.02]
Hopko_2008		0.29 [-0.02, 0.55]
Marquett_2013		-0.11 [-0.35, 0.14]
Steinmetz_1983		-0.18 [-0.38, 0.04]
Wang_2019		-0.21 [-0.38, -0.02]
RE Model		-0.15 [-0.21, -0.08]

Transformed Correlation Coefficient

Funnel Plot

Standard Error

Correlation Coefficient
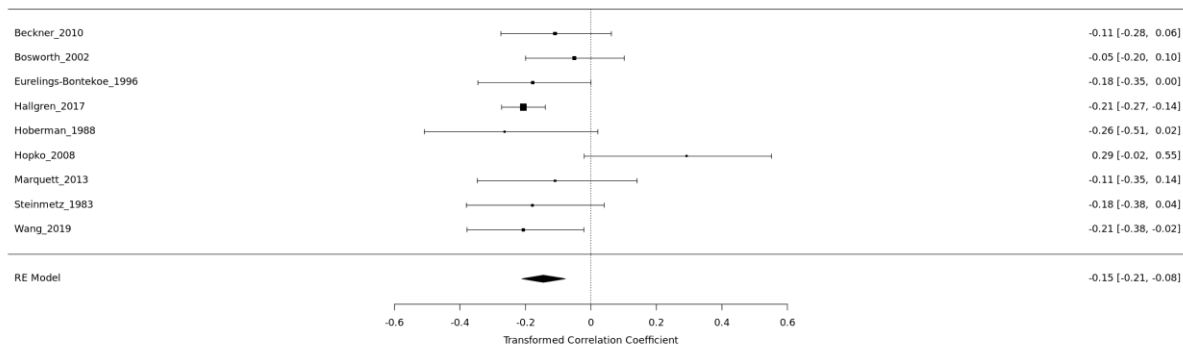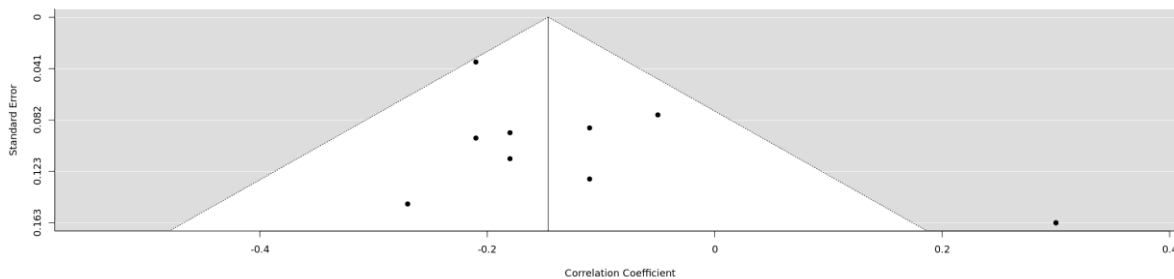
Removing samples from studies using BA

Forest Plot

Beckner_2010	-0.11 [-0.28, 0.06]
Bosworth_2002	-0.05 [-0.20, 0.10]
Hallgren_2017	-0.21 [-0.27, -0.14]
Hoberman_1988	-0.26 [-0.51, 0.02]
Kohen_ 2011	-0.02 [-0.21, 0.17]
Marquett_2013	-0.11 [-0.35, 0.14]
Oxman_2001	-0.12 [-0.30, 0.07]
Steinmetz_1983	-0.18 [-0.38, 0.04]
Wang_2019	-0.21 [-0.38, -0.02]
RE Model	-0.15 [-0.21, -0.09]

Transformed Correlation Coefficient

Funnel Plot

Standard Error

Correlation Coefficient
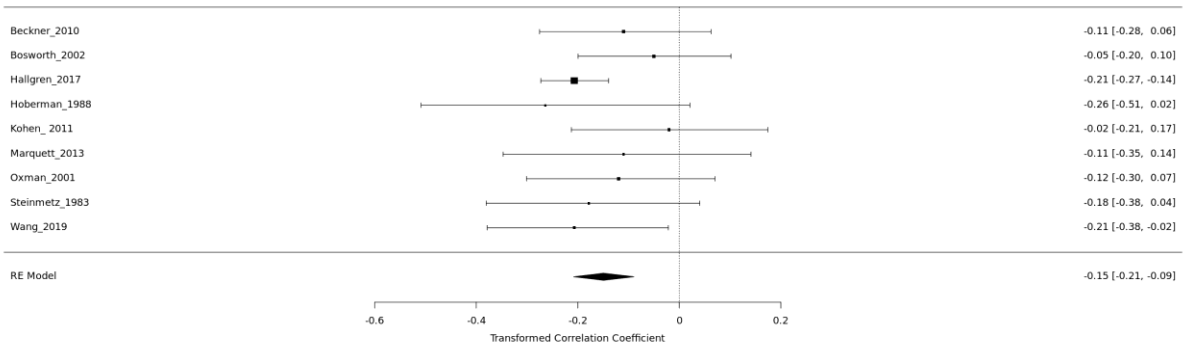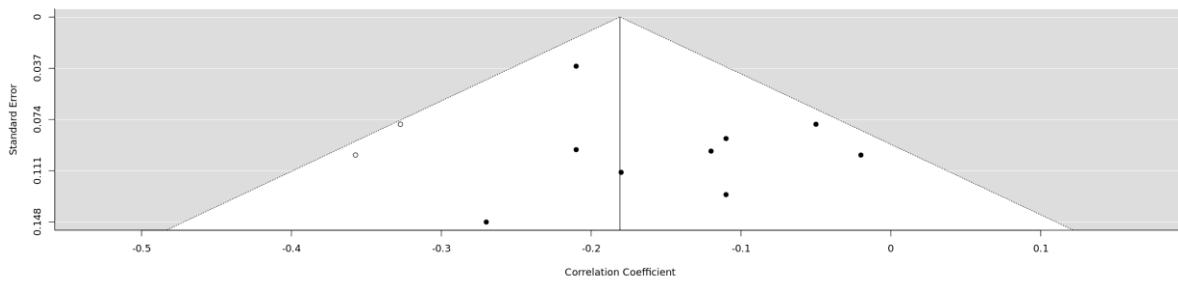
Depression outcome measure

Removing samples from studies with Beck measures

Forest plot
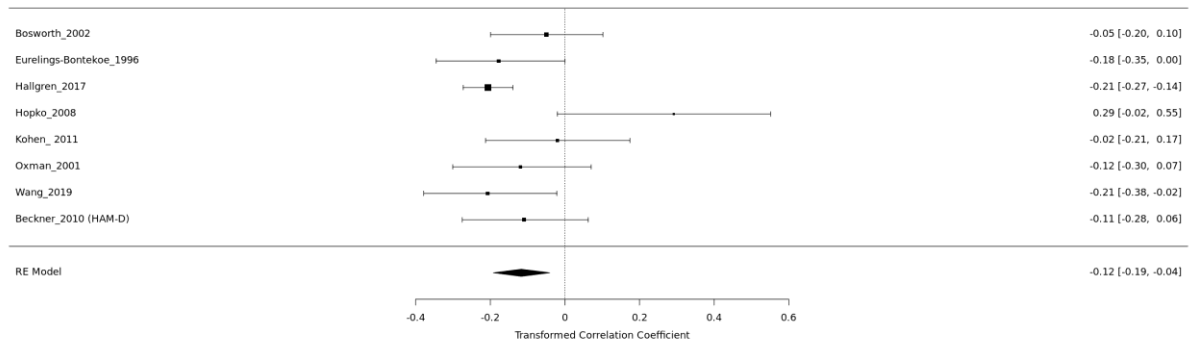
Funnel Plot
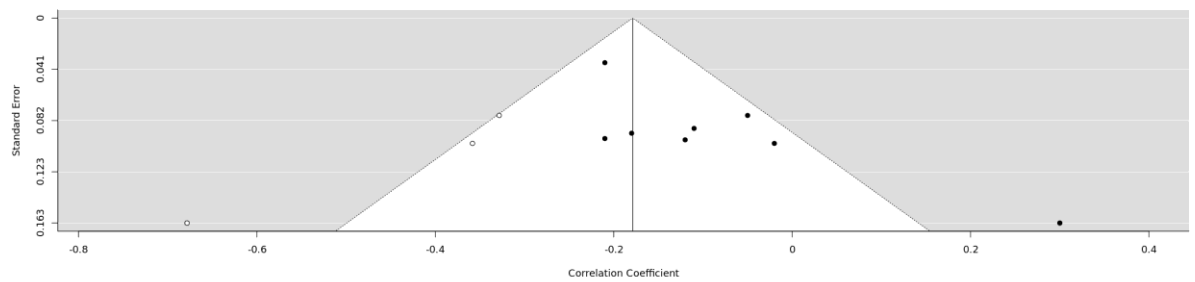
Removing samples from studies including the HAM-D

Forest Plot

Bosworth_2002	-0.05 [-0.20, 0.10]
Eurelings-Bontekoe_1996	-0.18 [-0.35, 0.00]
Hallgren_2017	-0.21 [-0.27, -0.14]
Hoberman_1988	-0.26 [-0.51, 0.02]
Hopko_2008	0.29 [-0.02, 0.55]
Hopko_2015	-0.01 [-0.23, 0.21]
Marquett_2013	-0.11 [-0.35, 0.14]
Steinmetz_1983	-0.18 [-0.38, 0.04]
Wang_2019	-0.21 [-0.38, -0.02]
Beckner_2010	-0.11 [-0.28, 0.06]
RE Model	-0.13 [-0.20, -0.07]

Transformed Correlation Coefficient

Funnel Plot

Standard Error

Correlation Coefficient
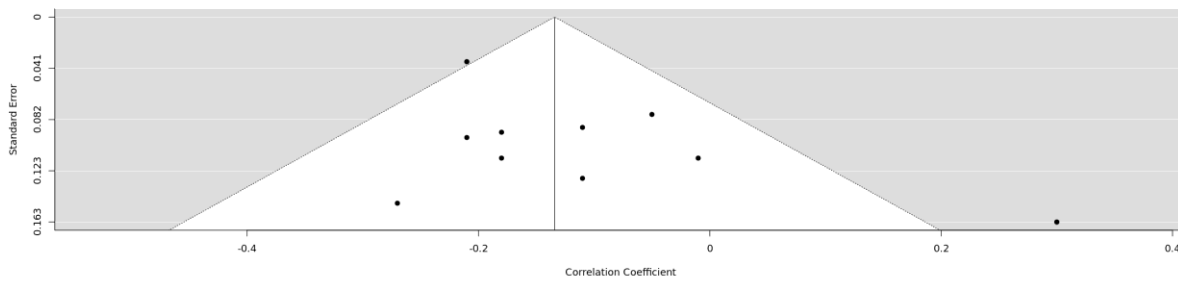
Removing samples from studies including the HRSD

Forest Plot

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Bosworth_2002		-0.05 [-0.20, 0.10]
Eurelings-Bontekoe_1996		-0.18 [-0.35, 0.00]
Hallgren_2017		-0.21 [-0.27, -0.14]
Hoberman_1988		-0.26 [-0.51, 0.02]
Hopko_2015		-0.01 [-0.23, 0.21]
Kohen_ 2011		-0.02 [-0.21, 0.17]
Marquett_2013		-0.11 [-0.35, 0.14]
Oxman_2001		-0.12 [-0.30, 0.07]
Steinmetz_1983		-0.18 [-0.38, 0.04]
FE Model		-0.15 [-0.20, -0.11]

Transformed Correlation Coefficient
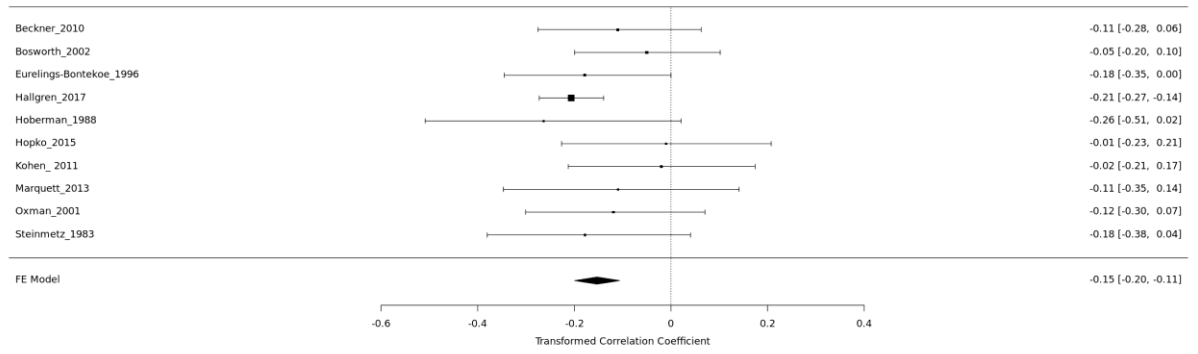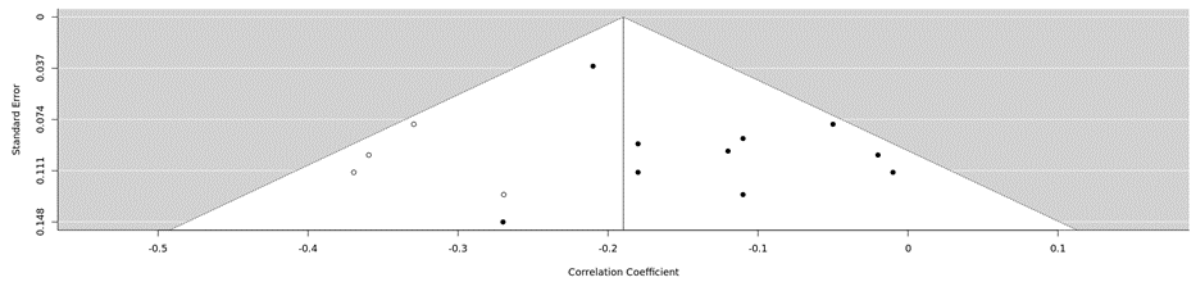
Funnel Plot

Removing samples from studies including the MADRS

Forest Plot
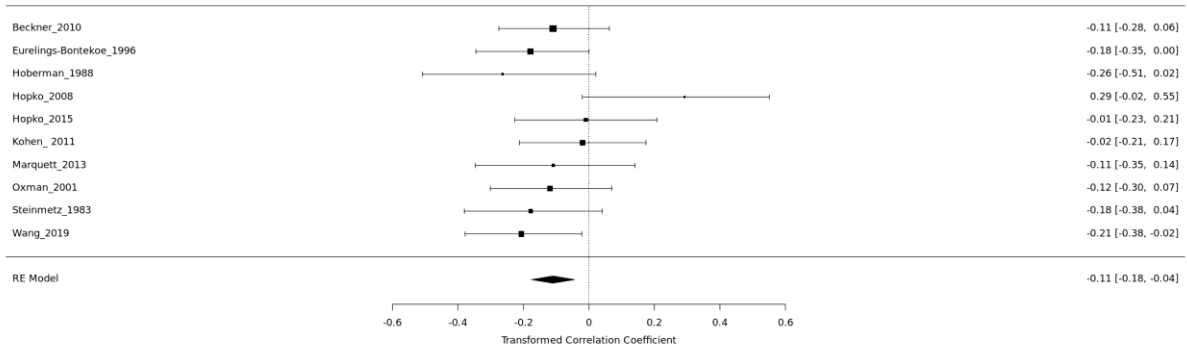
Funnel Plot
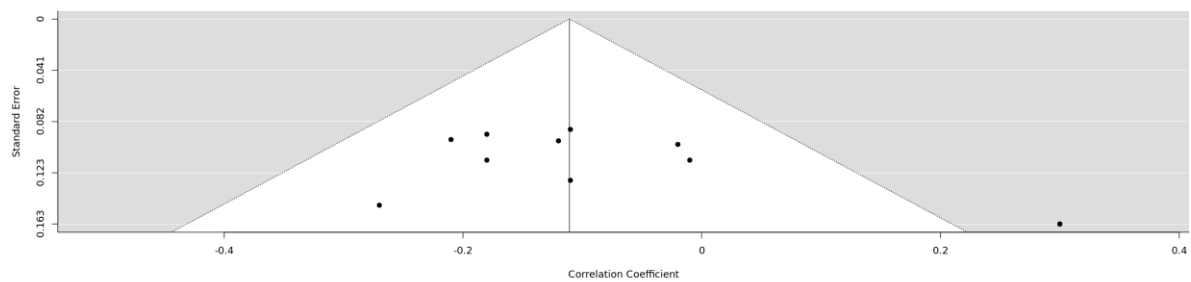
Study Design

Removing samples from RCTs

Forest Plot

Bosworth_2002		-0.05 [-0.20, 0.10]
Eurelings-Bontekoe_1996		-0.18 [-0.35, 0.00]
Hallgren_2017		-0.21 [-0.27, -0.14]
Hoberman_1988		-0.26 [-0.51, 0.02]
Hopko_2008		0.29 [-0.02, 0.55]
Hopko_2015		-0.01 [-0.23, 0.21]
Marquett_2013		-0.11 [-0.35, 0.14]
Steinmetz_1983		-0.18 [-0.38, 0.04]
Wang_2019		-0.21 [-0.38, -0.02]
RE Model		-0.13 [-0.21, -0.06]

Transformed Correlation Coefficient

Funnel Plot

Standard Error / Correlation Coefficient

59
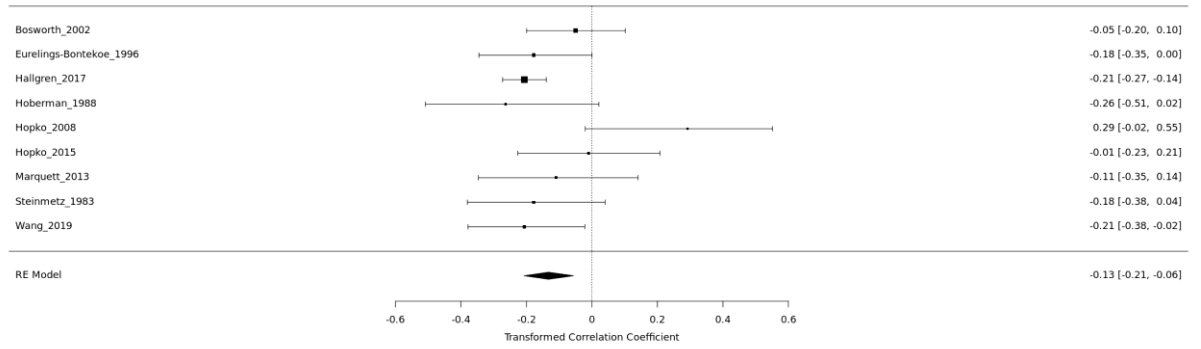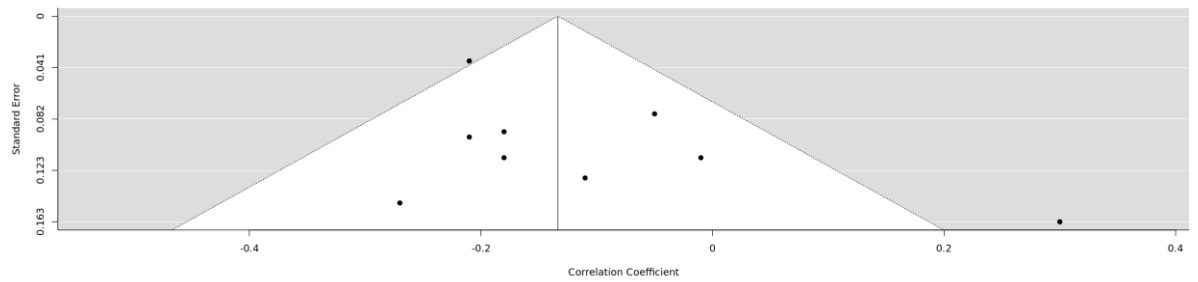
Methodological Quality
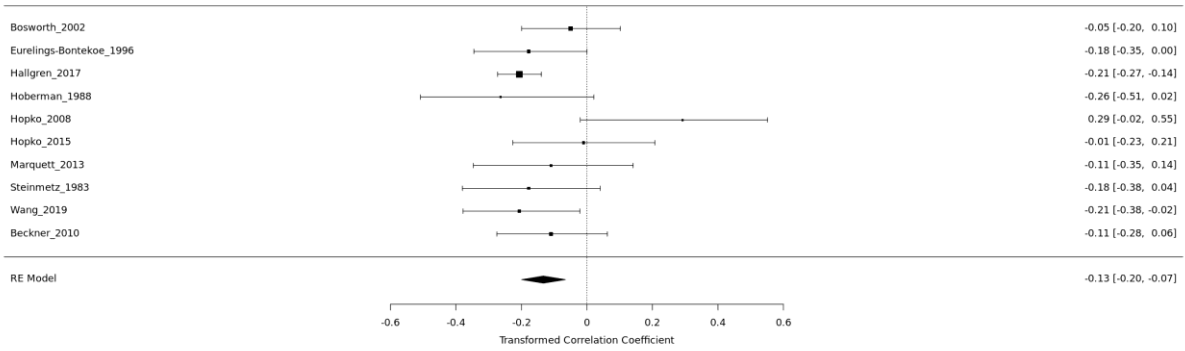
Removing samples from studies rated as low and moderate quality

Forest Plot
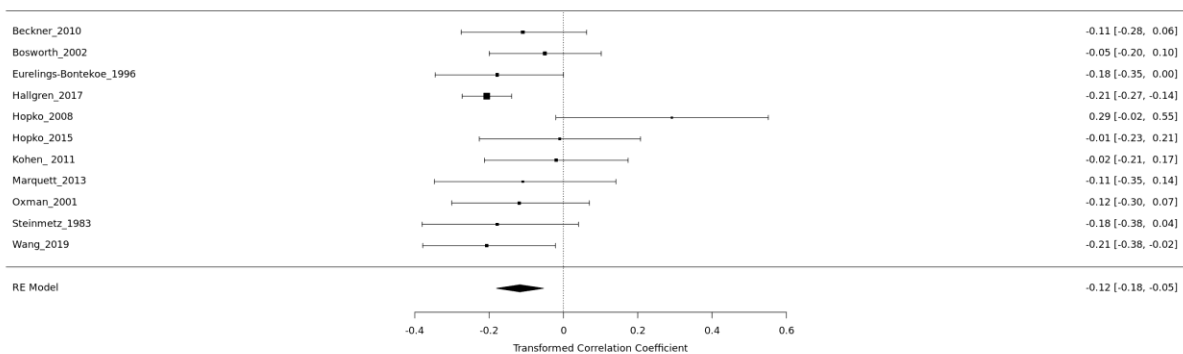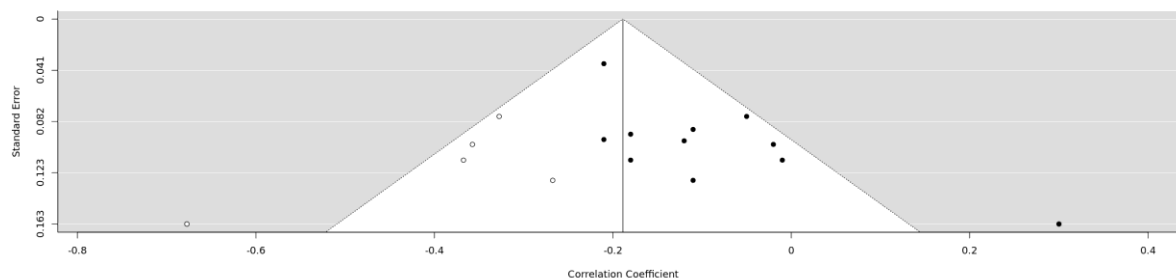
Funnel Plot

Removing samples from studies rated as high and medium quality

Forest Plot
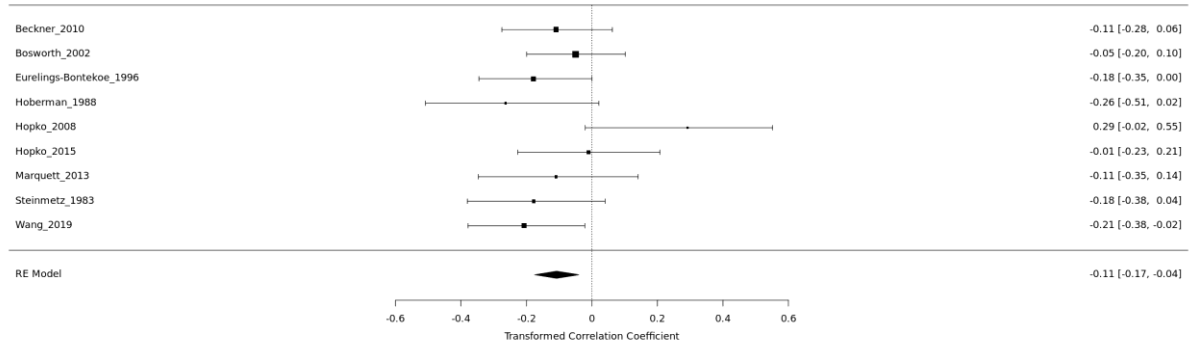
Funnel Plot
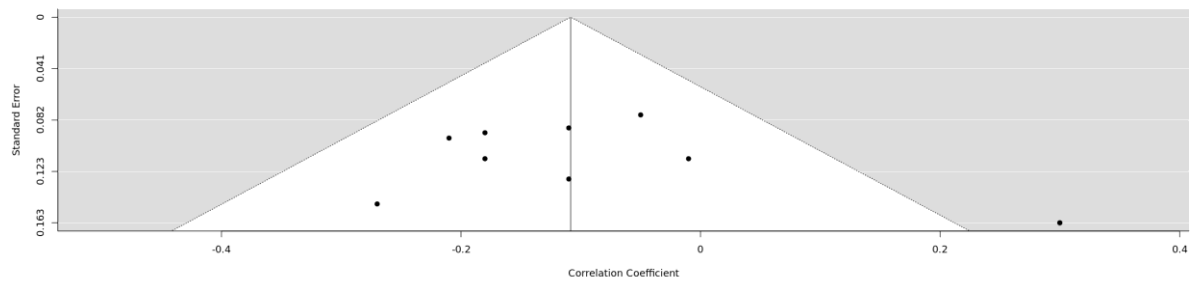
Part II

Research Report

Understanding common obstacles and solutions to deliver effective
psychological treatment for depression and anxiety

Abstract

Objectives

The finding that outcome feedback (OF) can improve outcomes in psychotherapy is well-established; however, there is still considerable uncertainty about the processes underlying its effectiveness. Therefore, this study aimed to investigate the underlying mechanisms of action in OF using an observational approach.

Method

Therapists (n=28) who used OF in routine practice were recruited from three Improving Access to Psychological Therapies (IAPT) services. They were asked to continue with usual OF-informed care and to document this process using a digital health application for all consenting patients (n=45). Qualitative process data from 192 clinical case notes was collected and analysed using a novel topic modelling method.

Results

The results indicated common treatment obstacles – including the longstanding impact of patient's past experiences, the patient's attitudes and behaviours within therapy, the patient's social network, current stressors, and therapy factors – and common solutions to these obstacles – including supporting the implementation of therapy tasks, ensuring focality of treatment, bridging between sessions, and developing a personalised formulation. The results also highlighted implementation barriers.

Conclusions

The study provides novel insights into the common obstacles to treatment progress and common solutions to these obstacles in OF-informed psychotherapy.

Practitioner Points

- The results could inform the foundations of a good practice guide for therapists.

- The study demonstrates how topic modelling can increase the scale of process research.

Limitations

- A lack of demographic and clinical information was collected which may challenge the study's generalisability.

- There was insufficient data to triangulate the results with outcome data.

Keywords: Outcome feedback, Psychotherapy, Process

Introduction

There is substantial evidence to suggest that psychological interventions are effective for the treatment of mental health issues; however, the outcome literature has also demonstrated the phenomenon of non-response to treatment (Lambert, 2013; Lambert & Ogles, 2004). Large-scale studies of psychotherapy demonstrate that approximately 30% of patients do not show statistically reliable improvement and around 10% of patients show deterioration following psychotherapy (Hansen et al., 2002; NHS Digital, 2016). One contemporary approach to improving outcomes in psychotherapy is the process of Outcome Feedback (OF). This quality assurance system relies on the tracking of outcomes to support therapists in identifying patients who may be at risk of a poor response to treatment (de Jong et al., 2021).

Specifically, OF involves the routine monitoring of a patient's symptoms using standardised measures. Outcomes are entered into a computer system that graphically display session-to-session trajectories of change. Patients' symptoms are plotted against visual benchmark values, representing expected responses to treatment, derived from comparable clinical samples. Patients are classified as being 'on track' (OT) or 'not on track' (NOT) to improve using these benchmark confidence intervals, where 'OT' patients demonstrate symptoms that are in line with symptoms observed in similar cases, and 'NOT' patients demonstrate symptoms that are significantly worse than similar cases. When patients are classified as 'NOT' an automated alert is generated, prompting therapists to assess why the patient is 'NOT' and apply trouble-shooting strategies to resolve barriers to treatment progression (Lambert et al., 2001).

Numerous reviews of empirical and practice-based studies have been conducted on the effectiveness of OF-informed psychotherapy (Bergman et al., 2018; de Jong et al., 2021; Kendrick et al., 2016; Knaup et al., 2009; Lambert et al., 2003; Lambert et al., 2018; Østergård et al., 2018; Shimokawa et al., 2010; Tam & Ronan, 2017). A general conclusion is that using OF enhances treatment outcomes when compared with usual psychological care, particularly for 'NOT' patients (Lambert et al., 2003; Lambert et al., 2018; Shimokawa et al., 2010). For example, a 2010 meta-analysis demonstrated that 'NOT' patients who were treated with usual care were over two times more likely to deteriorate when compared to 'NOT' patients who were treated with OF-informed care (Shimokawa et al., 2010). The most recent meta-analysis reported comparable effects of OF for both 'OT' and 'NOT' cases, when compared to control groups (de Jong et al., 2021). This review was a comprehensive, multilevel meta-analysis of 58 studies including over 21,000 patients; given the high quality and inclusivity of the design, the findings can be considered as offering compelling evidence for the effectiveness of OF throughout the therapy process.

Whilst the effectiveness of OF can thus be considered a robust finding, it is important to note that the OF literature has focused almost exclusively on determining whether the intervention works, with little consideration of its mechanisms of action. Few studies have investigated the underlying mechanisms of OF, and there is currently no consensus on which factors influence the effect of OF on treatment outcomes (de Jong et al., 2021; Solstad, et al., 2021). Therefore, recent studies have argued that more research is required to achieve a clearer understanding of how OF can be utilised in the most optimal way to enhance outcomes for patients (de Jong et al., 2021).

The empirically based, problem-solving approach referred to as Clinical Support Tools (CSTs) could be argued to provide some insight into the processes underlying OF. Whipple et al. (2003) developed this manualised approach to support therapists with 'NOT' cases. At the core of CSTs is the Assessment for Signal Cases questionnaire (ASC; Lambert et al., 2007), comprising a 40 item, self-report measure which aims to assess four prognostic variables (domains) that are argued to be empirically associated with clinical outcome. This includes the therapeutic relationship (Hill et al., 1996), motivation for change (Prochaska, et al., 1992; Prochaska & Prochaska, 1999), social support (Monroe et al., 1983; Bankoff & Howard, 1992), and life events (Lambert et al., 2007). The ASC measure provides therapists with feedback about which of the four domains fall below normative values and the CSTs support therapists to use this feedback to implement interventions using a clinical decision tree and intervention resources that correspond to the problem areas.

A recent meta-analysis reported that CSTs were particularly effective in enhancing OF in 'NOT' samples and a previous meta-analysis supports this finding, reporting that CSTs reduced deterioration rates in 'NOT' cases from 20% to 5% (de Jong et al., 2021; Shimokawa et al., 2010). Together these findings suggest that there is substantial evidence in favour of using CSTs alongside OF in routine practice and may offer some insight into why patients go off track and how therapists use OF to improve outcomes. However, it is important to note that another meta-analysis contradicted these findings, concluding that there were no significant differences between OF studies that utilised CSTs and those that did not (Kenrick et al., 2016). Therefore, the relevance of CSTs in OF remains unclear and more research is needed to understand the factors that predict and resolve 'NOT' signals.

Research that focuses on the predictive ability of the four ASC domains is relatively scarce. A recent study demonstrated that extra therapeutic problems with social support and adverse life events were consistently associated with extremely negative deviations in psychological distress; however, factors internal to the therapy process, including therapeutic alliance and motivation for change, were either not or not consistently related to poor treatment progress (Probst et al., 2020). Additionally, a previous study examining the ASC measure data from 'NOT' patients found that for more than 40% of patients, it was not possible to identify a potential obstacle to positive treatment outcome (White et al., 2015). This suggests that it is entirely possible that other factors not covered by the ASC may be relevant to 'NOT' signals. Building on these findings, Schilling et al. (2020) explored the existing four domains along with possible additional domains that could be incorporated into CSTs. They found that session number, suicidality, motivation, and life events were predictive of deterioration; however, social support, therapeutic alliance, and emotional regulation were not. Therefore, not all CST domains are empirically supported as predictors of 'NOT' signals.

The following questions thus remain largely unanswered: Why are some patients 'NOT'? What are the obstacles that interfere with their progress during evidence-based therapy? What treatment strategies are commonly applied by therapists who are experienced in the use of OF methods?

Until recently, most psychotherapy research has relied on self-report measures or on human coders to quantify processes within psychotherapy sessions. Whilst these methods make up the fundamental building blocks of psychotherapy research, they also have a range of recognised shortcomings that impact the validity and generalisability of the conclusions drawn (Vasileiou et al., 2018). For example, the restricted choice of responses in self-report measures

and the labour-intensity of human coding limits the amount of data that can be gathered and analysed. Therefore, new methods are required to "scale up" to larger evaluation tasks that analyse high-volume process information.

The psychotherapy literature has recently introduced a computational approach that draws on methods from machine learning to allow the direct analysis of session content with the potential to scale up research to thousands of sessions. There is a small literature demonstrating the utility of a specific method, topic modelling, to analyse text from psychotherapy sessions to generate useful information about the therapy process. For example, studies have demonstrated the utility of topic modelling techniques to identify productive processes in couple's psychotherapy, clinically relevant content in psychotherapy sessions, and functioning levels and alliance ruptures in psychotherapy (Atkins et al., 2012; Atzil-Slonim et al., 2021; Imel et al., 2015).

Topic modelling is a data-driven, machine learning procedure that views the observed words in a passage of text as a combination of underlying semantic topics (Blei et al., 2003; Steyvers & Griffiths, 2007). Topic modelling draws on Latent Dirichlet Allocation (LDA) which discovers underlying structure in a corpus of text (Atzil-Slonim et al., 2021). The LDA method organises a library of documents (cohesive units of text) by grouping dominant words within the documents into lists that represent semantic topics. The algorithm automatically infers the set of topics and their association with documents to best "explain" the data in a probabilistic sense, where inferred topics are not named but can be assigned coherent semantic concept labels by exploring dominant words and their context within documents (Blei et al., 2003; Steyvers & Griffiths, 2007). In addition to reducing the dimensionality of text, an advantage of this method is

that topics are typically highly interpretable, making them valuable in psychotherapy research.

Aims

The effectiveness of OF is well-established by meta-analytic evidence; however, when considering the processes underling OF, there is still considerable uncertainty about the underlying processes or risk factors associated with 'NOT' trajectories. There are currently few studies that have rigorously explored the process that leads some patients' treatment response to be 'NOT', and what treatment techniques or solutions may help to rectify this and even fewer from a perspective that is not constrained by pre-existing theories, such as the ASC model. Additionally, there are several barriers within traditional methodology that reduce the scale of process research. Therefore, this study aimed to investigate the underlying mechanisms of OF by utilising topic modelling analysis to explore large-scale qualitative process data collected during the course of therapy with clinical cases that were classified as 'NOT'.

Objectives

Two key objectives were to apply an observational approach to: [1] identify common obstacles (i.e. risk factors for 'NOT' signals) and [2] identify common solutions (i.e. treatment strategies) that experienced OF-users implement to attempt to improve treatment outcomes in routine care. An additional objective was to explore the feasibility of analysing a large text-based dataset using topic modelling.

Method

Design

This study applied a mixed-methods, observational, cohort design. Qualitative process data on common obstacles and solutions to effective psychological care was collected using a digital health technology application (app) completed by qualified psychological therapists on a session-by-session basis, during the course of treatment with a cohort of patients. This included open-text clinical case notes that were collated in a master spreadsheet, including data from multiple therapists across multiple treatment sessions and patients. Topic modelling was applied to analyse these data sources, supplemented by qualitative content analysis to elucidate the semantic meaning of topics automatically discovered (selected) by the topic modelling process.

Sample

Setting

IAPT services (N=3) across England that currently utilise OF technology in usual care were invited to participate in the study. This included Homerton University Hospital Foundation Trust, North East London NHS Foundation Trust (NELFT), and Leeds Community Healthcare NHS Trust.

The IAPT programme was established in England in 2008, following clinical and political developments that highlighted the need for increased access to psychotherapy (NICE, 2011; Clark, 2011). Just over a decade later, IAPT is considered the largest publicly funded implementation of evidenced psychological interventions worldwide (Wakefield et al., 2020). IAPT is organised by evidence-based stepped care principles, where individuals are offered brief

and low intensity therapies (approximately ≤ 8 sessions) initially and then offered more intensive, high intensity therapies (up to 20 sessions) if they do not make considerable improvement (Bower & Gilbody, 2005; Firth et al., 2015). The low intensity therapies typically involve guided one-to-one or group self-help, delivered by psychological wellbeing practitioners (PWPs), based on the principles of Cognitive Behavioural Therapy (CBT; Kellet et al., 2021). The high intensity therapies involve a range of one-to-one therapies – including CBT, person-centred experiential counselling, interpersonal psychotherapy (IPT), dynamic interpersonal therapy (DIT), eye movement desensitization and reprocessing (EMDR) and couples counselling for depression – delivered by qualified therapists (Wakefield et al., 2020).

IAPT is characterized by three core features: providing evidence-based psychological interventions, administering routine outcome monitoring, and ensuring regular outcome focused supervision. Routine outcome monitoring is supported by a system where patients are asked to complete a series of standardised measures on a sessional basis. This has enabled large-scale evaluations of IAPT services; for example, a recent systematic review and meta-analysis of 60 practice-based studies demonstrated that IAPT enables access to largely effective evidence-based psychological therapies for large numbers of patients (Wakefield et al., 2020).

The routine outcome monitoring system means that IAPT is particularly well placed to integrate OF. Recent randomised controlled trials (RCTs) exploring the implementation of OF in IAPT services have concluded that OF increases the probability of reliable improvement and is likely to be a cost-effective strategy for mental health services (Delgadillo et al., 2017; Delgadillo et al., 2018; Delgadillo

et al., 2021). However, as described previously, little is known about the underlying mechanisms of OF in routine care.

Sample

The study participants were N=28 qualified psychological wellbeing practitioners and psychotherapists delivering low and high intensity interventions in three IAPT services. The following inclusion and exclusion criteria applied:

Table 1

Participant inclusion and exclusion criteria

Inclusion criteria
Consenting therapists delivering evidence-based psychological interventions in a participating IAPT service.
Therapists who were employed by a participating IAPT service on a permanent contract.
Therapists who were employed by a participating IAPT service on a temporary contract that was at least as long as the predicted timescale for the data collection aspect of the study (6 months).

Exclusion criteria
Therapists whose contract was shorter than 6 months.
Therapists who were in training, due to the specific requirements for their caseloads and clinical supervision.

Recruitment

Peduzzi et al. (1996) recommend the following formula for sample size calculation: N=10k/p, where k is the number of covariates and p is the smallest of the proportions of negative or positive cases in the population. Based on the existing CST studies (Whipple et al., 2003), we expected at least 4 domains of

obstacles (therapeutic alliance, readiness to change, social support and life events), and the study was, therefore, powered on this basis. We expected the proportion (p) of 'NOT' patients who remain 'NOT' following an intervention to be 0.375 (i.e., 37.5%; Delgadillo et al., 2018). Therefore, the formula n=10k/p provided a required sample size of 107 clinical sessions for analysis, expecting that at least one third would be 'NOT' sessions.

Clinical leads and service managers of collaborating IAPT services shared the study information sheet (Appendix A) with all eligible therapists within their teams. Therapists were advised to contact the research team to express their interest and were subsequently invited to a local training day delivered by the research team, involving an evidence based OF clinical skills workshop (materials based on the clinical trial by Delgadillo et al., 2018) and training on the study procedures. Therapists who wished to participate in the study provided their written consent (Appendix B). All participants were informed that they had the right to withdraw at any point.

Procedure

After the training day, participating therapists were asked to start collecting data with all new patients for 6 months. Given that therapists were already using OF, they were asked to continue with usual practice. This involved entering scores from standardised outcome measures (Patient Health Questionnaire-9; Kroenke et al., 2001; Generalized Anxiety Disorder Scale-7; Spitzer et al., 2006) into the OF monitoring graphs on a sessional basis, reviewing the graphs at the start of each therapy session, and assessing if treatment was 'OT' or 'NOT'. In cases that were 'NOT', therapists were required to explore potential obstacles to improvement and consider implementing solutions to these obstacles. The only

additional task required was to document this process, using the data collection technology described below, after each session. They were also required to gain and document verbal consent from patients for the use of their non-identifiable information. They were encouraged to prioritise discussions of 'NOT' patients in their weekly clinical supervision, and to update the data collection technology accordingly. Therapists received regular updates from the research team throughout data collection with information about the study progress and encouragement to continue with data collection.

Measures

Data collection technology. Therapists were required to provide data using a digital health technology application (app) after each therapy session. This was an electronic form developed in collaboration with MindLife – a digital health company which develops software for healthcare research – and consultations with the clinical leads and service managers of the collaborating IAPT services. The final version of this technology was referred to as the Personalised Mental Health App (PERMHA; see Appendix C for an example form[1]). Therapists were enrolled onto the PERMHA app by the research team (i.e., they had a unique username and password) and were required to individually enrol consenting patients to their account, using a non-identifiable pseudonym.

The electronic form required scores from routine outcome measures, classification of the patient ('OT' or 'NOT') and an open text summary of the session. If patients were classified as 'NOT', therapists were also required to

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[1] *Removed for copyright purposes*

summarise their hypotheses about potential obstacles and actions taken to address the obstacles (i.e., solutions) in open text boxes. Before forms could be submitted, a warning box prompted therapists to check that they had not included any identifiable information.

Participant feedback. To address the feasibility of the app, participating therapists were asked for confidential written feedback about the usability and satisfaction with the PERMHA app approximately 3 months into data collection.

Analysis

Topic modelling

To analyse all available qualitative data, topic modelling was applied. Open text summaries of obstacles (total n=112) and solutions (total n=111) were downloaded from the PERMHA app, saved as individual documents, and divided into two distinct corpora of documents for the purposes of the analysis. In what follows, the expression "documents" refers to discrete open text entries (i.e., sentences, or lines as per qualitative analysis) contained across the full database of textual data input by participating therapists.

A free, open software – the Topic Modelling Tool (TMT) – was used in consultation with a supervising computer scientist to implement the Machine Learning for Language Toolkit (MALLET) topic model package (Falk, 2014). The TMT provides a simple way to automatically organise large volumes of text in documents into a pre-selected number of topics "k", each of which contains a list of words that commonly occur together across the full library of documents analysed. Since a list of words is not directly interpretable in the form of a narrative, topic modelling outputs require a reader/analyst to inspect and interpret the output (Steyvers & Griffiths, 2007). The default number of topics (i.e., general

themes) yielded by the TMT output is k=10; however, this number can be altered by the analyst to achieve an optimal (i.e., interpretable) separation of latent topics.

Therefore, the first step of the analysis was to determine the optimal k (i.e., clinically interpretable number of topics). Firstly, 25% of the obstacle and solution documents (N=28; N=27, respectively) were randomly selected and analysed, by hand, according to the principles of inductive content analysis. Content analysis is a systematic categorizing approach which is used to explore large amounts of text to determine patterns, frequency and relationships between words used, and the structures and discourses of communication (Mayring, 2004; Pope et al., 2006; Gbrich, 2007). Content analysis was selected as it is suitable for quantifying common issues in the data and is thus comparable with topic modelling outputs (Gbrich, 2007; Green & Thorogood, 2018). The content analysis revealed that an estimate of five obstacle themes (k=5) and six solution themes (k=6) were likely to achieve separation of latent topics in the TMT outputs (see Appendix D for initial content analyses).

Secondly, these optimal "k" estimates were used to inform the preliminary TMT analyses. Separate TMT analyses were run for "obstacle documents" and "solution documents", where all text entries corresponding to the obstacles or solutions summary sections (i.e., libraries) on the PERMHA app were entered as the input directories. In order to ensure confidence that the pre-selected "k" was optimal, the analyses were ran repeatedly for a range of obstacle (k=2 to k=8) and solution (k=3 to k=9) input directories (see Appendix E for outputs).

Finally, this wide array of possible outputs was examined thoroughly for the purposes of interpretation. The TMT generates data into a HTML output containing a browsable set of unlabelled topics. The TMT clusters text into lists

of 20 commonly linked words, where "k" topics generates "k" lists of 20 words. The lists are ordered at random; however, the words within each topic are listed in descending order according to the frequency in which they are associated with the topic (see Figure 1).

Figure 1

Example of TMT HTML output with weblinks to each topic

List of Topics

0. december 9 effects shared reflections commitments main found decided pattern triggering christmas overworking longstanding result impact past dymnamics mood sensations
1. client work trauma due patient change time session family relationship difficulties panic therapy things problems depression high lack problem treatment
2. homework anticipation retell started friends virus engage method waiting agoraphobia phq coronavirus complete today linked experiencies spent 06 memories easily
3. interpersonal anxiety doesn hopelessness risk emotional recovery pain long avoidance parents work difficult good distanced stabilisation set miscarriage stepped income
4. difficulties saftey therapy environment treatment isolated telephone decided stressful schemas completed level 2 relapse avoidance lead life practice putting health

To examine a particular topic list in more detail, analysts can click on the list which links to a webpage organising all the inputted documents in descending order of relevance to the topic and quantifies the number of words in the documents that belong to that topic (see Figure 2).

Figure 2

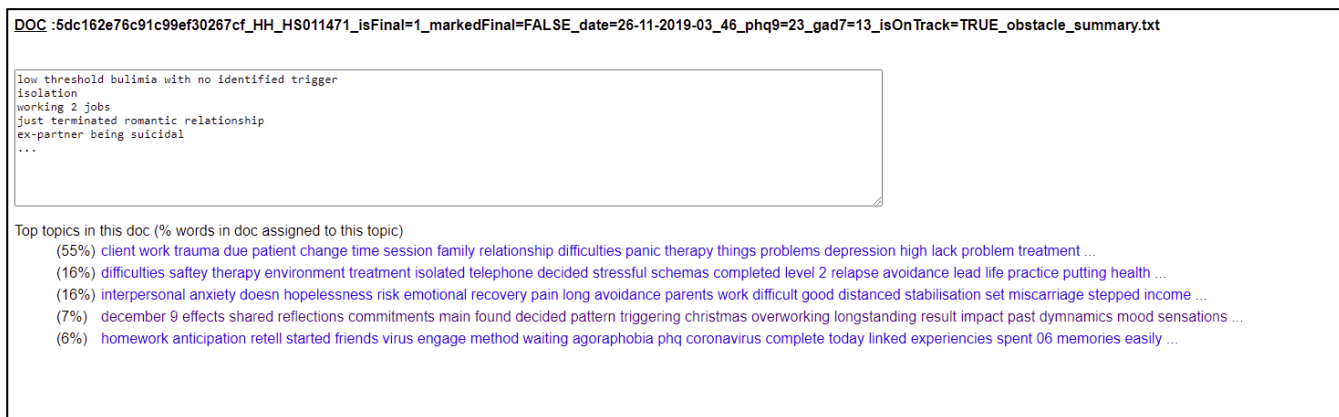*Example of TMT topic webpage depicting documents relevant to a topic*

TOPIC : december 9 effects shared reflections commitments main found decided pattern triggering christmas overworking longstanding result impact past dymnamics mood sensations ...

top-ranked docs in this topic (#words in doc assigned to this topic)
1. (2) 5db74a1bfe5435b3f900f43f_HH_LG000161_isFinal=3_markedFinal=TRUE_date=4-12-2019-04_31_phq9=15_gad7=11_isOnTrack=FALSE_obstacle_summary.txt
2. (0) 5db74a1bfe5435b3f900f43f_HH_HS013549_isFinal=9_markedFinal=FALSE_date=10-02-2020-01_00_phq9=6_gad7=6_isOnTrack=TRUE_obstacle_summary.txt
3. (0) 5db74a1bfe5435b3f900f43f_HH_HS013504_isFinal=4_markedFinal=FALSE_date=4-12-2019-08_58_phq9=11_gad7=8_isOnTrack=FALSE_obstacle_summary.txt
4. (0) 5de4e02145fc0c9e9fd10814_NE_BS004389_isFinal=2_markedFinal=FALSE_date=29-01-2020-04_02_phq9=18_gad7=19_isOnTrack=FALSE_obstacle_summary.txt
5. (0) 5de4e02145fc0c9e9fd10814_NE_BS003971_isFinal=4_markedFinal=FALSE_date=15-01-2020-12_48_phq9=23_gad7=21_isOnTrack=FALSE_obstacle_summary.txt
6. (0) 5de4e02145fc0c9e9fd10814_NE_AE006202_isFinal=2_markedFinal=FALSE_date=31-01-2020-01_18_phq9=24_gad7=21_isOnTrack=FALSE_obstacle_summary.txt
7. (1) 5dc9887ef4d8dcc2898b2556_HH_HS013642_isFinal=12_markedFinal=FALSE_date=16-03-2020-11_48_phq9=7_gad7=7_isOnTrack=TRUE_obstacle_summary.txt
8. (0) 5dc9887ef4d8dcc2898b2556_HH_HS011297_isFinal=1_markedFinal=FALSE_date=13-12-2019-04_44_phq9=13_gad7=15_isOnTrack=FALSE_obstacle_summary.txt
9. (1) 5dc9346cfb0a1d8af9d488fe_HH_HS011689_isFinal=1_markedFinal=FALSE_date=18-11-2019-01_06_phq9=13_gad7=5_isOnTrack=TRUE_obstacle_summary.txt
10. (1) 5dc162e76c91c99ef30267cf_HH_LG000661_isFinal=3_markedFinal=FALSE_date=13-12-2019-08_45_phq9=8_gad7=7_isOnTrack=TRUE_obstacle_summary.txt
11. (1) 5dc162e76c91c99ef30267cf_HH_HS016106_isFinal=2_markedFinal=FALSE_date=13-12-2019-08_51_phq9=24_gad7=12_isOnTrack=FALSE_obstacle_summary.txt
12. (0) 5dc162e76c91c99ef30267cf_HH_HS011471_isFinal=1_markedFinal=FALSE_date=26-11-2019-03_46_phq9=23_gad7=13_isOnTrack=TRUE_obstacle_summary.txt
13. (0) 5db74a1bfe5435b3f900f43f_HH_HS013504_isFinal=8_markedFinal=FALSE_date=30-01-2020-03_49_phq9=2_gad7=3_isOnTrack=TRUE_obstacle_summary.txt
14. (1) 5db74a1bfe5435b3f900f43f_HH_HS013504_isFinal=1_markedFinal=FALSE_date=11-11-2019-02_47_phq9=12_gad7=11_isOnTrack=TRUE_obstacle_summary.txt
15. (2) 5db74a1bfe5435b3f900f43f_HH_HS013464_isFinal=7_markedFinal=FALSE_date=15-01-2020-11_33_phq9=19_gad7=15_isOnTrack=TRUE_obstacle_summary.txt

To finalise the optimal "k" values, the top 10 ranked documents for each topic list generated from the possible topic model outputs (obstacles: k=2 to k=8; solutions: k=3 to k=9) were examined, where text entries were retrieved to

determine the context in which the words appeared (see Figure 3). These text entries were tabulated, and subject to manual qualitative analysis.

Figure 3

Example of retrieved text entry from the TMT output

DOC :5dc162e76c91c99ef30267cf_HH_HS011471_isFinal=1_markedFinal=FALSE_date=26-11-2019-03_46_phq9=23_gad7=13_isOnTrack=TRUE_obstacle_summary.txt

```
low threshold bulimia with no identified trigger
isolation
working 2 jobs
just terminated romantic relationship
ex-partner being suicidal
...
```

Top topics in this doc (% words in doc assigned to this topic)

(55%) client work trauma due patient change time session family relationship difficulties panic therapy things problems depression high lack problem treatment ...

(16%) difficulties saftey therapy environment treatment isolated telephone decided stressful schemas completed level 2 relapse avoidance lead life practice putting health ...

(16%) interpersonal anxiety doesn hopelessness risk emotional recovery pain long avoidance parents work difficult good distanced stabilisation set miscarriage stepped income ...

(7%) december 9 effects shared reflections commitments main found decided pattern triggering christmas overworking longstanding result impact past dymnamics mood sensations ...

(6%) homework anticipation retell started friends virus engage method waiting agoraphobia phq coronavirus complete today linked experiencies spent 06 memories easily ...

Deductive content analyses were performed repeatedly across the different potential outputs of the automated topic modelling process, where the relevant text entries assigned to each topic were condensed into meaning units, coded, and organised into categories. This resulted in semantic labels for the TMT topics that were conceptualised as themes. The most interpretable and coherent set of themes (optimal "k") was subsequently selected through discussions with experts in the fields of OF and topic modelling: k=5 was selected for obstacles; k=4 was selected for solutions.

Additional text entries from these outputs were then retrieved to ensure that contextual information from the top 25% of top ranked documents for obstacles and solutions were incorporated into the content-based analyses, where categories and themes were sense checked and revised if necessary. The finalised themes were subsequently used to describe the common obstacles and common solutions that presented within the data. Correlations between obstacles and solutions were hypothesised during the thorough exploration of text entries

and were depicted by a theoretical topic modelling map. See Figure 4 for a visual representation of the analysis process. A detailed reflective log was written, and a reflexivity statement is available (Appendix F).

Figure 4

Process of data analysis using topic modelling and content analysis

Step 1: Analyse random 25% of all entries using content analysis to determine approximate number of themes/topics ("k") to run in TMT.

Step 2: Run TMT repeatedly for k=2 to k=8 for obstacles and k=3 to k=9 for solutions.

Step 3: Retrieve the text from the top 10 ranked documents associated with all topics in all outputs to gain contextual information.

Step 4: Use the contextual information as a coding framework and use the principles of content analysis to select an optimal "k" for the obstacle and solution outputs.

Step 5: Retrieve text from the top 25% ranked documents in the selected "k" outputs and incorporate into the content analyses to sense check the themes.

Step 6: Label the selected "k" themes for obstacles and solutions.

Step 7: Hypothesise theoretical correlations between obstacle and solution themes.

Ethics

Ethical approval was obtained via the Integrated Research Application System (IRAS, 259658) following full Research Ethics Review (Appendix G) and Health Research Authority (HRA) approval (Appendix H). Additionally, scientific approval from the University of Sheffield (Appendix I) was obtained, alongside approval from the Research and Innovation (R&I) departments at the collaborating NHS Trusts (Appendix J). A range of ethical issues were considered and addressed in line with good practice guidelines before and during the study (see Table 2).

Table 2

Ethical considerations and measures taken to address issues

Ethical Issue	Measures Taken
Informed consent and right to withdraw	Clear written and verbal information, contact with researchers on training days and up-to-date contact details provided.
Pressure to participate in the study	Therapists were given two weeks to consider their participation and consented through the research team to avoid undue pressure from manager and clinical leads.
Anonymization of participating therapists	Participating therapists were allocated with randomly generated ID numbers by the research team, prior to data collection, to ensure full anonymity of therapist-level data.
Anonymization of patient-level data	All therapists were trained on how to fully anonymise patient data according to the NHS information governance policy and good practice guidelines.
Potential for observations of quality-of-care issues	All therapists were trained and encouraged to prioritise and discuss 'NOT' cases in their routine clinical supervision. It was considered the responsibility of the therapists and their supervisors to address clinical concerns, and this was communicated clearly in the training and information sheet.

Results

Feasibility

A total of 28 IAPT therapists were recruited and consented to participate in the study: 11 therapists from Homerton, 11 therapists from NEFLT, and six therapists from Leeds. Two therapists (from Homerton and NEFLT) withdrew

from the study due to leaving their current employment and insufficient time to complete the study measure. Of the remaining therapists, 10 used the PERMHA app to collect data. Whilst the further 18 therapists did not withdraw from participating in the study, they did not utilise the PERMHA app and did not provide any data for the analysis. The participant feedback survey revealed that most of these therapists disengaged with data collection due to having restricted time and prioritising clinical work. The 10 therapists who collected data enrolled 45 patients to the PERMHA app, entering data covering 192 clinical sessions. This exceeded the required sample size of 107 clinical sessions. The mean number of patients enrolled by individual therapists was 4.6, with a range of 7; the mean number of sessions recorded by individual therapists was 19.5, with a range of 48.

Topic models

Obstacles

Overall, the most interpretable number of topics among the total number of topic outputs that were analysed (N=7) was k=5 for the library of documents related to "obstacles" to improvement in cases classified as NOT. The TMT output topic lists and average percentage of words in documents assigned to the topic lists can be found in Table 3. The five superordinate themes were labelled: '*Longstanding impact of patient's past experiences', 'Patient's attitudes and behaviours within therapy', 'Patient's social network', 'Current stressors', and 'Therapy factors.'* The themes, categories and example quotations are presented

in Table 4 and will be systematically described below, in order of prevalence within the text entries.

Table 3

TMT output topic lists, percentage of words assigned and labels

Topics (word lists)	Average % of words in documents assigned to topic	Topic label (theme)
Client, work, trauma, due, patient, change, time, session, family, relationship, difficulties, panic, therapy, things, problems, depression, high, lack, problem, treatment.	55%	Longstanding impact of patient's past experiences
Difficulties, safety, therapy, environment, treatment, isolated, telephone, decided, stressful, schemas, completed, level, 2, relapse, avoidance, lead, life, practice, putting, health.	16%	Patient's attitudes and behaviours within therapy'
Interpersonal, anxiety, doesn't, hopelessness, risk, emotional, recovery, pain, long, avoidance, parents, work, difficult, good, distanced, stabilisation, set, miscarriage, stepped, income.	16%	Patient's social network
December, 9, effects, shared, reflections, commitments, main, found, decided, pattern, triggering, Christmas, overworking, longstanding, result, impact, past, dynamics, mood, sensations.	7%	Current stressors
Homework, anticipation, retell, started, friends, virus, engage, method, waiting, agoraphobia, PHQ, coronavirus, complete, today, linked, experiences, spent, 06, memories, easily.	6%	Therapy factors

Longstanding impact of patient's past experiences. On average, 55% of words in the obstacles text entries were associated with this theme. The

context of words in this theme generally centred on therapists' hypotheses about the long-lasting impact of patients' past experiences, particularly the enduring impact of early experiences of trauma. These impacts were divided into two categories: the impact on the patients' psychological distress and the impact on the therapy process. Regarding the impact of psychological distress, therapists proposed that the enduring consequences of early or previous negative experiences increased patients' levels of distress and played into their current presentation. Regarding the impact on the therapy process, therapists reported that the psychological and behavioural impacts of previous adverse experiences interfered with treatment, including hindering the therapeutic relationship and patients' ability to engage with therapy tasks.

Patient's attitudes and behaviours within therapy. On average, 16% of words in the obstacles text entries were associated with this theme**.** The context generally focused on therapists' descriptions of the negative impact of patients' attitudes and behaviours within therapy. These impacts were divided into three categories: lack of formulation, avoidance and engagement, and beliefs about the therapy process. Regarding lack of formulation, therapists wrote about patients' behaviours blocking the development of formulations and reported this impacted the focality and direction of treatment. Regarding avoidance and engagement, therapists reported that some patients' beliefs and behaviours led to avoidance and/or a lack of motivation to engage in therapy tasks. Regarding beliefs about the therapy process, therapists hypothesised that specific beliefs about the effectiveness of therapy hindered patients' engagement and, more generally, assumed that more global strongly held beliefs impacted patients' attitudes towards therapy.

Patient's social network. On average, 16% of words in the obstacles text entries were associated with this theme. The context generally focused on therapists' reports of the impact of patients' social network. These impacts were divided into four categories: social support, impact of complex family dynamics, social threat, and loss. Regarding social support, therapists reported a lack of social support from family and friends as an obstacle to a good treatment outcome. Regarding impacts of complex family dynamics, therapists hypothesised that difficult dynamics within patients' families increased their psychological distress. Regarding social threat, therapists described risks of bullying within the community as a barrier. Finally, regarding loss, therapists reported the significant impact of recent bereavement on progress within therapy.

Current stressors. On average, 7% of words in the obstacles text entries were associated with this theme. The context largely focused on therapists' reports of the impact of present-day stressors. These impacts were divided into two categories: occupational stress and relational stress. Regarding occupational stress, therapists described work or educational commitments having an impact on patients' ability to prioritise therapy and discussed general issues at work impacting psychological distress. Regarding relational stressors, these centred on therapist's hypotheses about the impact of difficulties with how patients related to themselves and others. Intra-relational difficulties appeared to impact on patient's understanding of themselves which hindered the process of formulation. Inter-relational difficulties appeared to increase psychological distress.

Therapy factors. Finally on average 6%, of words in the obstacles text entries were associated with this theme. The context generally focused on therapists' reports of the impact of therapy factors. These impacts were divided into four categories: patients' motivational deficits, treatment integrity, service

limitations and validity of outcome measures. Regarding patients' motivational deficits, therapists discussed the negative impact of patient's lack of motivation within the therapy process. In terms treatment integrity therapists reported therapist- and patient-level reasons for distancing from specific therapy models, generally revolving around anxiety. Regarding service limitations, therapists discussed waiting lists and the impact of the COVID-19 pandemic on the mode of treatment delivery. Finally, regarding validity of outcome measures, therapists discussed problems in the use of measures to determine therapy progress, including when confounding factors that increase scores on depression measures, such as fibromyalgia and the menopause, resulted in an inaccurate reflection of progress.

Table 4

Themes, categories, and quotations for the common obstacles reported by therapists

Theme (% of words assigned)	Categories	Example Quotations
Longstanding impact of patients' past experiences (55%)	Impact on psychological distress	"Client feels that time is repeating itself" "Client has had other recent bad working environments so appear 'on alert' for it to happen again - therefore getting defensive"
	Impact on therapy process	"The client's schemas of rejection and mistrust, which can become easily activated in the session, leading to ruptures" "Protective strategies linked to trauma which result in distancing from emotions and contribute to feelings of being out of control in panic"
Patient's attitudes and behaviours within therapy (16%)	Lack of formulation	"Patient unfocused - several different difficulties throughout treatment that changes weekly therefore difficult to get traction" "Possible difficulties speaking up in therapy particularly when discussing problems in therapy"
	Avoidance and engagement	"Completed Guided self help… not fully reduced saftey strategies and no tolerance to anxiety sensations" "Despite a huge improvement, patient does not feel ready to address eating meals in public --> this is what lead to relapse last time when re-referred"
	Beliefs about the therapy process	"Previous sessions ended because the therapist left the service before treatment was completed. Potentially, this could lead the client to become disillusioned with the therapy process."

"Strongly held beliefs related to hopelessness that may affect engagement with treatment, tendency towards self-criticism"

Patients' social network (16%)	Social support	"Lack of support from family" "She is single with little support"
	Impacts of complex family dynamics	"Client spent time with family over the festive period and this increases anxiety and low mood due to complex dynamics within her family" "Patient has history of family difficulties and these have been ongoing since she was a child. Parents have a bad relationship and now separated"
	Social threat	"Risk of transphobic or cyber bullying, perfectionism (self and socially prescribed)" "Risk of bullying because of her LGBT identity and high profile position in with the community"
	Loss	"She had a miscarriage 4 weeks ago which set her back on her recovery" "Mother had several relapses of cancer throughout life and client has a lot of responsibility within the household"
Current stressors (7%)	Occupational	"End sessions early due to university commitments and lack of time" "…going through a grievance at work and will find out if she needs to change her work pattern"
	Relational	"…found it difficult to describe main problem and to identify goals" "Complexity of gender identity and impact this has on her" "Client spent time with family over the festive period"

Therapy factors (6%)	Patients' motivational deficits	"Currently unwilling to change much about her daily routine - excuses getting in the way of not 'doing the homework'" "Client is struggling with motivation to complete home practice"
	Treatment integrity	"We haven't started addressing the trauma memories yet and it can be stressful for clients when they have to retell their story and anticipate addressing the memories" "Poor emotional tolerance to start processing the trauma memory"
	Service limitations	"Client has had 3 assessment sessions of Cognitive Behavioural Therapy which identified that an early childhood trauma may be the root of the agoraphobia . He was transferred to the EMDR waiting list" "Telephone treatment is a different delivery method due to coronovirus."
	Validity of outcome measures	"Physical effects of fibromyalgia and menopause on sleep, tiredness which may keep PHQ 9 scores high" "Client is on track on the PHQ-9 but not the GAD-7. I believe this is due to the anticipation of starting trauma work"

Overall, the most interpretable number of topics among the total number of topic outputs that were analysed (N=7) was k=4 for the library of documents related to "solutions" in cases classified as NOT. The TMT output topic lists and average percentage of words in documents assigned to the topic lists can be found in Table 5. Four superordinate themes were labelled: '*Supporting the implementation of therapy tasks', 'Focality of treatment', 'Bridging between sessions',* and *'Development of a personalised formulation.'* The themes, categories and example quotations are presented in Table 6 and will be systematically described below.

Table 5

TMT output topic lists, percentage of words assigned and labels

Topics (word lists)	Average % of words in documents assigned to topic	Topic label (theme)
Client, discussed, treatment, work, therapy, session, identify, focus, thoughts, past, trauma, discuss, address, experiences, ensure, anxiety, understanding, patient, OCD, impact.	40%	Supporting the implementation of therapy tasks
Problem, week, make, change, session, order, CBT, address, symptoms, plan, discussed, OCD, past, trauma, scores, increasing, reducing, BA, time, treatment.	25%	Focality of treatment
Continue, formulation, worry, due, explore, panic, sessions, coping, ensure, understanding, review, tolerating, context, model, protocol, bereavement, clients, related, informed, longer.	19%	Bridging between sessions
Anxiety, current, treatment, potential, panic, difficulties, working, aware, session, life, experiences, impact, cycle, therapist, explored, health, skills, doesn't, therapy, started.	16%	Development of a personalised formulation

Supporting the implementation of therapy tasks. On average, 40% of words in the obstacles text entries were associated with this theme. The context of words in this theme generally centred on therapists' reports of overcoming obstacles by supporting their patients to implement the tasks discussed in therapy. This strategy contained two categories: providing a clear explanation of the work involved and supporting engagement with therapy tasks. Regarding clear explanations of the work involved, therapists wrote about providing information about the rationale of therapy tasks and provided the opportunity for questions. They also discussed linking therapy tasks to formulations and psychological theory. Regarding supporting engagement with therapy tasks, therapists reported taking a collaborative, person-centred and flexible approach to setting tasks, remaining mindful of patients' formulations and how this might impact on engagement.

Focality of treatment. On average, 25% of words in the obstacles text entries were associated with this theme. The context generally focused on therapists' reports of overcoming obstacles by attending to the focus of treatment. This strategy contained three categories: determining the problem area, reviewing and monitoring the treatment focus, and implementing techniques that lead to the goal. Regarding determining the problem area, therapists reported ensuring that they communicated the importance of therapy having clear goals and reported collaboratively working with patients to determine these. Regarding reviewing and monitoring the treatment focus, therapists discussed collaboratively reviewing the focus of treatment throughout the therapy process and addressing when treatment appeared to be veering off track. Regarding implementing techniques that lead to the goal, therapists discussed the use of

therapeutic tasks and techniques and highlighted the responsibility that therapists had to ensure competence in delivering these.

Bridging between sessions. On average, 19% of words in the obstacles text entries were associated with this theme. The context generally focused on therapists' reports of overcoming obstacles by bridging between sessions and ensuring flow. This strategy contained four categories: continuation of specific techniques, building on the formulation, formulation in session and monitoring change over time. Regarding continuation of specific techniques, therapists reported discussing and implementing specific techniques over multiple sessions. Regarding building on the formulation, therapists described adapting and adding to the formulation in the light of new information. Regarding formulation in session, therapists reported monitoring how aspects of the formulations presented within sessions, understood obstacles by drawing on this information, and used the formulation to adjust their approach to appropriately meet patients' needs. Regarding monitoring change over time, therapists discussed noticing and drawing attention to positive changes in patient symptomology as a therapeutic tool. They also discussed attending to changes in the treatment focus overtime and taking a flexible approach to treatment protocols when new information revealed that the intended goal was no longer relevant.

Development of a personalised formulation. Finally on average, 16% of words in the obstacles text entries were associated with this theme. The context generally focused on therapists' reports of overcoming obstacles by developing a personalised formulation. This strategy contained four categories: attending to understanding and supporting psychological difficulties, psychoeducation, consolidating the formulation and techniques and the therapist role. Regarding attending to understanding and supporting psychological

difficulties, therapists discussed the importance of developing person-centred formulations and using them to meet patients' needs within session. Regarding psychoeducation, therapists reported sharing psychological theory to develop formulations with clients and to provide a rationale for specific techniques and tasks, particularly for patients with anxiety. Regarding consolidating formulations and techniques, therapists discussed the importance of revisiting psychoeducation to ensure continued understanding. Regarding the therapist role, therapists discussed acknowledging the responsibility they held in formulation and delivery of techniques and described attending to their own skills to ensure competence.

Table 6

Themes, categories, and quotations for the common solutions reported by therapists

Theme (% of words assigned)	Category	Example Quotations
Supporting the implementation of therapy tasks (40%)	Provide clear explanations of the work involved	"Identified that these aren't 'tick box' exercise but a continuous progress and experiments to learn from" "Written information given at the end of session and homework to recap to help consolidate treatment and identify any questions that may have been missed in treatment session"
	Support engagement with therapy tasks	"Considered small periods of time for homework that may fit within schedule" "Together we have set up targets for her to work towards for next week, e.g., returning to work 2 days a week (increasing it by 1) and walking up the road to the high street."
Focality of treatment (25%)	Determine the problem area	"Socialisation to CBT to reiterate the structure of CBT and necessity to find a problem area" "Given a problem focused statement to be clear on her needs, thoughts, emotions and current coping"
	Review and monitor treatment focus	"If no change, address motivation and whether CBT is appropriate or helpful" "Discussed client's bereavement as this is how she wanted to spend the session"

	Implement techniques that lead to the goal	"Continue working on BA/motivation to change within the next week or so" "Keep focus on stabilisation and address depression symptoms prior to trauma focused work." "Review additional therapist skills needed in treating panic within trauma in supervision"
	Continuation of specific techniques	"Continue with exposure" "Brief psychoeducation on rumination - but to continue this"
	Build on the formulation	"Combining understanding of trauma into OCD formulation and response to intrusive thoughts" "using formulation to address comorbid difficulties and incorporate them into the understanding of the development and maintenance of panic"
Bridging between sessions (19%)	Formulation in session	"Be aware of this avoidance of 'relaxing tasks' - start to bring this into session in order to model it" "Pacing sessions slowly due to high anxiety"
	Monitoring change over time	"Make a log of her progress in order to build faith in her ability to cope" "Taking to supervision to discuss how could adjust treatment protocol, if client should want to explore further"

	Attend to understanding and supporting psychological difficulties	"Ensure she can make sense of her anxiety and understands it can be the case that you feel worse before you feel better" "We discussed her difficulties in session and talked about addressing what we can change rather than ruminating about what has happened."
Development of a personalised formulation (16%)	Psychoeducation	"Detailed discussion on rationale for treatment" "Related in formulation to past experiences leading to increased doubt and trust in own thoughts. Used this to challenge the idea that she has no control over thoughts and could want to harm herself or others vs she is more aware of threats and distress due to past experiences and this is her brains way of trying to maintain her safety in alerting her to potential risks"
	Consolidate formulation and techniques	"Reviewed how to apply coping skills developed in treatment to current anxiety" "Further encouragement and continue reiterating the choice to make change and change doesn't happen without doing."
	Therapist role	"Therapist to brush up on skills around assertiveness and using role play" "Therapist to prepare fully for sessions and ensure all expected CBT techniques relevant to client are explored and client is competent at using them"

Topic modelling map

The theoretical correlations between obstacles and solutions hypothesised during the thorough exploration of text entries are presented in Figure 5. The red nodes represent obstacles; the blue nodes represent solutions. The nodes are ranked according to their prevalence within the documents. The grey arrows depict theoretical correlations between obstacles and solutions that were observed during the exploration of text entries. The density of the arrows reflects the hypothesised strength of the observed relationship. Obstacles relating to past experiences (O1) and attitudes and behaviours within therapy (O2) were hypothesised to be more strongly associated with supporting therapy tasks (S1); however, they were also observed to be linked with ensuring focality (S2), bridging between sessions (S3) and the development of a personalised formulation (S4). The obstacle relating to social networks (O3) did not appear to clearly correlate with any of the observed solutions. The obstacle involving current stressors (O4) appeared to be more clearly associated with the focality of treatment (S2) and somewhat linked to bridging between sessions (S3) and the development of a personalised formulation (S4). Finally, the obstacle relating to therapy factors (O5) was hypothesised to be clearly related to supporting therapy tasks (S1) and somewhat related to personalised formulation (S4).

Figure 5

Topic modelling map showing hypothesised correlations between obstacles and solutions

Topic labels and prevalence	
55%	O1 – Past experiences
16%	O2 – Attitudes and behaviours
16%	O3 – Social network
7%	O4 – Current stressors
6%	O5 – Therapy factors
40%	S1 – Supporting tasks
25%	S2 – Focality
19%	S3 – Bridging
16%	S4 – Personalised formulation
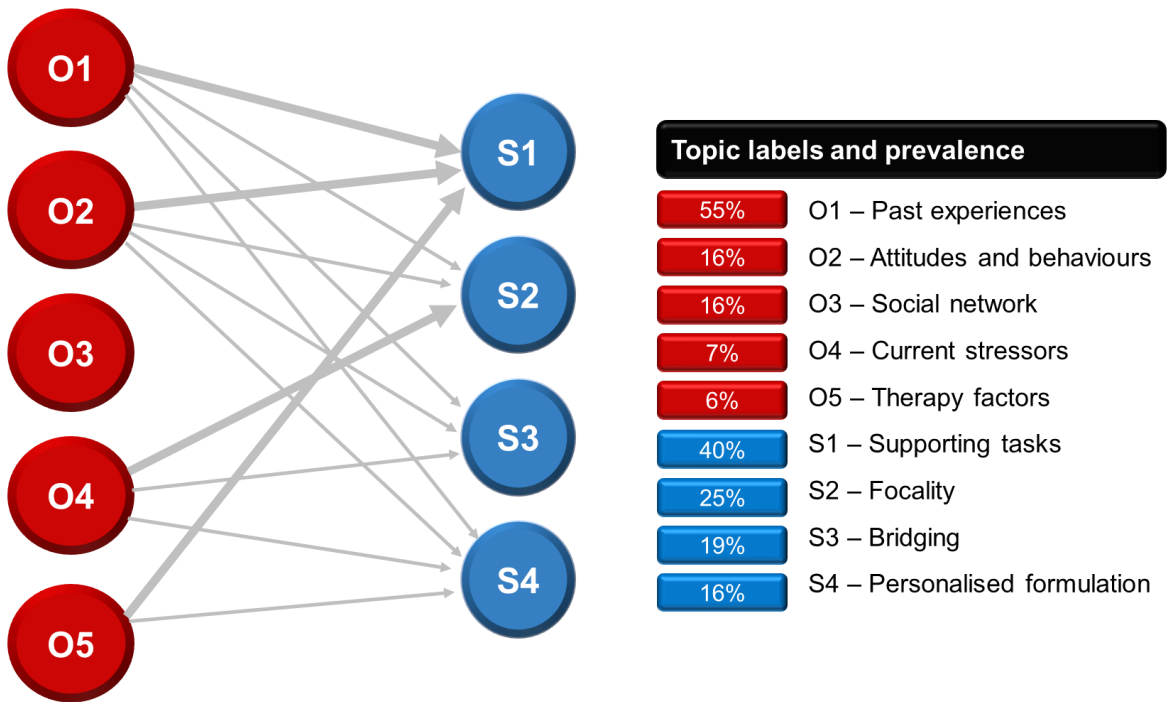
Discussion

Main findings

This cohort study is one of few studies investigating processes and mechanisms of action underlying outcome feedback in routine psychotherapy practice. This is also the first study in this field that uses automatic topic modelling, based on machine learning, to analyse a large qualitative dataset from over 190 clinical case notes collected during feedback-informed treatment. The results indicated several common obstacles to treatment progress and several common solutions to these obstacles, reported by a range of therapists utilising outcome feedback in their clinical practice across several psychological services in England.

The most common obstacle reported by therapists was the longstanding impact of adverse past experiences. This was hypothesised by therapists to increase presentations of psychological distress and hinder patients' ability to engage with therapy tasks. The second leading obstacle reported by therapists was the impact of patients' current attitudes and behaviours within therapy, where patient presentations blocked progression through therapy. This is consistent with the literature on childhood adversity and psychopathology, where meta-analytic evidence suggests that past experience of childhood maltreatment predicts unfavourable courses of enduring mental health difficulties which progressively increases vulnerability to poor therapy outcome (Nanni et al., 2012). Interestingly, the most dominant solution theme reported by therapists corresponds directly to these obstacles, where therapists described incorporating psychological formulations of the impact of past experiences and current presentations into the collaborative approach to setting and supporting the implementation of appropriate therapy tasks.

It is noteworthy that therapists highlighted formulation as a therapeutic tool in the context of setting therapy tasks, where they introduced a variety of interventions to interrupt, challenge, and destabilise patients' unhelpful patterns, with the intention of creating behavioural change. Whilst developing personalised formulations to increase therapist and patient insight into patients' psychological distress did present as a potentially related solution theme, this was the most subordinate solution theme derived from the data.

Case formulations are well-recognised in addressing many of the difficulties therapists experience during psychotherapy (Persons, 2006). However, a recent study exploring decision support tools in over 800 patients receiving CBT found that having a case formulation was not associated with post-

treatment outcome. Instead, the authors found an association between having a list of treatment goals and post-treatment outcome (Gates et al., 2021). This relates to the findings of the present study, where therapists appeared to place more value on the application of insights gained from formulations to establish a stable environment to work towards therapy goals, than the insights gained from the formulation alone.

The third and fourth obstacles related to extra therapeutic factors, where therapists reported that deficits in patients' social networks and current stressors, particularly occupational difficulties, hindered good therapy outcomes. Deficits in the patient's social network presented more frequently, where therapists particularly noted insufficient social support. Interestingly, a recent meta-analysis suggested that, after adjusting for routinely assessed clinical characteristics, the prognostic value of social support is unlikely to be of clinically important magnitude (Buckman et al., 2021). This corresponds to the findings of the present study, where therapists did not commonly report clear solutions for insufficient social support, potentially implying that they did not consider it problematic enough to directly target.

Regarding current stressors, therapists most frequently reported occupational and relational adversities. Therapists discussed solutions to this generally within the context of the focality of treatment, where they appeared to narrow the breadth of discussions in sessions by incorporating current stressors into collaborative and focused goals, monitoring these goals, and agreeing on tasks that would lead to the goals. This links to the concept of therapeutic alliance, defined as the agreement on goals, agreement on tasks and the relational bond (Bordin, 1979). The robustness of the positive relationship between therapeutic alliance and outcome has been demonstrated in multiple reviews over several

decades (Horvath & Symonds, 1991; Flückiger et al., 2018). However, the OF literature presents contradictory findings, where some studies report results suggesting that alliance improves outcomes in OF and other studies report no effects (Brattland et al., 2019; de Jong et al., 2021). Whilst the focality of treatment theme identified in the present study fits with agreement of goals and tasks elements of therapeutic alliance, there was little reference to the relational bond, suggesting that the therapeutic effects of alliance were exclusive to agreement on tasks and goals. This may be explained by previous exploratory factor analyses which suggest that the therapeutic alliance has two independent factors, where the goal and task aspects are grouped on one factor and the bond aspects on the other (Andrusyna et al., 2001; Hatcher & Barends, 1996).

Several of the obstacles – including past experiences, attitudes and behaviours within therapy and current stressors – also appeared to be somewhat linked to the bridging solution, where therapists highlighted the importance of joining sessions and ensuring flow in the face of patients' reports of new insights, experiences, and stressors across the therapy process. This links with a theory of psychological change, referred to as the assimilation model. This model characterises psychotherapy as a process where patients' relation to their problematic experiences gradually changes through the process of recognising, reformulating, understanding and resolving (Stiles et al., 1990). It is possible that the bridging solution acted as a scaffold for the other solutions, where they became meaningful when they bridged the changing conceptualisation of patients' problems with therapeutic goals to be achieved.

Finally, the most subordinate obstacle reported by therapists was therapy factors, where several issues – including patient motivational deficits and treatment integrity – were reported to impact treatment progression. Regarding

motivation, readiness for change has been thoroughly investigated and demonstrated to reliably predict psychotherapy outcome (Norcross et al., 2011; Krebs et al., 2018). However, the extent to which motivation was reported as an obstacle in the present study was limited, and solutions appeared to associate with the theme around supporting patients with therapy tasks rather than interventions directly targeting motivation.

Regarding treatment integrity, therapists discussed their competence and the extent to which therapeutic models were implemented as intended. The only observed solution that corresponded to this fell within the subordinate theme regarding development of a personalised formulation, where therapists acknowledged their role in improving their skills for the purposes of formulating and supporting therapy tasks. However, this was the least prevalent obstacle and the least prevalent theme implying that, relative to the other themes, the role of the therapist in improving outcome was considered less important. Interestingly, research has argued that therapists may over-rate their competence in therapy (Brosan et al., 2008). This may suggest a potential bias, where therapists did not accurately acknowledge their role as a barrier to a good therapy outcome.

When comparing the results of the present study with the existing literature exploring the ASC domains, there are overlaps and discrepancies. All four domains (life events, social support, motivation, and therapeutic alliance) were, to some extent, found to be obstacles within the present study. However, the extent to which therapists reported and acted on these factors varied, and there were some discrepancies between established overarching definitions of the factors and the elements of relevance noted by therapists; for example, life events appeared to be limited to adverse past experiences and the therapeutic alliance appeared to be limited to agreement on tasks and goals. The results are broadly

consistent with findings by Probst et al. (2020), which demonstrated that adverse life events and social support were particularly associated with poor treatment progress but therapy factors – including therapeutic alliance and motivation – were less so. However, in this study whilst the relational bond element to therapeutic alliance did not appear to be of importance, the agreement on tasks and goals elements appeared as relatively central. In line with predictions by White et al. (2020), there were additional obstacles not covered in the ASC; these appeared more general in nature, including attitudes and behaviours within therapy. The additional obstacles found by Schilling et al. (2020), including session number and suicidality, were not discovered. Finally, unlike the CSTs, the observed solutions did not appear to directly map onto specific obstacles. Instead, solutions appeared to focus more on general approaches to delivering effective psychotherapy, resulting in a network of obstacle-solution interactions.

Strengths and limitations

To our knowledge, this is the first study to take an observational approach to explore the underlying mechanisms in OF-informed psychotherapy. The study describes a procedure for analysing data in psychotherapy process research using topic modelling, which could be used to inform future studies to increase the scale of research of this kind. The analysis involved a rigorous approach to examining various possible topic model outputs and selecting the most clinically interpretable version by applying content analysis to a proportion of the data that was automatically identified by the TMT as being relevant to latent topics. This reduced the labour-intensity of manually analysing a rich and extensive dataset of qualitative data from a relatively large sample. The findings provide insights into the obstacles and solutions that occur in OF which were gained from multiple

therapists working with multiple patients in several services across England, thus increasing generalisability of the results.

However, there are limitations that should be considered when interpreting the results. Firstly, whilst the sample involved numerous therapists and patients, there was little demographic or clinical information about individuals, including years of training, therapy models and presenting problems. This information was not captured to limit the burden of participation; however, the lack of contextual information may challenge the study's generalisability. Additionally, the study focuses on therapist's perceptions which introduced a potential bias around overlooking the therapist role; gaining insights from patient's perceptions may have been interesting to compare against.

Secondly, whilst there was little formal drop out, approximately two thirds of participating therapists did not collect any data. Feedback from therapists suggested that this resulted from having restricted time and prioritising clinical work. Implementation issues are a recognised barrier associated with outcome feedback (Hovland & Moltu, 2020). Therefore, whilst the issues with implementation present as a limitation for the study, they also provide valuable information which is relevant to clinical practice.

Furthermore, the TMT required the number of topics to be pre-selected and even the most optimal number of topics presented with blurred decision boundaries – where topics were not always neatly clustered – resulting in some overlap between themes. Additionally, whilst the TMT automatically organised inputted datasets, the outputs required large amounts of interpretation that are subject to potential bias (see Appendix F for reflexivity statement).

Finally, due to contextual factors, data collection finished early, and, whilst there was sufficient data for the primary analysis, there was not sufficient power to determine statistical associations between obstacles and solutions. Therefore, the relationships between obstacles and solutions were considered theoretically based on observations during the extensive review of qualitative data, resulting in potential bias and subjectivity. However, consultations with experts in the fields of OF and topic modelling were used as an additional mechanism to minimise bias and influence on subjectivity. There was also insufficient data to triangulate the results with outcome data. Future research with a larger sample should explore the correspondence between obstacles, solutions, and outcome more robustly.

Conclusion

The results from this study indicated common obstacles to treatment progress and common solutions to these obstacles in OF-informed psychotherapy. The obstacles were somewhat related to the theory-derived obstacles currently recognised, whereas the solutions differed from those in the existing literature, presenting as more broad strategies to utilise across the therapy process, rather than specific obstacle interventions. The general solutions highlighted the importance of having clear goals and establishing an environment, informed by personalised formulations, where therapy tasks can be agreed and accomplished to achieve goals. Bridging between sessions, to ensure continuity across the therapy process, may be a potential scaffold for these solutions.

The findings from the study have implications for clinical practice, where the obstacles and solutions could inform the foundations of a good practice guide

for therapists utilising OF in routine practice. Future research should aim to replicate and expand on the findings of this study, to increase the robustness of conclusions drawn and to gain further insights to develop the good practice guide. An additional clinical implication of the study is the issue with implementation. This reflects the high pressure on throughput that is typical in IAPT services and highlights the value of good practice guides. Psychotherapy is a complex process involving intricate interactions between therapists, clients and their wider contexts, and, accordingly, therapists utilising OF are required to explore a wide range of plausible variables which may interfere with the therapy outcome (Delgadillo et al., 2017). Therefore, readily accessing clear, evidence-based guides for assessing and managing obstacles is likely to be of benefit in the face of competing demands. Finally, this study also provides an example of how topic modelling can increase the scope of process psychotherapy research, resulting in more vigorous, larger-scale studies. Future research could explore how to reduce the large amounts of interpretation required to translate the outputs into meaningful themes.

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Appendices

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Appendix A: Information Sheet

Participant Information Sheet

1.   Research Project Title

Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety

2.   Invitation paragraph

You are invited to take part in a research project. Before you decide whether you would like to participate, it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear, or if you would like more information. Take your time to decide whether you wish to take part. Thank you for reading this.

3.   What is the study about?

Numerous reviews of controlled trials and practice-based studies have concluded that using outcome feedback (OF) can help to improve psychological treatment outcomes. OF involves the routine monitoring of a patient's symptoms using standardised measures and plotting these onto a graph that displays a trajectory of changes from session-to-session. These graphs help therapists to identify cases that are 'on track' or 'not on track' to a good treatment outcome. 'On track' patients show typical symptoms that are comparable to those observed in similar cases, whereas 'not on track' cases show symptoms that are significantly worse than those of similar cases. The OF method therefore supports therapists to make treatment decisions based on objectively measured, individualised treatment responses, rather than relying on clinical judgment alone.

Although the effectiveness of this OF method is well-established, there is scarce research about its mechanism of action. Previous studies have suggested that the OF method helps therapists to identify and resolve obstacles to improvement in a timely way; however, less is known about the types of obstacles that are identified using OF, or the solutions and strategies that are applied by therapists to improve outcomes.

We therefore aim to investigate the OF process and mechanisms of action. Processes will be captured using qualitative case notes including a summary of hypotheses about obstacles to improvement, a plan for trouble-shooting strategies and the implementation and outcomes of that plan. We also aim to explore if certain obstacles and certain solutions are associated with clinical outcomes. We will therefore be gathering quantitative outcome data and qualitative process data.

The time scale for the study will be 9 months: including 6 months for data collection and 3 months for analyses and dissemination. This study is being conducted as a requirement of the doctorate in clinical psychology (DClinPsy) at the University of Sheffield.

4. Why have I been chosen?

You have been chosen because you meet the inclusion criteria for our study. That is, you are a qualified psychotherapist contracted to work within an IAPT service for the expected timescale of the project.

5. Do I have to take part?

No, you do not have to take part. Participation in the study is voluntary and you are not obliged to consent. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You can still withdraw at any time without any negative consequences and you do not have to provide a reason. If you wish to withdraw from the research, please do not hesitate to contact Eleanor Williams (see **16.** for contact details).

6. What will happen to me if I take part? What do I have to do?

If you decide to take part, you will be involved in the research for 6 months. You will be invited to attend one 3-hour training session, to learn how to apply OF methods in your clinical practice, and one 90-mintue booster webinar session half-way through the study.

You will then be asked to use OF methods in your usual clinical practice. You will have access to OF monitoring graphs; you will be required to enter scores from the PHQ-9 and GAD-7 into the graph on a sessional basis, in accordance with standard IAPT practice. You will review the graph at the start of each therapy session, to assess if treatment is 'on track' or 'not on track'. In cases that are assessed as 'not on track', you will explore potential obstacles to improvement and consider and implement trouble-shooting strategies. You will also be encouraged to prioritise these discussions in your weekly clinical supervision.

You will be asked to document the above process using an electronic form, which provides a template for you to keep structured case notes. The case notes template will ask you to summarise: your hypotheses about obstacles to improvement, and the actions or strategies taken to address these obstacles. You will be able to type into the boxes on the electronic form and will be able to copy and paste your text to your own routine case notes, to reduce the administrative burden.

You will require verbal consent from patients before completing the electronic form. You will be provided with a script to gain consent and will need to document that the patient has consented on the PCMIS system. The process of gaining patient consent has been designed to be as least burdensome as possible.

You will not require consent from supervisors to participate in this study, since the procedures overlap with routine care (using Outcome Feedback graphs and keeping structured case notes) although you may wish to discuss the study with your supervisor prior to consenting to participate.

7. What are the possible disadvantages and risks of taking part?

It is possible that being notified when your cases are at risk of poor outcomes may be anxiety provoking for you and there is the possibility that OF may raise quality of care issues. You will be encouraged to address these issues within your formal and contractual setting of clinical supervision. Responsibility for the quality of care will lay with you and your supervisor through the duration of the study. The research team will not be monitoring the data in 'real time' and it is therefore considered the responsibility of you and your supervisor to address clinical concerns.

8. What are the possible benefits of taking part?

You will gain access to a clinical skills workshop developed by experts in the field of outcome feedback. You may find OF helpful in your practice and you may develop skills in utilising outcome monitoring and strategies to resolve obstacles to improvement in a consistent and timely manner. You will also be contributing to an important gap in the literature which may help to improve the efficacy of psychotherapy in the future.

9. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. You will not be able to be identified in any reports or publications. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.

10. What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

11. What will happen to the data collected, and the results of the research project?

Prior to data collection, you will be assigned a unique ID number which you will be asked to enter onto the electronic forms you fill out. Your data will therefore be anonymised. Only the data processors (the lead researcher and two supervisors) will have access to this anonymised data. The results will be analysed by the lead researcher under the supervision of the two supervisors. The results will be written up as a journal article and will be submitted for publication in approximately September 2020. You will not be identified in any publication and you will be informed on how to obtain a copy of the results.

The data you provide will be stored in an anonymised form for 10 years. Identifiable personal data, including the key which links you to the data you provide, will be destroyed once it is clear that this will not affect the research purpose.

Due to the nature of this research, it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way.

12. Who is organising and funding the research?

This study will be funded by the University of Sheffield.

13. Who is the Data Controller?

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 10 years 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 by contacting Eleanor Williams (see **16.** contact details).

14.   Who has ethically reviewed the project?

This project has been ethically approved via the NHS research ethics committee.

15.   What if I wish to complain about the research?

If you wish to raise a complaint about the research, you should contact Eleanor Williams (see **16.** for contact details). If you feel that your complaint has not been handled to your satisfaction, you should contact the Gillian Hardy (see **16.** for contact details), Head of Department, who will escalate the complaint through the appropriate channels. If your complaint relates to how your personal data has been handled, you can find information about how to raise a complaint in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

16.   Contact details

Please see below for contact details. Please contact Eleanor Williams (lead researcher) if you wish to obtain further information about the project. If you do not hear back from the lead researcher after one week, please email Jaime Delgadillo (supervisor). Please only email the head of department if you are escalating a complaint.

Lead Researcher	Supervisor	Supervisor	Head of Department
Eleanor Williams	Jaime Delgadillo	Heidi Christensen	Gillian Hardy
Ewilliams9@sheffield.ac.uk	j.delgadillo@sheffield.ac.uk	heidi.christensen@sheffield.ac.uk	g.hardy@sheffield.ac.uk
	0114 222 6614	0114 222 1950	

If you wish to participate in this study, please complete the consent form and send it to the research team at the University of Sheffield – either via email (scanned copy of signed consent form) or via post. If you wish to post your consent form, please send it to:

Eleanor Williams
Clinical Psychology Unit
Cathedral Court
The University of Sheffield
1 Vicar Ln
Sheffield
S1 2LT

Thank you for reading this information sheet.

Appendix B: Consent form

Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety

Consent Form

Please tick the appropriate boxes	Yes	No
Taking Part in the Project		
I have read and understood the project information sheet dated 18/06/2019 or the project has been fully explained to me. (If you will answer No to this question please do not proceed with this consent form until you are fully aware of what your participation in the project will mean.)	☐	☐
I have been given the opportunity to ask questions about the project.	☐	☐
I agree to take part in the project. I understand that taking part in the project will include using outcome feedback technology in my routine practice and documenting the processes that underly this via qualitative case notes on an electronic form.	☐	☐
I understand that my taking part is voluntary and that I can withdraw from the study at any time; I do not have to give any reasons for why I no longer want to take part and there will be no adverse consequences if I choose to withdraw.	☐	☐
How my information will be used during and after the project		
I understand my personal details such as name, phone number, address and email address etc. will not be revealed to people outside the project.	☐	☐
I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.	☐	☐
I understand and agree that other authorised researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
I understand and agree that other authorised researchers may use my data in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
I give permission for the data that I provide to be deposited in University of Sheffield repository, so it can be used for future research and learning.	☐	☐
So that the information you provide can be used legally by the researchers		
I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.	☐	☐

Name of participant [printed]   Signature   Date

| Name of Researcher [printed] | Signature | Date |

Project contact details for further information:

Lead Researcher	**Supervisor**	**Supervisor**	**Head of Department**
Eleanor Williams	Jaime Delgadillo	Heidi Christensen	Gillian Hardy
Ewilliams9@sheffield.ac.uk	j.delgadillo@sheffield.ac.uk	heidi.christensen@sheffield.ac.uk	g.hardy@sheffield.ac.uk
	0114 222 6614	0114 222 1950	

Appendix C: Screenshot of the PERMHA

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Appendix D: Initial inductive content analyses

Obstacles content analysis

Condensed meaning unit	Code	Category	Theme
Comorbidity	Comorbidity	Comorbidity	Patient factors
Chronic pain	Physical health		
Headaches	Physical health		
Pain	Physical health		
Physical health	Physical health		
Physical health problems	Physical health		
Repetitive strain	Physical health		
Chronic low mood	Impact of low mood	Patient psychological distress	
Anticipation of trauma work	Impacts of past trauma		
Avoidance of trauma	Impacts of past trauma		
Avoidance of trauma	Impacts of past trauma		
History of trauma impacting on emotional regulation	Impacts of past trauma		
History of trauma which causes panic	Impacts of past trauma		
Sharing a traumatic memory	Impacts of past trauma		
Anxieties about the future	Patient anxiety		
Impact of panic	Patient anxiety		
Self-harm	Self-harm		
Perfectionism causing overplanning	Impact of perfectionism	Patient traits and behaviours	
Perfectionism makes takes take longer	Impact of perfectionism		
Activated mistrust schema	Impact of self-schema		
Activated schema causing rupture	Impact of self-schema		
Activated self-critic schema	Impact of self-schema		
Negative self-schemas	Impact of self-schema		
Language barrier	Language barrier		
Making excuses	Lack of motivation for homework		
Patient has difficulties with speaking up in therapy	Patient assertiveness		

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Avoidance	Patient avoidance		
Lack of motivation to change	Patient behavioural rigidity		
Lack of motivation to do things differently	Patient behavioural rigidity		
Unwilling to change routine	Patient behavioural rigidity		
Intolerance of uncertainty	Patient capacity to accept uncertainty		
Defensiveness	Patient defesniveness		
Long standing emotional instability	Patient emotional instability		
Black and white thinking	Patient thinking style		
PD traits	Patient traits		
Low expectation of recovery	Patients beliefs about therapy		
Low expectation of treatment working	Patients beliefs about therapy		
Poor sleep	Sleep difficulties		
Death in family	Bereavement	Difficulties within patients social network	Patients wider system
Loss of grandmother	Bereavement		
Difficult family situation	Difficult family dynamics/siutation		
Difficult relationship with parents	Difficult family dynamics/siutation		
Issues with relationship with parents	Difficult family dynamics/siutation		
Unsupportive family	Difficult family dynamics/siutation		
Miscarriage	Miscarriage		
Argument with boyfriend	Relationship difficulties		
Marital tension	Relationship difficulties		
Relationship difficulties	Relationship difficulties		
Social isolation due to COVID	Social isolation		
Domestic violence	Domestic violence		
Financial difficulties due to lack of work	Financial difficulties	Occupational issues	

Difficulties with workplace environment	Workplace difficulties		
Grievance at work	Workplace difficulties		
Impact of micromanager boss	Workplace difficulties		
Interpersonal difficulties at work	Workplace difficulties		
Interpersonal difficulties at work	Workplace difficulties		
Issues at work	Workplace difficulties		
Poor working environment	Workplace difficulties		
Stress at work	Workplace difficulties		
Unhappy at work due to unhealthy culture	Workplace difficulties		
Unhappy working environment	Workplace difficulties		
Unsupportive work	Workplace difficulties		
Life stresses	Stressful wider circumstances	Stressful wider circumstances	
Stressful time of the year (Christmas)	Stressful wider circumstances		
Therapist unsure of appropriate treatment path	Therapist hesitation	Therapist confidence	Therapist factors
Therapists confidence in own ability (outskilled)	Therapist confidence		
Needed to be stepped up	Stepped up	Service constraints	Therapists wider system
DNA leading to potential discharge	Service rules		
Supervisor on leave	Lack of supervision		
Lack of goal consensus	Lack of goal	Ambiguous focus of therapy	Therapy factors
Patient not focused enough therefore therapy not focused	Therapy not focused		
Not putting theory from therapy into practice	Difficulties applying therapy	Demands of therapy tasks	
Not putting tools from therapy into practice	Difficulties applying therapy		
Patient overwhelmed from reflecting on distress	Impact of therapy insights		
Therapy insights overwhelming the patient	Impact of therapy insights		
Lack of motivation to complete homework	Lack of motivation for completing homework		

Making excuses for HW	Lack of motivation for completing homework		
Limited engagement with homework	Lack of motivation for homework		
No time or motivation to relax	Lack of motivation for homework		
Not doing homework	Lack of motivation for homework		
Not completing homework	Lack of motivation to complete homework		
Delicate working alliance	Therapeutic alliance	Therapeutic alliance	
Telephone sessions causing a barrier to alliance (COVID)	Barrier to therapeutic alliance		

Solutions content analysis

Condensed meaning unit	Code	Category	Theme
Managing counter transference	Counter transference	Attend to the therapy process	Clinical skills
Ensure that client is working within the window of tolerance	Assess window of tolerance	Therapist reflection	
Provided empathy	Empathy	Therapist response	
Normalised as is normal to feel overwhelmed early in therapy	Normalisation		
Discussed the work issue	Discussion about life stressors	Explore obstacle through discussion	
Considered early discharge	Early discharge	Flexible approach	Collaborative approach
Decided a clear focus of treatment	Establish a clear focus for therapy	Clarify the treatment goal	
Given goal focused sheet to develop joint goals for therapy	Establish goals		
Given problem focused statement to be clear on current problem	Establish the problem		
Choice given to patient re treatment path	Establish a collaborative focus for therapy	Empower the patient	
Discussed bereavement as this is what the patient wanted	Following the clients lead		
Change treatment focus	Adjust focus	Flexible approach	

Taking to supervision to discuss how treatment protocol could be adjusted following disclosure	Amending treatment plan		
Treatment check in with client	Check in		
Discussed whether the client wants to take a break in therapy	Establish if patient wants a break		
Taking a break from therapy to focus on employment	Taking a break from therapy		
Discussed risk with duty	Discussion with supervisor	Supervision	External resources
Discuss in supervision	Discussion with supervisor		
Discussion with employment support	Discussion with employment support	Intervene with the wider system	
Discussed motivation for engaging in treatment	Discussion about motivation	Increase motivation	Motivation
Use client goals to motivate change	Revisit goals to motivate change		
Considered small periods of time for homework that may fit with schedule	Increase achievability of homework	Increase motivation for homework	
Discussed benefits of prioritising homework	Increase motivation for homework		
Discussed impacts of the life stressors on therapy	Explore how life impacts on therapy	Use of psychological theory	Psychological theory
Use the health psychology model to address health problems	Draw on model		
Tied argument into rigidity	Making psychological links		
Discussed trigger to fear of losing control to increase understanding	Making psychological links		
Used formulation to help make sense of how to reduce symptoms further	Making psychological links		
Identified related emotions/triggers in the context of past trauma	Making psychological links		
Psychoeducation on rumination	Psychoeducation		
Discussed impact of trauma on panic	Psychoeducation		
Given information re trauma	Psychoeducation		

Ensure patient can make sense of anxiety and understand you can feel worse before you feel better	Psychoeducation		
Psychoeducation	Psychoeducation		
Continue to highlight the cons of planning and making assumptions	Psychoeducation		
Anxiety habituation graph discussed and explored	Psychoeducation		
Behavioural activation	Behavioural activation	Behavioural tools	Therapy tools
Behavioural experiment	Behavioural experiment		
Ensure distress management strategies are in place	Distress management strategies		
Model relaxing tasks	Relaxation techniques		
Relaxation/meditation	Relaxation techniques		
Cognitive work on challenging thoughts	Challenging thoughts	Cognitive techniques	
Focus on cognitive restructuring	Cognitive restructuring		
Started work on compassionate self	Compassionate self		
Encouraged to practice self-reflection	Encouraged self-reflection		
Developed a flashcard to help distance from negative thoughts	Flashcard for negative thoughts		
Use of thought diary to document rumination	Thought diary		
Use of worry diary	Worry diary		
Use of worry tree	Worry tree		
Writing worries down so can start to socialise patient on how to manage	Write worries down		
Discussed ways to improve communication with family	Improve patient communication	Developing skills	

Appendix E: TMT outputs

Obstacles

K=2

1: work family treatment anxiety difficulties high avoidance due therapist stress time session taking recent overwhelmed distancing past depression trauma recovery

2: client work patient trauma therapy relationship difficulties difficult due change panic eating time session anxiety distress problems chronic risk level

K=3

1: perfectionism high eating making difficult assessment increased saftey level criticism symptoms violence physical university recovery poor previous house meant lead

2: current due 2 trauma family session change impacting panic bullying sessions sense depression part thinks term long relapse time environment

3: client work difficulties trauma therapy anxiety relationship patient due time treatment avoidance change past problems lack motivation session doesn impact

K=4

1: panic therapy anxiety past family change bad pressure complexity mood memories chronic sessions witness current physical 2 identified feel eating

2: client work difficulties due trauma relationship avoidance treatment anxiety patient problems problem difficult level therapy time things history session change

3: client time motivation health distancing risk tiredness recovery negative situations previous high taking doesn found past limited obstacles schemas extreme

4: patient criticism lack family telephone decided focus impacting identity depression university upset back working high environment social history session work

K=5

1: december 9 effects shared reflections commitments main found decided pattern triggering christmas overworking longstanding result impact past dymnamics mood sensations

2: client work trauma due patient change time session family relationship difficulties panic therapy things problems depression high lack problem treatment

3: homework anticipation retell started friends virus engage method waiting agoraphobia phq coronavirus complete today linked experiencies spent 06 memories easily

4: interpersonal anxiety doesn hopelessness risk emotional recovery pain long avoidance parents work difficult good distanced stabilisation set miscarriage stepped income

5: difficulties saftey therapy environment treatment isolated telephone decided stressful schemas completed level 2 relapse avoidance lead life practice putting health

K=6

1: problems physical relationship work addressing overwhelmed impact comorbidity sessions witness overplanning change boss husband friends lock interpreter engage weeks 4

2: trauma client depression history session change distancing impact obstacles risk therapist identified responsibility negative leave eating making childhood motivation environment

3: time family work schemas criticism things homework scores 9 assessment strategies problems fear process relax feeling therapy social treatment clear

4: phq therapist long poor previous therapy childhood week work patient client anticipation gad story retell started stabilisation telephone 2019 waiting

5: client work difficulties anxiety trauma due avoidance patient panic lack health relationship difficult recent chronic current low high therapy life

6: income december agoraphobia menopause country make pattern regulation emoitonal comorbidity complexity fatigue missed requested passivity speaking evaluation unsuccessful domestic abuse

K=7

1: coronavirus processing increase 2019 9 phq complete struggling loss thoughts planning respond protective deficit witnessing ruptures engagement chronicity violence cycles

2: difficult strategies limited easily addressing friends coronovirus income hard menopause shared country experienced married single grievance issues emoitonal feleing distancing

3: therapist working poor high life social practice session health behavioural anticipate addressing haven language isolated delivery lose phq state initial

4: overwhelmed memories low situations leave anticipation weeks 4 miscarriage december reflections end mum night conditions gender christmas cov inability combined

5: past employed pain eating therapy lack parents clients due story focused usual effects found move decided today regulation stressful overworking

6: client work difficulties trauma patient due anxiety avoidance therapy relationship time family change motivation session problems distress panic risk depression

7: criticism treatment living chronic fear extreme witness back relapse home perfectionism environment starting husband lock virus agoraphobia 9 memory disturbed

K=8

1: house problem story friends focused waiting 9 state struggling thoughts issues emoitonal ocd employment intial comorbidity increases traumatic constraints services

2: client work difficulties due therapy patient trauma avoidance history anxiety difficult panic depression physical high things session taking change problems

3: long working past leave relationship delivery miscarriage 9 overwhelmed identify breakdown triggering christmas emotions impact complexity ambivelence engamenet reduced syndrome

4: family current anticipate addressing thirds loss mum today overworking appropraite emotions limited panic engaged vulnerable puts pt therapist abuut young

5: obstacles pain learning lack time recent starting anticipation gad haven processing lock interpreter isolated telephone workload 2019 emdr commitments married

6: coronavirus motivation health virus increase income list agoraphobia root early grandmother emotionally caring conditions assessment distancing impact deficit stressors tolerance

7: trauma family work criticism saftey recovery problem treatment session relationship anxiety change patient interpersonal overwhelmed mood 19 easily risk level

8: distress decided abuse skills finding migraines childhood treatment relationship client job good distanced stepped memory reflections bereavement motivated main pattern

Solutions

K=3

1: discussed client session treatment thoughts change work anxiety therapy problem formulation address experiences make week order panic trauma continue ways

2: review treatment barriers potential give idetified safety mood health sessions ruminative days motivation time employment reiterate statement goals hw planning

3: understanding explore focus therapy identify past trauma current copingcbt due address place ocd related improve explored goals context diary

K=4

1: problem week make change session order cbt address symptoms plan discussed ocd past trauma scoresincreasing reducing ba time treatment

2: anxiety current treatment potential panic difficulties working aware session life experiences impactcycle therapist explored health skills doesn therapy started

3: continue formulation worry due explore panic sessions copingensure understanding reviewtolerating context model protocol bereavement clients related informed longer

4: client discussed treatment work therapy session identify focus thoughts past trauma discuss address experiences ensure anxiety understanding patient ocd impact

K=5

1: client discussed start identify developed focus sessions motivation continue depression bereavement clients life improve past factors psychology difficulties explored regular

2: trauma therapy address session experiences work increase supervision sessions anxiety formulation explore starting offered ocd triggers alternative past impactidetified

3: low underlying focused exposure treatment formulation client change patient session distress tolerance expressed prior seekers refugees regulation installed meaningful track

4: discussed treatment client change work session therapy thoughts week panic problem due make address identify order ocd current anxiety understanding

5: focus past thoughts statement goals reflection safety mood difficulties explored process ensure working make order worry advice worse groups agency

K=6

1: discussed client session work therapy treatment change focus trauma week identify anxiety thoughts panic understanding problem explore current make formulation

2: cbt past cognitive supervision sessions due feel day relaxation agreed identifying staying understands local groups baby seekers installed carers isolation

3: distress ocd treatment order considered difficulties copingdiscuss address link centre prior read services isolation meaningful sand motivate lock rush

4: thought increase ensure treatment address disucssed factors decisions ba worries making client needed video stabilisation agency solutions qualitycompetent prepare

5: safety ruminative doesn continue aware worry providing expressed safe arrive judgmentally techniques relaxed play watching reclaiming hygiene normal home spend

6: barriers experiences past ensure helpfulsupport tolerance window differently regulation solutions track relevant adjust attention grounding benefits lack monitoring mother

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K=7

1: continue   offered   trauma   provide   treatment   week   worse centre local   carers meaningful   findingtrack
relevant   fully   brush practical   benefits   feel   home

2: avoidance client   safety solutions   watching   appointments   bereavement place happened   guilt   ocd   maintain
schallenging relating   changed   feelings   fit   potential   space engage

3: break   barriers   past   links   impactidetified   issues social obstacles   session   identify   understands
window   differently   read   regulation   installed   isolation   relaxed   pause

4: positive   related   homework   focus exposure   making   symptoms   ways model starting   rescripting
seekers   aloneness   quality sand   service   lock   news attention   important

5: patient   life   behaviours   management order staying   providing   asylum   judgmentally techniques   reflection
feel   commit   lack   clients monitoring   briefly talk   talked resolved

6: assertiveness   anxious   low   implementingday   ruminative   helpfulunderstanding   support   goals video
groups   agency   solutions   mindful   competent   expected   prepare   adjust refocusing

7: discussed client   treatment   session   work   therapy   address   thoughts   problem   change   focus
make formulation   experiences panic trauma   difficulties   anxiety   explore   week

K=8

1: assertiveness   considered   cognitive   zoom sand prepare   pose home lack   ruminating   intrusive
combining   compassionate   ocd   harm   doubt ideas interpretation incorporate   comorbid

2: discussed client treatment   session   therapy   address   change   work   week thoughts   make order
experiences trauma   focus sessions   current   problem   formulation explore

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3: psychology rumination helpful problem video differently baby prior refugees quality fully reflect
depression present protocol letting attention habituation overwhelming understand

4: thought statement schedule health strategies link worse seekers read aloneness play practical
practise normal offered monitoring talk tuesday exist idea

5: feel impacting expressed centre nightmare competent role protocol news decreasing reflection place
opinions solved related looked judgements concept risk barriers

6: past feels positive plan advice local stabilisation meaningful depression beleifs esteem priortising
reveiwed potential impact reported challenging diuscssed completed education

7: continue impact tolerance stabilisation aloneness mindful expected pause watching information
reclaiming grounding graph appointments briefly guilt increaseing rejection tohelp values

8: symptoms patient clients sheet making start tolerating work identified identify providing children
groups regulation finding outcomes brush adjust refocusing feel

K=9

1: order focus make identify treatment client trauma anxiety week ocd increase ensure
ways past potential give panic cycle homework health

2: discussed session client therapy change address work problem sessions copingthoughts
treatment formulation past panic trauma difficulties current anxiety explore

3: client factors exposure treatment return staying expressed differently prior stabilisation
emotional lock uderstanding reagrding judgements achievement view pattern periods open

4: increased read installed service arrive cognitions happened ruminating today timeline opinions
ideas life related interpretation stressors sesison alternative fit staements

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5: cbt depression improve process positive refugees agency regulation solutions track pay
   hygiene commit spend place guilt tohelp development decided benifits

6: experiences discussed distress diary solved longer safety thought time discuss planning start
   link asylum stabilisation services carers sand motivate mindful

7: protocol improve disucssed social understands news offered form ocd leading rejection impact
   superviison repeat idetified panic properly health timeframe prescription

8: comorbid employment hw meaningful habituation feel life related weeks barriers disucssion anxious
   low tirgger maintenance reading 5 negative workload ptsd

9: treatment relating control taking problem worry nightmare seekers competent fully pause rush
   empathy asked ccbt telephone place talked resolved shame

Appendix F: Reflexivity statement

The researcher is a white, female clinical psychology trainee. She has a background working in physical health and neuropsychology services with young people and adults. This includes psychotherapy work, primarily using CBT and Acceptance and Commitment Therapy (ACT). The researcher has never worked using OF or in an IAPT service; however, during her clinical psychology training the researcher developed a reasonable understanding of the IAPT services that the participants worked in through discussions with patients, colleagues and in teaching. This was a more general understanding of IAPT, which emphasised the high pressure on throughput and time limitations, rather than a specific view of the individual services that collaborated in the research. Therefore, the researcher may have had a pre-existing narrative about potential obstacles in IAPT services. Through her training, the researcher draws upon psychological formulations in her clinical practice and to some extent expected formulations to present as a solution more clearly within the data. Additionally, the researcher was immersed into the outcome literature before interpreting the TMT outputs and consequently had an awareness of the pre-existing obstacles and solutions.

Appendix G: Evidence of IRAS ethical approval

NHS
Health Research
Authority

Yorkshire & The Humber - South Yorkshire Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 1048091

Please note: This is the
favourable opinion of the
REC only and does not allow
you to start your study at NHS
sites in England until you
receive HRA Approval

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16 July 2019

Dr Jaime Delgadillo
Lecturer in Clinical Psychology
University of Sheffield
Clinical Psychology Unit
Cathedral Court, Floor F
1 Vicar Lane, Sheffield
S1 1HD

Dear Dr Delgadillo

Study title:	**Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety**
REC reference:	19/YH/0178
Protocol number:	160383[##IfProtocolRef##]
IRAS project ID:	259658

Thank you for your letter of 8 July 2019, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering letter on headed paper [Cover letter]	V1	26 March 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Certificate]	V1	01 February 2019
IRAS Application Form [IRAS_Form_26032019]		26 March 2019
IRAS Checklist XML [Checklist_08072019]		08 July 2019
Letter from sponsor [Sponsorship Letter]	V1	24 January 2019
Non-validated questionnaire [Process measure]	V1	23 January 2019
Other [Response to Provisional Opinion from REC]	V1	18 June 2019
Other [Patient Consent Script]	V2	21 June 2019
Other [Patient Information Sheet]	V1	18 June 2019

Other [Participant Information Sheet]	V4	18 June 2019
Other [Amended Protocol]	V4	18 June 2019
Other [MindLife Security Document]	V1	18 June 2019
Participant consent form [Consent Form]	V2	18 June 2019
Participant information sheet (PIS) [Participant Information Sheet]	V4	18 June 2019
Referee's report or other scientific critique report [Letter from reviewer]	V1	17 September 2018
Referee's report or other scientific critique report [Letter to reviewer]		22 October 2018
Referee's report or other scientific critique report [Scientific Approval Letter]	V1	24 January 2019
Research protocol or project proposal [Protocol]	V4	18 June 2019
Summary CV for Chief Investigator (CI) [Supervisor CV]	V1	08 February 2019
Summary CV for student [Student CV]	V1	13 February 2019
Summary CV for supervisor (student research) [Supervisor CV]	V1	08 February 2019
Validated questionnaire [GAD-7]		
Validated questionnaire [PHQ-9]		

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

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

19/YH/0178	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Ian Woollands
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Andrew Thompson

Appendix H: Evidence of HRA ethical approval

Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
**Health Research
Authority**

Miss Eleanor Williams
Department of Clinical Psychology
University of Sheffield
University of Sheffield
Sheffield
S1 1HD

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

15 August 2019

Dear Miss Williams

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	**Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety**
IRAS project ID:	**259658**
REC reference:	**19/YH/0178**
Sponsor	**University of Sheffield**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **259658**. Please quote this on all correspondence.

Yours Sincerely
Beverley Mashegede

Email: hra.approval@nhs.net

Copy to: Dr Andrew Thompson, Sponsor Contact
             Dr Jaime Delgadillo, Chief Investigator, Academic Supervisor

List of Documents

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

Document	Version	Date
Costing template [Costing]	V3	23 February 2019
Covering letter on headed paper [Cover letter]	V1	26 March 2019
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) [Insurance certificate]		31 August 2018
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) [Insurance Support Letter]	V1	01 February 2019
HRA Schedule of Events	1	06 August 2019
HRA Statement of Activities	1	06 August 2019
IRAS Application Form [IRAS_Form_26032019]		26 March 2019
IRAS Application Form XML file [IRAS_Form_26032019]		26 March 2019
IRAS Checklist XML [Checklist_26032019]		26 March 2019
Letter from sponsor [Sponsorship Letter]		24 January 2019
Non-validated questionnaire [Process measure]	V1	23 January 2019
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Summary CV for student [Student CV]	V1	13 February 2019
Summary CV for supervisor (student research) [Supervisor CV]	V1	08 February 2019
Validated questionnaire [GAD-7]		
Validated questionnaire [PHQ-9]		

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Multicentre study with same site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No funds will be provided to the participating organisation to support this study.	A Principal Investigator (PI) is expected at each participating NHS organisation.	No access arrangements are expected for this study.

Other information to aid study set-up and delivery

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

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

No sites were listed on Part C of the IRAS Form. Confirmation has been received and these are; North East London NHS Foundation Trust, Homerton University Hospital NHS Trust, Barnett Enfield and Haringey Mental Health Trust and Whittington Health Trust.

Appendix I: Evidence of scientific approval

The University Of Sheffield.

Department Of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy) Programme
Clinical supervision training and NHS research training
& consultancy.

Clinical Psychology Unit
Department of Psychology
University of Sheffield
Floor F, Cathedral Court
1 Vicar Lane
Sheffield
S1 2LT

Dr A R Thompson, Clinical Training Research Director
Please address any correspondence to Amrit Sinha
Research Support Officer
Telephone: 0114 2226650
Email: a.sinha@sheffield.ac.uk

24th January 2019

To: Research Governance Office

Dear Sir/Madam,

RE: Confirmation of Scientific Approval and indemnity of enclosed Research Project

Project title: Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety.

Investigators: Eleanor Williams (DClin Psy Trainee, University of Sheffield); Dr Jaime Delgadillo, Dr Heidi Christensen (Academic Supervisors, University of Sheffield)

I write to confirm that the enclosed proposal forms part of the educational requirements for the Doctoral Clinical Psychology Qualification (DClin Psy) run by the Clinical Psychology Unit, University of Sheffield.

Three independent scientific reviewers usually drawn from academic staff within the Psychology Department have reviewed the proposal. Review includes appraisal of the proposed statistical analysis conducted by a statistical expert based in the School of Health and Related Research (ScHARR). Where appropriate an expert in qualitative methods is also appointed to review proposals.

I can confirm that approval of a proposal is dependent upon all necessary amendments having been made to the satisfaction of the reviewers and I can confirm that in this case the reviewers are content that the above study is of sound scientific quality. Consequently, the University will if necessary indemnify the study and act as sponsor.

Given the above, I would remind you that the Department already has an agreement with your office to exempt this proposal from further scientific review. However, if you require any further information, please do not hesitate to contact me.

Yours sincerely

Dr. Andrew Thompson
Director of Research Training

Cc. : Eleanor Williams, Jaime Delgadillo, Heidi Christensen

Appendix J: Evidence of R&I approval

Homerton Confirmation of Capacity and Capability

Confirmation of Capacity & Capability for the study Common obstaclesand solutions to deliver effective psychotherapy

FT **FAMUREWA, Olawale (HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST) <olawale.famurewa@nhs.net>**
09/09/2019 11:59

To: Eleanor Williams Cc: CORFE, Adam (HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST)

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742.07 KB

Dear Eleanor,

Please find attached SOA and approval for your study.
Regards,
Ola

From: Homerton University Hospital NHS Foundation Trust, Research & Innovation

Dear Ellie Williams,

RE: IRAS 259658 . Confirmation of Capacity and Capability at Homerton University Hospital NHS Foundation Trust
Attachment: Document Set & HRA Approval of Non Commercial Non Portfolio Study or Academic/Student Study

Full Study Title: Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety

This email confirms that Homerton University Hospital NHS Foundation Trust has the capacity and capability to deliver the above referenced study.

We agree to start this study on :9th of September 2019

"It is the PI's responsibility to update the R&I and REC annually with their progress report.

Please find here the annual progress report link from HRA".

Progress reports
Last updated on 20 Mar 2018

NELFT Confirmation of Capacity and Capability

Dear Jamie and Ellie,

Study title: Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety
IRAS project ID: 259658
REC reference: 19/YH/0178
Sponsor: University of Sheffield

I am writing to confirm capacity and capability for the above titled research to proceed at North East London NHS Foundation Trust.

This confirmation is based on the HRA approval letter 15th August 2019 and the attached Statement of Activities and corresponding appendix B. The study is considered to be commencing at NELFT today 23rd August 2019. I am delighted to attach your NELFT letter of access to this email.

It is a requirement of the Department of Health's Research Governance Framework to ensure the NHS R&D Offices are conducting continuous monitoring of NHS research projects. Myself and our Data Manager Kellie Allen will be in touch at 3 and 6 months for interim monitoring purposes. Please could you also inform us when your study has completed so that we can provide you with a close out monitoring form for return.

Should you have any other queries regarding the research here at NELFT please do feel free to contact me. We wish you every success with your work here at the Trust.

Kind regards,

Krisha

Krisha Hirani
Senior R&D Officer
Research and Development Department
1st Floor Maggie Lilley Suite
Goodmayes Hospital
Barley Lane, Ilford, Essex.
IG3 8XJ

Tel: 0300 555 1200 Ext. 64478

NelftResearch   NelftRD   @NELFTResearch

NELFT NHS

Leeds Confirmation of Capacity and Capability

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NHS

**Leeds Community
Healthcare**

NHS Trust

</div>

Telephone enquiries, please contact:
Phone: 0113 843 3432
Email: lch.research@nhs.net

14ᵗʰ January 2020

<div align="right">

Stockdale House
Headingley Office Park
Victoria Road
Leeds LS6 1PF

</div>

Address

IRAS Project ID: 259658
LCH Ref: P0263

Dear Dr Jaime Delgadillo

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Letter to confirm Capacity and Capability

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Re: Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety

Registered study end date:

We are now in receipt of the letter of HRA Approval and the Statement of Activities for the above study and have reviewed relevant study documentation. We are happy to agree to the Statement of Activities and pleased to confirm that the Leeds Community Healthcare NHS Trust (LCH) has capacity and capability to undertake the study, which can now proceed.

Please ensure that you have accepted LCH as a recruiting site to your study in EDGE, you can contact our Research Department for help if you require it.

You should be aware that

- The Trust will be expected to recruit the first participant into the study within 30 days of the date of this letter. Please confirm the date of the first recruitment with the research team. If recruitment within 30 days is unlikely please contact the research team to clarify the circumstances.

- LCH may wish to audit your project

- All research staff working upon the study are required to update their HSCIC accredited information governance training every 12 months. Externally employed staff should use the organisation code and name: "RY6 Leeds Community Healthcare" and access training on the following link:

  https://www.igtt.hscic.gov.uk/igte/index.cfm

  An employee number should not be required. (Contact the research team in case of any issues.)

- Any serious adverse event(s) that occur throughout the course of the study should be notified to LCH using the contact details set out above

Chair: Neil Franklin OBE   Chief Executive: Thea Stein

- Study information will be registered and held on the EDGE research management system to facilitate study management. If not already an account holder, you and/or study staff will be assigned an EDGE account.
- Unless you are providing study information directly using the EDGE research management system, you are required to provide the following to the LCH research team using the above contact details:
    - details of monthly study recruitment
    - any amendments or updated study documentation

- Upon completion of the study you should fill in a completed study outcome form

- This letter confirms capacity and capability until the registered study end date noted above. Should your study require an extension to the registered end date you must contact the R&D department to extend your registration period.

Should you require any clarification regarding any of the points raised above, or have any further queries please contact the research team on the numbers above.

Finally, I would like to take this opportunity to wish you well with your study. I look forward to hearing about your progress in due course.

Yours sincerely,

Stacey Phillips
Research Development Manager for Specialist and Childrens Services

Chair: Neil Franklin OBE   Chief Executive: Thea Stein