Evaluating the Evidence of Group Metacognitive Therapy and Exploring the Applicability of the Metacognitive Model to Burns, Plastics, and Reconstructive Surgery Patients

A thesis submitted to the University of Manchester for the degree of Doctor of Clinical Psychology in the Faculty of Biology, Medicine and Health

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Abstract

The metacognitive model provides a transdiagnostic, evidence-based approach to conceptualising and treating patients' distress using metacognitive therapy (MCT). This thesis examines the use of group MCT (g-MCT; paper 1) and whether the key concepts of the cognitive and metacognitive models can be elicited from the accounts of patients with burns and other injuries requiring plastic and/or reconstructive surgery (BPRS; (paper 2). This is important because the efficacy of existing psychological support may be limited and the psychological needs of BPRS patients are poorly understood.

Paper One is a systematic review and meta-analysis of the acceptability and efficacy of g-MCT. Sixteen studies were included, with MCT being delivered across a range of psychological disorders. Intervention groups receiving G-MCT had a low drop-out rate and large pre/post and pre/follow-up reductions in symptoms of anxiety and depression. G-MCT also demonstrated preliminary evidence of superiority above active control conditions, however further large-scale randomised controlled trials are needed.

Paper Two is a qualitative investigation using Thematic Analysis to understand the psychological experiences of BPRS patients and to explore whether key concepts underpinning the cognitive and metacognitive models can be elicited from their accounts. Eleven BPRS patients completed a semi-structured interview. Patients described a range of feelings, all reported engaging in repetitive negative thinking, and described engaging in various coping strategies (i.e. distraction, thought suppression) in an effort to control their thoughts and feelings. Using the cognitive model, there were multiple examples of all ten pre-specified types of distorted thinking. Patient talk was consistent with several problem-specific models. Some concerns had their basis in the patient's clinical reality making judgement about the distorted nature of the concern more challenging. Regarding the metacognitive model, patients engaged in talk characterised as the cognitive attentional syndrome and endorsed both positive and negative metacognitive beliefs. The possible implications for applying each model in clinical practice are discussed and a number of hypothesised benefits to using the metacognitive model with BPRS patients could be explored in future research.

Paper Three is a critical reflection of the research process, outlining decisions that were made, the rationale behind them, and a summary of the learning outcomes of the trainee in undertaking this thesis.

Declaration

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The support from my colleagues on the ClinPsyD programme has been important to me throughout the last three years, thank you for always being there. A special thanks to Fiona O'Donovan who completed a linked project – we worked through this process together and I owe you a great deal for sharing your vast experience and knowledge with me.

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Dedication

Annie, I could not have done this without your unwavering love and encouragement

Paper One | Group Metacognitive Therapy: A Systematic Review and Meta-analysis

This paper has been formatted in line with the publication guidelines of Clinical Psychology Review (see Appendix 1.1), however tables and figures have been included in line with text for ease of reading.

Abstract (max 200; excluding keywords and highlights): 198 words

Main text (including footnotes, tables, and in-text citations, excluding title page, figures, and references): 9,455 words

Group Metacognitive Therapy: A systematic review and meta-analysis

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Abstract

Group therapies reduce service pressure and offer broader patient choice. This systematic review and meta-analysis aimed to assess the acceptability (retention) and efficacy of Group Metacognitive Therapy (g-MCT). Six electronic databases were searched (PsychINFO, MEDLINE, Embase, Web of Science, CINAHL, and PubMed) on 27-Feb-2022. Sixteen studies ($n = 1,010$) were included for review: nine (56%) uncontrolled trials, five (31%) randomised-controlled trials (RCTs), and two (13%) service evaluations. Study quality was rated 'fair' with potential bias from lack of randomisation, control conditions, and blinding procedures in some studies. There was risk of researcher and publication bias and considerable heterogeneity and inconsistency across studies. Studies treated a variety of primary presenting problems (i.e. depression, generalised anxiety, transdiagnostic samples) mainly in adult samples, with two studies of younger people. G-MCT offered a mean sixteen hours ($SD = 5.12$) of therapy and drop-out at post-therapy was low (8%). Meta-analyses showed very large uncontrolled pre/post effects ($g = 1.72, k = 15$) and pre/follow-up effects ($g = 1.74, k = 14$). G-MCT outperformed active control conditions in the short-term ($g = 0.39, k = 4$) but no statistically significant differences were found at follow-up. There is support for g-MCT being an acceptable and effective treatment across a range of disorders and populations, with an indication that short-term effects favour MCT.

Keywords

Group metacognitive therapy, transdiagnostic treatment

Highlights

- Both uncontrolled and controlled studies have evaluated g-MCT
- There was a low drop-out rate for g-MCT
- Large reductions in symptoms of anxiety and depression were seen in g-MCT groups
- G-MCT performed better than active control conditions in the short-term
- Heterogeneity and inconsistency was high; future studies should be larger RCTs

1. Introduction

Metacognitive Therapy (MCT; Wells, 2009) has developed through a theory-driven, cognitive science approach and has been argued as marking a paradigm shift in psychotherapy (Capobianco & Nordahl, 2021). MCT is based on the metacognitive model (Wells, 2009; Wells & Matthews, 1994, 1996) which states that psychopathology results from a common perseverative thinking style termed the cognitive attentional syndrome (CAS). The CAS is characterized by worry, rumination, threat monitoring, and unhelpful coping strategies (i.e. thought suppression). The activation and maintenance of the CAS is linked to biases in metacognitive control and dysfunctional metacognitive beliefs are considered a key factor in this process (Wells, 2009). Metacognitive beliefs are beliefs an individual holds about their thinking. These beliefs can be positive (e.g. worrying helps me be prepared), or negative. Important negative beliefs being that thoughts are uncontrollable (e.g. my worrying is out of control) and that thoughts can be dangerous (e.g. worrying can cause me harm).

MCT (Wells, 2009) aims to reduce activation of the CAS and to challenge unhelpful metacognitive beliefs. MCT has been evaluated in randomised controlled trials (RCTs) and shown to reduce symptoms of psychopathology in populations with depression (Hagen et al., 2017; Jordan et al., 2014) and generalised anxiety disorder (GAD; Nordahl et al., 2018; van der Heiden et al., 2012; Wells et al., 2010), as well as in transdiagnostic samples (Capobianco et al., 2018; Johnson et al., 2017; Wells et al., 2021). There is also preliminary evidence for MCT leading to reductions in symptoms of post-traumatic stress disorder (PTSD; Wells & Colbear, 2012; Wells et al., 2015) and obsessive-compulsive disorder (OCD; Papageorgiou et al., 2018; Shareh et al., 2010).

A recent systematic review and meta-analysis conducted by Normann and Morina (2018) included twenty-five efficacy studies (60% of which were controlled trials) comprising of 780 adult participants, 468 of whom received MCT. Across nine RCTs that compared MCT to waitlist controls there was a substantial advantage of MCT in the reduction of primary outcome measures, with controlled effects of $g = 2.06$ at post-treatment. Furthermore, across eight RCTs that compared MCT to CBT, there was a moderate and significant advantage of MCT at post-treatment ($g = 0.69$) and a small significant advantage of MCT above CBT at follow-up ($g = 0.37$). It should be noted that change scores were used to calculate effects in the Normann and Morina (2018) review which may lead to an overestimation of the effects in RCTs (Fu & Holmer, 2016) compared to other methods

such as comparing post-intervention scores alone. Further, these meta-analyses consisted of a small number of studies and many of the studies have small sample sizes, increasing the likelihood of error. There was also considerable heterogeneity and inconsistency in the size of effects calculated for each study.

Studies included in the review by Normann and Morina (2018) predominantly delivered MCT on an individual basis, however seven studies in the review evaluated the delivery of MCT in a group format. Subgroup analyses conducted on the pre/post effects suggested that MCT delivered as a group was significantly more effective than MCT delivered individually. This finding was strongly influenced by an outlier and when this was removed the subgroup differences became non-significant, making conclusions hard to determine. Thus, indicating that further analysis of the effectiveness of group MCT is needed.

Group therapies widen patient choice and provide an opportunity to offer psychological interventions in a more cost-effective way. It has been estimated that therapist time-per-client can be reduced by up to 75% by offering group rather than individual therapy (Himle et al., 2003). This increase in efficiency could help to reduce long waitlists in services. Furthermore, Yalom and Leszcz (1985) describe group therapies as being an opportunity for patients to experience a sense of universality (i.e. they can be normalising), as well as providing peer modelling and support. Group therapies have been shown to be both acceptable and effective at reducing symptoms of anxiety and depression in adults (Okumura & Ichikura, 2014) and younger people (Guo et al., 2021).

To date, no review has been conducted to evaluate the effectiveness of group MCT (g-MCT) on reducing symptoms of anxiety and depression across psychological disorders. This review has two aims. First, to systematically evaluate studies that have been conducted using g-MCT within populations presenting with elevated psychological distress to assess if g-MCT appears acceptable. Second, to conduct a meta-analysis of appropriate studies to evaluate if g-MCT is an effective treatment for people experiencing psychological distress.

2. Methods

The methods followed the PRISMA statement for conducting and reporting systematic reviews (see Appendix 1.6; Page et al., 2021). The study was registered with PROSPERO (ID: CRD42022311694; see Appendix 1.2 for registered protocol).

2.1 Search strategy

A systematic search was conducted to identify all studies delivering g-MCT published in peer-reviewed journals in the English Language. Six electronic databases were searched: PsychINFO, MEDLINE, Embase, Web of Science, CINAHL, and PubMed. Search terms were agreed through discussion with three authors (JTB, LC, AW) and the search string "(metacognitive OR meta cognitive) AND (therapy OR trial OR intervention OR treatment OR psychotherap*) AND (group)" was used (see Appendix 1.3).

2.2 Inclusion and exclusion criteria

Studies were eligible if they were published in the English language in a peer-reviewed journal and reported original data of g-MCT being offered as an intervention in populations presenting with a psychological disorder or elevated symptoms of anxiety/depression with the outcome of interest being improvements in psychopathology symptoms. In order to maximise the inclusion criteria, no restrictions were placed on whether the study was a controlled or an uncontrolled design, or the nature of the control conditions if they were present. Furthermore, no restrictions were placed on the age group of participants (e.g. adult, adolescent, or child) or the statistical approaches used (i.e. completer only, or the method of data imputation for missing data with intention-to-treat analysis). Systematic reviews, meta-analyses, qualitative studies, book chapters, book reviews, conference abstracts, grey literature, and theoretical articles were excluded from the review.

2.3 Study selection and data extraction

After removing duplicate results, the titles and abstracts of all search hits were screened with those not meeting the inclusion criteria being excluded. The full texts of the remaining studies were retrieved and assessed by the first author according to the inclusion and exclusion criteria. The final list of studies was discussed among the research team. For each included study, the following information was extracted: psychological disorder treated, comparison conditions (if applicable), sample size, drop-out rates at the

end of the intervention and at follow-up, sex distribution, mean age, any relevant comorbidity information, number and length of therapy sessions, size of therapy groups, follow-up time from the end of the intervention, statistical procedures, and attendance statistics. Information pertaining to the outcomes measured was also extracted, this included: primary outcome measure (deemed as most relevant for study population if not stated), secondary outcome measures, means and standard deviations at pre- and post-treatment and longest follow-up time points.

2.4 Quality assessment and risk of bias

All studies were assessed for methodological quality using the Downs and Black (1998) checklist (see Appendix 1.4). The tool is a 27-item checklist assessing aspects of reporting quality, external validity, internal validity (risk of bias and confounding), and power. All but one item were rated as: met (scored 1), not met (scored 0), not known (scored 0, marked NS), or not applicable (marked NA). One item (question 5) was scored two for being met, with a score of one meaning 'partially met'. The question relating to statistical power was simplified; this was considered 'met' if a power analysis had been calculated regardless of sufficient statistical power. All studies were rated twice, once by the first author and again independently by a member of the research team (Fiona O'Donovan). A subsection of studies (20%) were used as a training set; researchers assessed the quality of studies together with discrepancies being resolved through discussion with the two co-authors (LC, AW) and a consistent approach agreed for subsequent studies. Cohen's Kappa (Cohen, 1960) was calculated for the 80% of studies rated independently and given a grade of 'none to slight' $(0.00 - 0.20)$, 'fair' $(0.21 - 0.40)$, 'moderate' $(0.41 - 0.60)$, 'substantial' $(0.61 - 0.80)$, or 'almost perfect' agreement $(0.81 - 1.00)$. A total possible score for quality was calculated for each study which was the total score possible for all applicable questions for the study design. A percentage was calculated for the proportion of the score attained against the possible maximum for each study[1]. Studies were rated as poor (0-53%), fair (54-70%), good (71-92%), or excellent (93-100%) in line with previous studies using the same quality assessment checklist (Hooper et al., 2008).

2.5 Statistical analysis plan (meta-analysis)

All statistical analyses were conducted within Comprehensive Meta-Analysis (CMA) Version 3 (Borenstein et al., 2013). Within group pre/post and pre/follow-up effect sizes

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[1] For discussion about the decision around this and alternative approach see Paper Three, page 113

were calculated for primary and secondary outcome measures. An adjusted Hedges' g effect size was used[2]. Similar to Cohen's d, Hedges' g is an effect size based on the standardized mean difference but applies a correction factor to obtain an unbiased estimate in small samples (Borenstein et al., 2009). A further adjustment was made within the CMA software to account for repeated measures of within-group effects. This required the correlation coefficient between the measure at the two time points. This value was not provided in the studies so a correlation value of $r = 0.50$ was used, consistent with previous reviews (Normann & Morina, 2018; Normann et al., 2014) and in line with recommendations (Morris & DeShon, 2002). Values of 0.2, 0.5, and 0.8 can be interpreted as small, medium, and large magnitudes of effect, respectively (Cohen, 1988). Similarly, between-group comparisons were made by the CMA software computing the difference in within-group effects for g-MCT and control conditions respectively, creating an overall effect size for the study; a positive effect showing favour for g-MCT, and a negative effect showing favour for the control condition. A random-effects model was used for all meta-analyses (Borenstein et al., 2009).

Heterogeneity, the variability in observed effects between studies, was measured with Cochrane's Q test for statistical heterogeneity. Inconsistency, the percentage of total variation across studies that is due to heterogeneity rather than chance, was measured using the I^2 statistic with values of 25, 50, and 75% representing low, moderate, and high levels of inconsistency respectively (Higgins et al., 2003). Publication bias was assessed through visual inspection of funnel plots (Sterne et al., 2011) which map effect size against variance. Asymmetry in these plots indicate that publication bias may have occurred. The Trim and Fill procedure (Duval & Tweedie, 2000a, 2000b) was conducted to determine whether there were any studies deemed to be 'missing' for both pre/post and pre/follow-up effects, and what impact these studies would have on the overall effect size if they were imputed.

Sensitivity analysis was conducted in the form of the one-study-removed approach. This assesses the impact of removing individual studies in turn on the pre/post and pre/follow-up pooled effect sizes. This approach gives an indication as to whether any one study is responsible for a considerable proportion of the overall effect. The effect of

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[2] For further discussion of this topic and a rationale for the decision-making process involved, please see Paper Three, pages 111/112

removing multiple outliers was also assessed. Any studies deemed to have a considerable impact on the overall effect was removed from any further analyses.

Subgroups consisted of whether the research team had an MCT registered clinician delivering and/or supervising the delivery of MCT or not (registered therapist vs not registered) and follow-up period length (short: 1-3 months; long: 6-12 months)[3]. Subgroup analyses were undertaken when at least two studies were represented by any given group (Cheung & Vijayakumar, 2016).

3. Results
3.1 Search results and study selection

Figure 1 displays the PRISMA flow diagram of the study selection process (Page et al., 2021). Database searches yielded 2,489 results, of which there were 948 unique records after duplicates were removed. Fifty-four records remained after 894 records were removed after screening titles and abstracts. Reasons for removal at this stage included the record not being relevant ($k = 740$), the intervention being investigated either being delivered on an individual basis or not being g-MCT as defined by Wells (2009) ($k = 89$), published study protocols ($k = 19$), reviews ($k = 18$), studies investigating the effect of a single MCT technique such as the attention training technique or detached mindfulness ($k = 16$), conference abstracts ($k = 8$), or studies utilising a solely qualitative approach ($k = 1$). Full texts were screened for inclusion and 38 were removed, resulting in 16 studies included in the final review.

There were a number of studies that were excluded despite appearing to initially meet the inclusion criteria. One example of this is studies relating to 'metacognitive training' (Moritz, Veckenstedt, Bohn, Köther, et al., 2013; Moritz & Woodward, 2007), a treatment designed to increase metacognitive awareness of unhelpful cognitive biases primarily in people with a schizophrenia diagnosis (Moritz, Andreou, et al., 2014; Moritz et al., 2011) but that has also been applied to depression (Moritz et al., 2018). Metacognitive training has been critiqued for being referred to as a metacognitive intervention (Capobianco & Wells, 2018) as it does not focus on metacognitive beliefs and regulation of the CAS, but instead focusses on changing the content of thoughts and cognitive biases through raising metacognitive awareness and CBT procedures. Thus, studies utilising this model in a

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[3] Additional subgroups were considered and a more comprehensive discussion on this topic is provided in Paper Three, page 114

group context (Moritz, Veckenstedt, et al., 2014; Moritz, Veckenstedt, Bohn, Hottenrott, et al., 2013) have not been included as they are not metacognitive therapy as devised by Wells (2009). Other studies that were excluded which used the term metacognitive therapy but referred to other forms of interventions included a group psychosocial treatment for Attention Deficit Hyperactivity Disorder (ADHD) which combines behavioural and cognitive principles to target difficulties with time management, organization, and planning skills (Solanto et al., 2008; Solanto et al., 2010) and 'meta cognitive-behavioural therapy' (Dehkordi et al., 2017) which employs psychoeducation to increase awareness of cognitive processes in Bipolar Disorder.

A study utilising an integrative approach (Cheli et al., 2019) consisting of some aspects of metacognitive therapy, but also aspects of compassion-focussed therapy, metacognitive interpersonal therapy, and narrative exposure therapy was also excluded. A study which utilised metacognitive therapy but delivered initial sessions individually (Farahmand et al., 2014) was also excluded for not being solely a group intervention.

Two studies were not included due to a lack of usable data. One used performance on a cognitive task as the primary outcome rather than improvements in psychopathology symptoms (Bayegan et al., 2021) and the other (Esbjørn et al., 2015) did not report raw or summary data as it provided an in depth case report of the first four participants in a larger trial (Esbjørn et al., 2018) which was included in this review.

Studies that re-analysed study data were also not included due to not wanting to duplicate representation of participants (Dammen et al., 2016; Lassen et al., 2021; McEvoy, Erceg-Hurn, Anderson, Campbell, & Nathan, 2015; Walczak et al., 2021).

Figure 1 | PRISMA flow diagram

Identification of studies via databases and registers

Identification

Records identified from:
PsychINFO   (n = 454)
Embase   (n = 392)
Medline   (n = 306)
CINAHL   (n = 186)
WoS   (n = 708)
PubMed   (n = 443)
Total   **(n = 2,489)**

Records removed *before screening*:

Duplicate records removed
(n = 1,541)

Screening

Records screened
(n = 948)

Records excluded
(n = 894)

Reports sought for retrieval
(n = 54)

Reports not retrieved
(n = 0)

Reports assessed for eligibility
(n = 54)

Reports excluded:

Individual MCT   (n = 21)
Not English language (n = 2)
No data   (n = 1)
No mental
health outcome   (n = 1)
Not 'true' g-MCT   (n = 13)
Total   **(n = 38)**

Included

Studies included in review
(n = 16)

3.2 Study and patient characteristics

Table 1 provides an overview of the 16 studies that met the inclusion criteria and were included in the systematic review. A total of 1,010 participants were included across the studies with 652 allocated to receive g-MCT. Females made up the majority of the population (64%). Fourteen studies were conducted with adults, one with children, and one with adolescents. The average age across all studies which reported it was 38.52 years ($SD = 14.74$).

Nine (56%) of the studies were uncontrolled trials, five (31%) randomised-controlled trials (RCTs), and two (13%) service evaluations, one of which made comparisons to five years of benchmark data involving group CBT. The studies were conducted in the United Kingdom ($k = 4$), Australia ($k = 4$), Denmark ($k = 2$), Iran ($k = 2$), Norway ($k = 2$), Italy ($k = 1$), and the Netherlands ($k = 1$). As per the inclusion criteria, all were published in peer-reviewed journals.

Depression and anxiety symptoms were the most common presenting problem in the studies included in this review. Four studies investigated the effects of g-MCT in a sample presenting with mixed depression and anxiety, three of which were adult populations, and one being adolescents aged 14-17 years. Four studies investigated the effects of g-MCT on Generalised Anxiety Disorder (GAD), with three of these being in an adult sample, and one being in a child sample (aged 7-13 years). Four investigated the effect of g-MCT on depression, all of which were in adults. One of these studies (Papageorgiou & Wells, 2015) required the depression to be treatment-resistant and one (Zahedian et al., 2021) was investigating the effect of g-MCT in reducing symptoms of depression in women with breast cancer. Two studies investigated the effects of g-MCT on symptoms of OCD in adults. One study looked at the effect of g-MCT on the impact of tinnitus in adults and the final study investigated the effect of g-MCT on Prolonged Grief Disorder (PGD) in adults.

The majority of studies ($k = 11$) (Dammen et al., 2015; Esbjørn et al., 2018; Haseth et al., 2019; McEvoy, Erceg-Hurn, Anderson, Campbell, Swan, et al., 2015; Papageorgiou et al., 2018; Papageorgiou & Wells, 2015; Rees & van Koesveld, 2008; Thorslund et al., 2020; van der Heiden et al., 2013; Zahedian et al., 2021; Zemestani et al., 2016) required the presence of a psychiatric diagnoses using either the Structured Clinical Interview for DSM-IV Axis II (SCID-II; First, 2014), the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998), the adapted MINI for children and adolescents (MINI-KID; Sheehan

et al., 2010) or the Anxiety Disorders Interview Schedule (ADIS; Wood et al., 2002). In addition to using diagnostic screening to confirm the presence of a diagnosis of Major Depressive Disorder (MDD) Papageorgiou and Wells (2015) required the classification of treatment resistant depression as defined by the Modified Antidepressant Treatment History Form (MATHF; Prudic et al., 1996; Sackeim, 2001). The remaining five studies did not conduct a diagnostic interview for study inclusion (Callesen et al., 2019; Capobianco et al., 2018; Ferraro et al., 2019; Wells et al., 2021; Wenn et al., 2019) and instead recruited on the basis of elevated symptom scales: two required elevated scores on the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983); one used the Prolonged Grief-13 (PGD-13; Prigerson et al., 2013), one required elevated scores on the Beck Depression Inventory (BDI-II, Beck et al., 1996), and one required elevated scores on either or both of the Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) or Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006). One study included anyone who met the criteria for the service the study was conducted in, and another recruited individuals from a wider study who had chronic tinnitus and scored above a threshold on the HADS.

Table 1 | Summary of included studies

Study	Comorbidity	Population	Age (m, SD)	Sex (M:F)	Design	Comparison	n	n g-MCT	Primary outcome	Analysis		Quality	
										Post	*FU*	*Score*	*Rating*
Depression													
Dammen et al 2015	91%	Adult	42.27 (14.01)	0:11	Uncontrolled trial	NA	11	11	BDI	Full	Full	18/24	Good
Papageorgiou and Wells 2015	90%	Adult	41.70 (10.19)	2:8	Uncontrolled trial	NA	10	10	BDI	Full	Full	16/24	Fair
Zemestani et al 2016	19 dx[a]	Adult	24.20 (NS)	16:25[c]	RCT	Group BA Non-treatment	45	15	BDI-II	Full	Full	18/28	Fair
Zahedian et al 2021	NS	Adult	50.75 (11.34)	0:24	RCT	Patient-centred psychoeducation	24	12	BDI	Full	Full	22/28	Good
GAD													
van der Heiden et al 2013	73%	Adult	31.33 (8.96)	12:21	Uncontrolled trial	NA	33	33	PSWQ	NS	NS	16/24	Fair
McEvoy et al 2015	67%	Adult	38.00 (14.3)	21:31	Uncontrolled trial	NA	55	55	PSWQ	MI	MI	16/24	Fair
Esbjørn et al 2018	84%	Child	9.68 (1.60)	22:22	Uncontrolled trial	NA	44	44	RCADS	LOBF	LOBF	15/24	Fair

Study	%	Age group	Mean age (SD)	M:F	Design	Comparison	N	n	Measure			Quality	Rating
Haseth et al 2019	74%	Adult	29.7 (9.21)	1:22	Uncontrolled trial	NA	23	23	PSWQ	Full	LOBF	17/24	Good

Mixed depression and anxiety

Capobianco et al 2018	NS	Adult	28.55 (10.71)	12:28	RCT	Group MBSR	40	20	HADS	MEM	MEM	22/28	Good
Callesen et al 2019	37%	Adult	42.10 (12.73)	37:87[d]	Service evaluation	NA	131	131[d]	HADS	FULL	COMP	17/24	Good
Thorslund et al 2020	70%	Adolescent	15.2 (1.03)	3:7	Uncontrolled trial	NA	10	10	PSWQ-C	NS	NS	12/22	Fair
Wells et al 2021	NS	Adult	60.35 (11.09)	218:114	RCT	TAU (CR)	332	163[e]	HADS	MI	MI	24/28	Good

OCD

Rees and van Koesveld 2008	50%	Adult	NS	2:6	Uncontrolled trial	NA	8	8	CR Y-BOCS	Full	Full	16/24	Fair
Papageorgiou et al 2018	CBT: 44.8% MCT: 57.9%	Adult	33.59 (9.99)	109:111	Benchmark data	Group CBT	220	95	Y-BOCS	MI	NA	19/27	Fair

Tinnitus distress

Ferraro et al 2019	NS	Adult	49.10 (4.70)	5:4[c]	Uncontrolled trial	NA	12	12	HADS	Full	Full	16/24	Fair

Prolonged Grief Disorder

Wenn et al 2019	PGD: 46%[b] Dep: 50%[b] ANX: 64%[b]	Adult	62.00 (11.20)	1:21	RCT	Waitlist	22	21[f]	PG-13	NS	NS	20/28	Good

GAD = Generalised Anxiety Disorder; OCD = Obsessive-Compulsive Disorder; NS = Not Stated; unable to determine comorbidity from data; RCT = Randomised Controlled Trial; BA = Behavioural Activation; MBSR = Mindfulness-Based Stress Reduction; TAU (CR) = Treatment as Usual (Cardiac Rehabilitation); CBT = Cognitive Behavioural Therapy; n = total population recruited to the study; n g-MCT = number of patients allocated to receive Group MCT; BDI (II) = Beck Depression Inventory (version two); PSWQ (C) = Penn State Worry Questionnaire (Child); RCADS = Revised Childs Anxiety and Depression Scale; HADS = Hospital Anxiety and Depression Scale; (CR) Y-BOCS = (Clinician rated) Yale-Brown Obsessive Compulsive Scale; PG-13 = Prolonged Grief – 13; Full = no missing data; MI = missing data imputed with multiple imputation method; LOBF = missing data dealt with using last-observation-brought-forward approach; MEM = Mixed Effect Model (does not impute missing data); COMP = completer sample only; a = 19 anxiety diagnoses within 45 participants; b = proportion of total sample reaching diagnostic criteria; c = data only available for completer sample; d = data provided for n=124; e = Group MCT + TAU (CR); f = 12 initially received Group MCT with a further 9 receiving Group MCT post-waitlist to compete a combined sample receiving Group MCT of 2.

3.3 Group Metacognitive Therapy

There is no published protocol for g-MCT, thus studies created their own based on the treatment manual by Wells (2009). These protocols were predominantly based on the generic MCT model. The majority of studies did not assess adherence to the protocol, and studies varied in the level of training in MCT that any member of the research team had (see Table 2). Six studies included the treatment originator, and eight studies had a registered MCT therapist on the research team. Three studies (Esbjørn et al., 2018; Thorslund et al., 2020; Wenn et al., 2019) reported supervision of therapists by someone with 'experience' of MCT, although the extent of this was not made clear and they did not appear on the MCT Institute register (MCT-Institute) of trained therapists at the time of this review.

Studies varied in the number, frequency, and length of treatment sessions and in the provision of booster sessions (see Table 2). The average number of sessions offered was 8.75 ($SD = 2.62$) and the length varied from 60-120 minutes. On average 16 hours of g-MCT intervention were offered ($SD = 5.12, range: 12 - 24$ hours). Esbjørn et al. (2018) offered two pre-treatment primer sessions for the parents of children attending g-MCT which no other study did. G-MCT was offered as a standalone intervention in all but one study (Wells et al., 2021), which was the largest study included for review ($n = 332$). This study involved a randomised-controlled trial of the effects of g-MCT when added to the treatment-as-usual (TAU) of cardiac patients who screened positive for anxiety and/or depression. TAU consisted of Cardiac Rehabilitation (CR), a weekly group exercise and educational programme including relaxation techniques. It should be highlighted that four out of five sites included cognitive therapy techniques within CR.

3.4 Follow-up period

One study (Papageorgiou et al., 2018) had no follow-up time due to study design; it compared g-MCT with a benchmark of outcome data for Group CBT conducted over five-years of routine clinical practice. For the remaining studies, follow-up periods ranged from one- to twelve-months post-therapy, with an average of 4.7 months, as shown in Table 2.

3.5 Retention

Retention rates were high, suggesting good acceptability of g-MCT. Table 3 outlines retention rates at post-therapy (92%, range: 71-100%) and follow-up (87%, range: 52-

100%). This means only 8% of participants dropped out at post-therapy. Retention was similar in studies that had a short follow-up (1-3 months; 93%) and studies with a longer follow-up (6-12 months; 82%).

3.6 Attendance

Studies varied in whether they reported attendance rates and varied in how they reported this if they did. There was not enough consistency in the approach to enable effective comparison. Table 3 shows a summary of these findings. Five studies (Callesen et al., 2019; Dammen et al., 2015; Ferraro et al., 2019; Haseth et al., 2019; Zahedian et al., 2021) reported that all participants had 'completed', 'received', or 'concluded' treatment but did not define what the criteria was for this beyond not dropping out of the study, meaning this should be interpreted with caution.

3.7 Outcome variables

Primary outcome measures are shown in Table 1. Secondary outcome variables categorised into anxiety, depression, repetitive thinking, metacognitions (total, positive and negative), and quality of life are summarised in Table 4.

3.8 Comparator groups

Six studies compared g-MCT to a control condition (see Table 1). Two used non-active control conditions: one waitlist control (Wenn et al., 2019) and one non-treatment control group (Zemestani et al., 2016). Five studies used comparator conditions that were classed as active controls. These conditions consisted of group behavioural activation (g-BA; Zemestani et al., 2016), group Mindfulness-based Stress Reduction (g-MBSR; Capobianco et al., 2018), group patient-centred psychoeducation (Zahedian et al., 2021), the TAU condition consisting of CR (Wells et al., 2021), and five years-worth of data of the routine clinical practice delivering Group CBT (Papageorgiou et al., 2018).

Five studies utilised randomisation procedures to allocate to different treatment arms (Capobianco et al., 2018; Wells et al., 2021; Wenn et al., 2019; Zahedian et al., 2021; Zemestani et al., 2016).

Table 2 | Format of g-MCT intervention by study

Study	Location	Training level[a]	Adherence measure	Number of sessions	Length of sessions	Frequency of sessions	Therapy time[b] (hours)	Booster sessions	Group size	Follow up (months)
Depression										
Dammen et al 2015	Norway	Master clinician	None	10	90	Weekly	15	1-2 in 6 months	NS	6
Papageorgiou and Wells 2015	UK	Master clinician	None	12	120	Weekly	24	2 in 6 months	10	6
Zemestani et al 2016	Iran	None	None	8	90	Weekly	12	None	15	3
Zahedian et al 2021	Iran	None	None	8	NS	Weekly	NA	None	NS	1
GAD										
van der Heiden et al 2013	Netherlands	None	None	14	90	Weekly	21	None	10-14	6
McEvoy et al 2015	Australia	None	None	6	120	NS	12	1 after 1 month	3-7	1
Esbjørn et al 2018	Denmark	Level 2	None	8	120	Weekly	16	2 pre-treatment sessions for parents + 1 voluntary five	5-6	6

								weeks post treatment		
Haseth et al 2019	Norway	Master clinician	None	10	90	Weekly	15	Not stated	NS	3
Mixed depression and anxiety										
Capobianco et al 2018	UK	Master clinician	None	8	90	Weekly	12	None	4-6	6
Callesen et al 2019	Denmark	Master clinician	None	6	120	Weekly	12	None	8	6
Thorslund et al 2020	Australia	None	Recorded sessions	6	120	NS	12	1 after 1 month	NS	3
Wells et al 2021	UK	Master clinician	Checklist	6	NS	Weekly	NA	None	NS	12
OCD										
Rees and Koesveld 2008	Australia	None	None	12	120	Weekly	24	1 after 3 months	NS	3
Papageorgiou et al 2018	UK	Master clinician	None	12	120	12 in 4 months	24	Not stated	5–10	n/a
Tinnitus distress										
Ferraro et al 2019	Italy	None	None	8	NS	Fortnightly	NA	1 after 3 months	NS	3

Prolonged Grief Disorder										
Wenn et al 2019	Australia	None	Checklist	6	120	Weekly	12	None	NS	6

a = Training level is the highest level of training by a member of the study team either delivering or supervising the intervention, according to MCT Institute clinician register April 2022; b = Length of session x number of sessions. Level 1 training = "diploma with training in essential skills in MCT"; level 2 training = "diploma with training in more advanced applications in MCT"; Master Clinician = substantial knowledge and training in MCT.

Table 3 | Retention and attendance outcomes for g-MCT

Study	Retained post-treatment	Follow-up length (months)	Retained at follow-up	Attendance	Number of sessions
Depression					
Dammen et al 2015	100%	6	100%	NS	10
Papageorgiou and Wells 2015	100%	6	100%	All attended 9+	12
Zemestani et al 2016	100%	3	100%	All attended 5+	8
Zahedian et al 2021	100%	1	100%	NS	8
GAD					
van der Heiden et al 2013	73%	6	52%	Mean 10.76 (SD = 3.71), 1-14	14
McEvoy et al 2015	71%	1	71%	88% attended 5+	6
Esbjørn et al 2018	98%	6	98%	NS	8
Haseth et al 2019	100%	3	91%	NS	10
Mixed anxiety and depression					
Capobianco et al 2018	91%	6	86%	Mean: 7.07 (SD = 1.00)	8
Callesen et al 2019	100%	6	73%	NS	6

Thorslund et al 2020	90%	3	90%	All 4+; 90% attended all sessions	6
Wells et al 2021	76%	12	74%	61% 4+ sessions	6
OCD					
Rees and van Koesveld 2008	100%	3	100%	NS	12
Papageorgiou et al 2018	93%	NA	NA	Mean: 11.33 (SD = 0.95)	12
Tinnitus distress					
Ferraro et al 2019	100%	3	100%	NS	8
Prolonged Grief Disorder					
Wenn et al 2019	75%	6	75%	NS	6
Average	92%	-	87%	-	-

NS = Not stated; SD = Standard Deviation

3.9 Quality Assessment

Studies were assessed for their methodological quality according to the Downs and Black (1998) checklist and given a rating based on performance against a possible maximum for each study (see Table 1, Appendix 1.5). No studies were rated excellent, seven (44%) were good, nine (56%) fair, and none poor[4]. Inter-rater reliability was substantial ($Cohen's\ Kappa = 0.80$), suggesting a high level of consistency between raters.

Underreporting was most common in the following areas: listing possible adverse events, the characteristics of participants who dropped out, the comparability between the sample and population of interest, and power calculations. It should be noted that this latter point may not be relevant for some of the studies included, with arguments made that conducting power analyses is not recommended for feasibility trials (Lancaster et al., 2004).

Studies often did not list potential confounding variables a-priori, however, many did highlight proportions of important factors such as the number on psychotropic medications, the number and duration of prior depression episodes, and key demographic variables.

Table 1 shows the statistical approach to account for missing data, which varied. Some studies used the last-observation-brought-forward which has been criticised as it makes an assumption of no change, which may or may not be the case and can systematically skew the data (Altman, 2009). One study (Callesen et al., 2019) utilised ITT for post-therapy, but only reported data for group completers at follow-up.

Treatment integrity appeared good, however studies could go further in defining attendance (see Table 3). One study (Wenn et al., 2019) offered group sessions on an individual basis for two patients with their data retained within the analysis and Esbjørn et al. (2018) also notes that four families (9.1%) had additional treatment during the follow-up period without noting whether this data was included in the follow-up data. The highest risk of bias was from potential confounding as many studies were single-arm

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[4] Utilising the stricter criteria of comparing actual scores against total score available on the Downs and Black (1998) Checklist regardless of whether this was attainable due to study design, there were no excellent studies, four (25%) good, twelve (75%) fair, and none rated poor.

trials not allowing for randomisation or blinding procedures, reducing confidence in their findings.

3.10 Meta-analysis

One study was excluded from all meta-analyses due to g-MCT being an add-on therapy to CR which often contained elements of CBT (Wells et al., 2021). Data for Wenn et al. (2019) utilised the combined group of those initially receiving g-MCT and subsequently treated controls as the authors report no statistical difference in the effect of g-MCT between the two groups at either time point. Pre/post and pre/follow-up effects were calculated for intervention groups in all remaining studies and pooled to give an uncontrolled effect on primary and secondary outcomes.

For studies that utilised more than one condition, a controlled effect size was calculated using the pre/post and pre/follow-up effects for both intervention and comparison conditions regardless of whether these studies were randomised or otherwise. Comparisons of g-MCT against waitlist and non-treatment control conditions were not possible due to only one study utilising each type of condition.

In all cases except where specified positive effect sizes show the magnitude of reduction in symptoms.

3.10.1 Pre/post and pre/follow-up effects on primary outcome measures

The pooled pre/post effect for those receiving g-MCT on primary outcome measures across the fifteen included studies was large and statistically significant ($g = 1.72, 95\% \ CI \ [1.29 - 2.15], p < 0.001$; see figure 2). Heterogeneity across the studies was high and significant, as suggested by the Q-statistic ($Q[14] = 106.85 , p < 0.001$). Inconsistency in the observed effects, measured by the I^2 statistic, was also high ($I^2 = 86.90\%$).

Fourteen studies reported summary statistics to calculate pre/follow-up effects on the primary outcome measures. When pooled, there was a large, statistically significant, pre/follow-up effect ($g = 1.74, 95\% \ CI \ [1.35 - 2.13], p < 0.001$; see figure 3). Heterogeneity across the studies was high, as suggested by the Q-statistic, which was significant ($Q[13] = 55.02, p < 0.001$). Inconsistency in the observed effects, measured by the I^2 statistic, was also high ($I^2 = 76.38\%$).

3.10.2 Pre/post and pre/follow-up effects on secondary outcome measures

Secondary outcome measures were categorised into those which measured symptoms of anxiety, depression, repetitive thinking, total metacognitive beliefs, negative metacognitive beliefs, positive metacognitive beliefs, and quality of life (QOL; a positive effect for these measures relates to an increase in score and improvement in QOL).

For secondary measures of anxiety the uncontrolled pre/post effect for intervention groups was $g = 1.44$ and the pre/follow-up effect was $g = 1.54$. For secondary measures of depression, the uncontrolled pre/post effect was $g = 1.03$ and the pre/follow-up effect was $g = 1.02$. For secondary measures of repetitive thinking, the uncontrolled pre/post effect was $g = 1.60$ and the pre/follow-up effect was $g = 1.85$. The pre/post effect on measures of total metacognitions was $g = 0.80$ and the pre/follow-up effect was $g = 0.84$. The pre/post effect on measures of negative metacognitive beliefs was $g = 1.63$ and the pre/follow-up effect was $g = 1.65$. The pre/post effect on measures of positive metacognitive beliefs was $g = 0.98$ and the pre/follow-up effect was $g = 1.01$. Positive effects on quality of life (QoL) measures reflects an increase in QoL; the pre/post effect was $g = 0.87$ and the pre/follow-up effect was $g = 0.79$. All were large statistically significant effects (see Table 4 for details).

3.10.3 Effects of g-MCT on primary outcomes in comparison to active control conditions

Meta-analyses were conducted to determine whether there was a significant pooled effect of g-MCT when compared to active control conditions. Active control conditions were g-BA, g-MBSR, group patient-centred psychoeducation, and five years-worth of data of the routine clinical delivery of g-CBT.

There was a small significant controlled effect in favour of g-MCT across four studies in the changes from pre- to post-treatment ($g = 0.39, 95\% \ CI \ [0.16 - 0.61], p = 0.001$; see figure 4). Heterogeneity across the studies was low, as suggested by the Q-statistic, which was not significant ($Q[3] = 2.62, p = 0.445$). Inconsistency in the observed effects, measured by the I² statistic, was low ($I^2 = 0\%$).

Three studies reported follow-up data for both g-MCT and an active control condition. There was a medium controlled effect favouring g-MCT above active control conditions in the change of primary outcome measures from pre-treatment to follow-up ($g =$

$0.70, 95\% \ CI \ [-0.08 - 1.48], p = 0.081, k = 3$; see figure 5), however, this was not statistically significant. Heterogeneity across the studies was high, as suggested by the Q-statistic, which was significant ($Q[2] = 6.11, p = 0.047$). Inconsistency in the observed effects, measured by the I² statistic, was also high ($I^2 = 67.25\%$).

Figure 1 | Forest plot showing adjusted Hedges' g within-group pre/post effect sizes g-MCT intervention groups

Study name	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit
Dammen et al 2015	BDI	6.14	1.34	1.79	3.52	8.76
Papageorgiou and Wells 2015	BDI	2.58	0.65	0.42	1.32	3.85
Zemestani et al 2016	BDI	4.34	0.83	0.69	2.71	5.96
Zahedian et al 2021	BDI	0.70	0.30	0.09	0.11	1.30
Capobianco et al 2018	HADS	1.21	0.34	0.12	0.54	1.88
Callesen et al 2019	HADS	1.80	0.14	0.02	1.53	2.08
Ferraro et al 2019	HADS	0.40	0.28	0.08	-0.15	0.95
Wenn et al 2019	PGD-13	1.51	0.37	0.14	0.79	2.24
van der Heiden et al 2013	PSWQ	1.13	0.26	0.07	0.63	1.63
McEvoy et al 2015	PSWQ	1.68	0.23	0.05	1.23	2.13
Haseth et al 2019	PSWQ	2.63	0.44	0.19	1.77	3.48
Thorslund et al 2020	PSWQ-C	1.11	0.40	0.16	0.33	1.89
Esbjørn et al 2018	RCADS-C	0.99	0.18	0.03	0.63	1.34
Rees and van Koesveld 2008	Y-BOCS	1.49	0.49	0.24	0.53	2.45
Papageorgiou et al 2018	Y-BOCS	2.87	0.23	0.05	2.42	3.33
	Overall	1.72	0.22	0.05	1.29	2.15

Statistics for each study — Hedges's g and 95% CI

-4.00   -2.00   0.00   2.00   4.00

Figure 2 | Forest plot showing adjusted Hedges' g within-group pre/follow-up effect sizes for g-MCT intervention groups

Study name	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Hedges's g and 95% CI
							Statistics for each study
Dammen et al 2015	BDI	5.71	1.25	1.56	3.26	8.16	
Papageorgiou and Wells 2015	BDI	2.21	0.57	0.33	1.09	3.33	
Zemestani et al 2016	BDI	4.21	0.81	0.65	2.63	5.78	
Zahedian et al 2021	BDI	1.08	0.35	0.12	0.40	1.77	
Capobianco et al 2018	HADS	1.26	0.37	0.14	0.53	1.99	
Callesen et al 2019	HADS	1.53	0.15	0.02	1.24	1.82	
Ferraro et al 2019	HADS	0.46	0.28	0.08	-0.10	1.02	
Wenn et al 2019	PGD-13	1.86	0.45	0.20	0.98	2.73	
van der Heiden et al 2013	PSWQ	1.16	0.31	0.09	0.57	1.76	
McEvoy et al 2015	PSWQ	1.98	0.28	0.08	1.43	2.53	
Haseth et al 2019	PSWQ	2.95	0.50	0.25	1.97	3.93	
Thorslund et al 2020	PSWQ-C	1.37	0.44	0.20	0.51	2.24	
Esbjørn et al 2018	RCADS-C	1.31	0.22	0.05	0.89	1.74	
Rees and van Koesveld 2008	Y-BOCS	2.36	0.67	0.45	1.05	3.67	
	Overall	1.74	0.20	0.04	1.35	2.13	

-4.00   -2.00   0.00   2.00   4.00

Figure 3 | Forest plot showing between-group adjusted Hedges' g effect sizes between g-MCT and active control conditions from pre- to post-treatment

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit
Zemestani et al 2016	Group BA	BDI	0.04	0.36	0.13	-0.66	0.73
Zahedian et al 2021	Group psychoeducation	BDI	0.78	0.41	0.17	-0.03	1.58
Capobianco et al 2018	Group MBSR	HADS	0.71	0.39	0.15	-0.05	1.46
Papageorgiou et al 2018	Group CBT benchmark	Y-BOCS	0.36	0.14	0.02	0.09	0.62
		Overall	0.39	0.12	0.01	0.16	0.61

Hedges's g and 95% CI

-2.00   -1.00   0.00   1.00   2.00

Favours control   Favours Group MCT

Figure 4 | Forest plot showing between-group adjusted Hedges' g effect sizes between g-MCT and active control conditions from pre-treatment to follow-up

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Hedges's g and 95% CI
Zemestani et al 2016	Group BA	BDI	0.12	0.36	0.13	-0.58	0.82	
Zahedian et al 2021	Group psychoeducation	BDI	1.53	0.45	0.20	0.65	2.42	
Capobianco et al 2018	Group MBSR	HADS	0.55	0.38	0.15	-0.20	1.30	
		Overall	0.70	0.40	0.16	-0.08	1.48	

-2.00   -1.00   0.00   1.00   2.00

Favours control   Favours Group MCT

Table 4 | Adjusted within-group Hedges' g pre/post and pre/follow-up effect sizes for primary and secondary outcomes

	Pre/post effect				Pre/follow-up effect			
	Adjusted Hedges' g	95% CI	k	Z	Adjusted Hedges' g	95% CI	k	Z
Primary outcome	1.72	1.29 – 2.15	15	7.82	1.74	1.35 – 2.13	14	8.75
Anxiety as secondary	1.44	0.96 – 1.91	9	5.91	1.54	1.12 – 1.97	9	6.96
Depression as secondary	1.03	0.72 – 1.35	7	6.38	1.02	0.64 – 1.41	6	5.16
Repetitive thinking as secondary	1.60	0.91 – 2.29	5	4.53	1.85	1.16 – 2.54	5	5.28
Total metacognition	0.80	0.55 – 1.04	4	6.34	0.84	0.48 – 1.21	4	4.51
Negative meta-beliefs	1.63	1.46 – 1.80	11	8.02	1.65	1.25 – 2.05	11	8.11
Positive meta-beliefs	0.98	0.54 – 1.42	11	4.38	1.01	0.58 – 1.43	11	4.62
Quality of Life	0.87	0.16 – 1.58	3	2.41	0.79	0.38 – 1.20	2	3.76

For Primary outcomes see table 1; for anxiety: BAI, STAI-T, HADS-A, GAD-7, DASS-21 anxiety subscale; for depression: BDI, HADS-D, PHQ-9, DASS-21 depression subscale; for repetitive thinking: PSWQ-c, RTQ-10, RRS; for metacognition: MCQ-30, MCQ-C, CAS-1, GADS-R, PBRS, NBRS; for quality of life: QLESQ-SF, QLESQ-18, EQ5D, WSAS

3.11 Heterogeneity and inconsistency

As reported with each result above, heterogeneity was high and significant in all but one comparison, suggesting that the null hypothesis (that heterogeneity is due to random chance) can be rejected. Likewise, inconsistency in the observed effects was high in all but one comparison. These findings suggest the variance in effect sizes between studies likely represents true variance in the effect across these studies. High levels of heterogeneity and inconsistency are not unusual for effects calculated using within-group change scores (Cuijpers et al., 2017).

3.12 Sensitivity analysis

Sensitivity analysis was conducted in the form of the one-study-removed approach which re-runs the meta-analysis with each study removed in turn to determine the impact of each study on the overall pooled pre/post effect and pre/follow-up effect (see figures 6 and 7, respectively). The overall pooled effects sizes did not vary substantially, suggesting that no single study appears to account for a large proportion of either effect. Two studies produced a pre/post effect which may be considered outliers from the pooled effect of $g = 1.72$. These were $g = 6.14$ (Dammen et al., 2015) and $g = 4.34$ (Zemestani et al., 2016). When both of these studies were excluded, the pooled pre/post effect did not change substantially ($g = 1.51, 95\% \, CI \, [1.11 - 1.91]$, suggesting these studies were not responsible for a large proportion of the pooled effect.

3.13 Subgroup analysis

Subgroup analyses were conducted on MCT therapist registration status (within-group pre/post and pre/follow-up and between-group effects of g-MCT and active controls from at both time points) and follow-up length (within-groups pre/post and pre/follow-up only). No subgroup analyses were possible for between-group comparisons at follow-up due to the number of studies ($k = 3$). A summary of subgroup analyses results can be seen in Table 5.

To assess if pooled effects were impacted by training in MCT, a category was created based on whether any member of the research team was registered with the MCT-Institute . For the within-group pre/post and pre/follow-up comparisons the effect of g-MCT on primary outcome measures was larger for subgroups containing studies with a registered MCT therapist and bordered on significance ($p = 0.051$) for pre/post effect (see Table 5). There was no observed or statistically significant difference in effect for

studies with or without a registered MCT therapist in between-group (g-MCT vs active control) changes from pre- to post-treatment (see Table 5) although it should be noted that the pooled effect of the two studies with no registered MCT therapist on the research team showed no significant difference between g-MCT and active controls, whereas studies with a registered MCT therapist on the team did show this difference.

To assess if the pooled effects were impacted by follow-up length, studies were categorised by whether they had a short (1-3 month) or long (6-12 month) follow-up time. There were no significant differences between studies with a short or long follow-up time, however, effects were larger in studies with short follow-up compared to studies with long follow-up.

3.14 Publication bias

A visual inspection of the funnel plots for studies included in the pre/post effect size calculation (see figure 8) and the pre/follow-up calculation (see figure 9) suggests that there is possible publication bias. Smaller studies with below the observed pooled effect appear to be missing in both cases. When Duval and Tweedie (2000a, 2000b) trim and fill procedure was used, there were no missing studies identified for the pre/post effects, however three studies were identified as missing from the pre/follow-up effects, with a suggested effect of $g = 1.45$ if the missing studies were imputed, suggesting minimal overall impact.

Table 5 | Subgroup analyses on within-group adjusted Hedges' g pre/post and pre/follow-up effects

		Pre/post effects					Pre/follow-up effects				
		Adjusted Hedges' g	*95% CI*	*k*	*Z*	*p*	*Adjusted Hedges' g*	*95% CI*	*k*	*Z*	*p*
Registration status	Registered	2.17	1.49 – 2.86	7	6.21	0.051	1.93	1.34 – 2.52	6	6.45	0.466
	Not registered	1.33	0.83 – 1.83	8	5.24		1.62	1.04 – 2.21	8	5.46	
Registration status - between	Registered	0.39	0.14 – 0.65	2	3.06	0.966	-	-	-	-	-
	Not registered	0.38	-0.35 – 1.10	2	1.03		-	-	-	-	
Follow-up length	Short (1-3 months)	-	-	-	-	-	1.91	1.13 – 2.70	7	4.76	0.47
	Long (6-12 months)	-	-	-	-		1.58	1.18 – 1.99	7	7.69	

Figure 5 | One study removed analysis for within-group pre/post effects

Study name	Outcome	Point	Standard error	Variance	Lower limit	Upper limit
			Statistics with study removed			
Papageorgiou et al 2018	Y-BOCS	1.58	0.20	0.04	1.18	1.97
Zemestani et al 2016	BDI	1.61	0.21	0.05	1.19	2.03
Dammen et al 2015	BDI	1.62	0.21	0.04	1.21	2.03
Haseth et al 2019	PSWQ	1.65	0.23	0.05	1.21	2.10
Papageorgiou and Wells 2015	BDI	1.68	0.23	0.05	1.23	2.12
Rees and van Koesveld 2008	Y-BOCS	1.74	0.23	0.05	1.29	2.19
McEvoy et al 2015	PSWQ	1.74	0.24	0.06	1.27	2.22
Wenn et al 2019	PGD-13	1.74	0.23	0.05	1.29	2.20
Callesen et al 2019	HADS	1.74	0.25	0.06	1.25	2.24
Capobianco et al 2018	HADS	1.77	0.23	0.05	1.31	2.23
Thorslund et al 2020	PSWQ-C	1.77	0.23	0.05	1.32	2.22
van der Heiden et al 2013	PSWQ	1.78	0.24	0.06	1.32	2.24
Esbjørn et al 2018	RCADS-C	1.79	0.24	0.06	1.33	2.26
Zahedian et al 2021	BDI	1.80	0.23	0.05	1.36	2.25
Ferraro et al 2019	HADS	1.82	0.22	0.05	1.39	2.24
		1.72	0.22	0.05	1.29	2.15

Hedges's g (95% CI) with study removed

-4.00   -2.00   0.00   2.00   4.00

Figure 6 | One study removed analysis for within-group pre/follow-up effects

Study name	Outcome	Statistics with study removed					Hedges's g (95% CI) with study removed
		Point	Standard error	Variance	Lower limit	Upper limit	
Zemestani et al 2016	BDI	1.61	0.18	0.03	1.25	1.97	
Dammen et al 2015	BDI	1.63	0.18	0.03	1.27	1.99	
Haseth et al 2019	PSWQ	1.63	0.19	0.04	1.25	2.01	
Rees and van Koesveld 2008	Y-BOCS	1.71	0.20	0.04	1.31	2.10	
Papageorgiou and Wells 2015	BDI	1.71	0.21	0.04	1.31	2.11	
McEvoy et al 2015	PSWQ	1.72	0.21	0.05	1.30	2.14	
Wenn et al 2019	PGD-13	1.74	0.21	0.04	1.32	2.15	
Thorslund et al 2020	PSWQ-C	1.77	0.21	0.04	1.36	2.19	
Capobianco et al 2018	HADS	1.79	0.21	0.05	1.37	2.21	
Zahedian et al 2021	BDI	1.80	0.21	0.05	1.39	2.22	
van der Heiden et al 2013	PSWQ	1.80	0.22	0.05	1.38	2.23	
Esbjørn et al 2018	RCADS-C	1.81	0.22	0.05	1.37	2.25	
Callesen et al 2019	HADS	1.81	0.24	0.06	1.34	2.28	
Ferraro et al 2019	HADS	1.83	0.19	0.04	1.46	2.20	
		1.74	0.20	0.04	1.35	2.13	

-4.00   -2.00   0.00   2.00   4.00

Figure 7 | Funnel plot showing standard error against Hedges g' pre/post effect sizes (k=15)

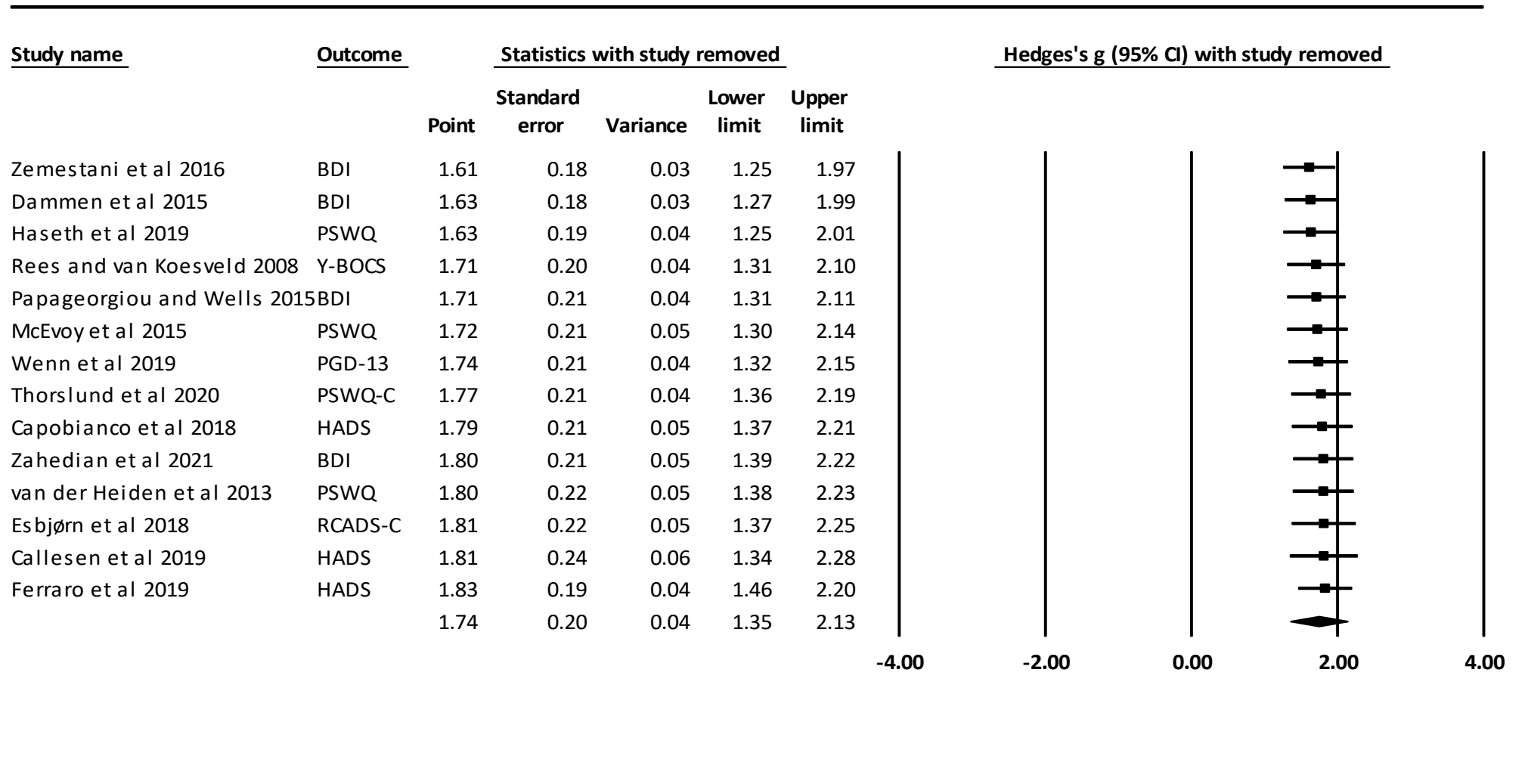
Funnel Plot of Standard Error by Hedges's g
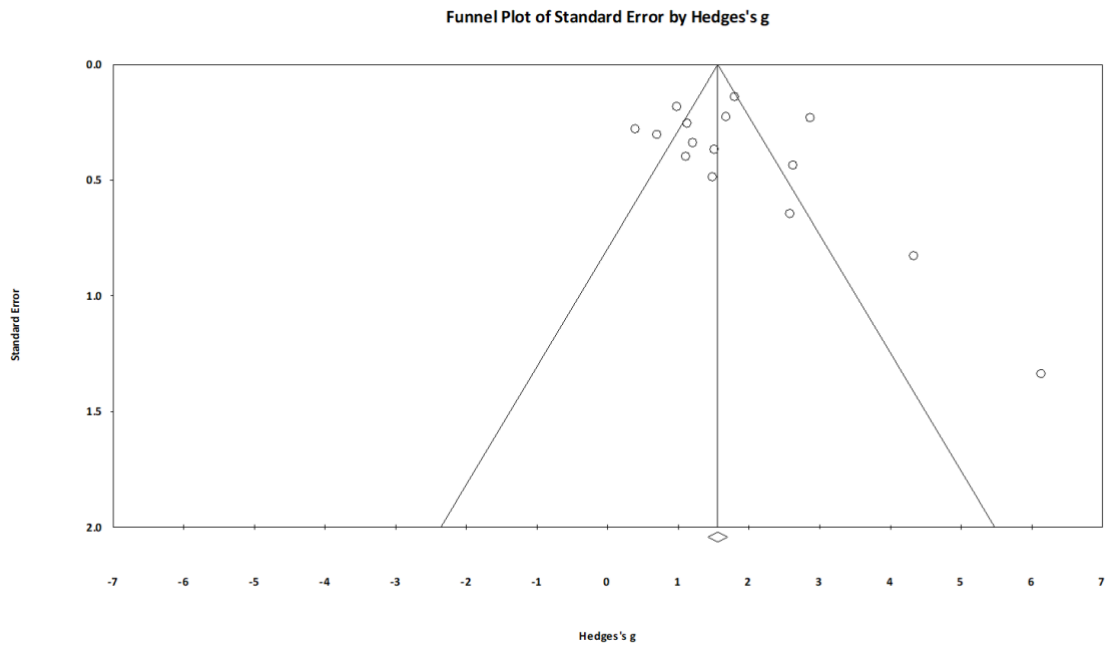
Figure 8 | Funnel plot showing standard error against Hedges g' pre/follow-up effect sizes (k=14)

Funnel Plot of Standard Error by Hedges's g
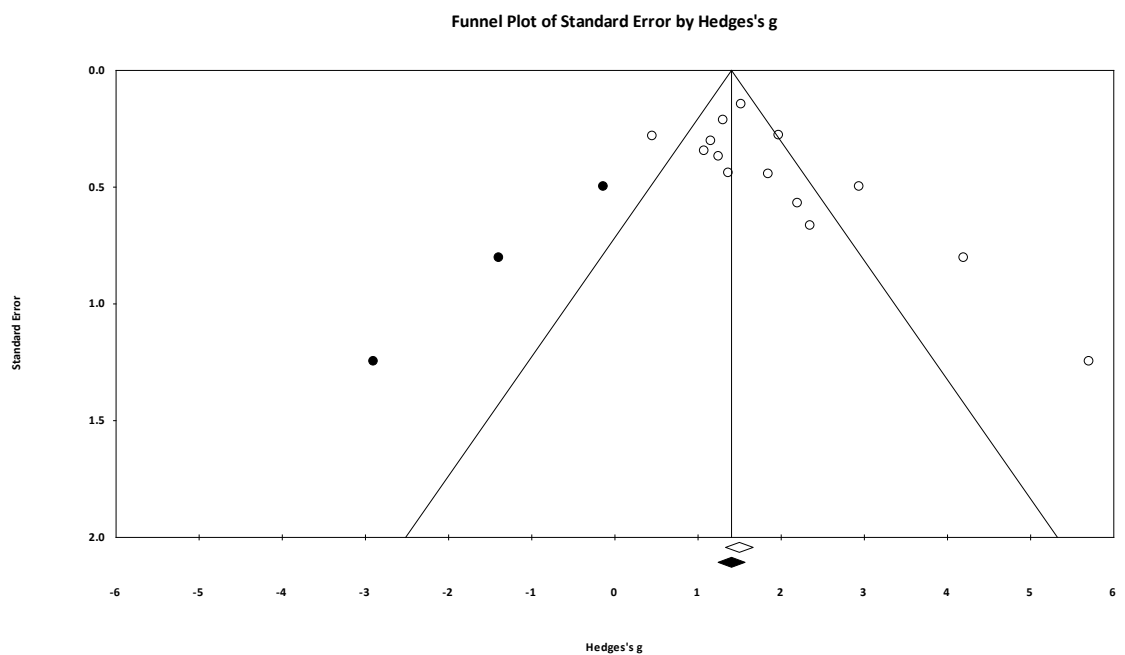
Note: circles with no infill are observed, infilled circles are imputed missing studies

4. Discussion

This review included all studies published in English that evaluated g-MCT with the aim of assessing whether it is an acceptable and effective treatment for symptoms of anxiety and depression. Sixteen papers were included in the review which included 1,010 participants with 652 allocated to receive g-MCT across one-arm trials, multi-arm RCTs, and assessments of routine clinical practice.

4.1 Acceptability and drop-out rates

Drop-out rates at post-treatment were low in g-MCT intervention groups (8%), suggesting good acceptability. These results are comparable to a previous meta-analysis of MCT delivered in any format that found drop-out rates at post-treatment of 10% (Normann & Morina, 2018). Group CBT has shown a higher drop out, with 24.6% of people dropping out by post-treatment across 32 studies (Fernandez et al., 2015). A recent meta-analysis of 48 RCTs found that on average 18% of people dropped out of group Acceptance and Commitment therapy (g-ACT) by post-treatment (Ferreira et al., 2022). It should also be noted that drop-out rates are not an ideal measure of treatment acceptability and that average attendance rates would be a better measure. This, unfortunately, was inconsistently reported and difficult to assess due to the differences in number of sessions being offered and future studies could address this through utilising a shared protocol for g-MCT. This review did not explore other measures of treatment acceptability, such as qualitative analysis of patient narratives, which could be a useful topic for further review.

4.2 Uncontrolled pre/post and pre/follow-up effects on primary outcomes

This study found a very large pre/post effect on primary measures of anxiety and depression ($g = 1.72$). This is slightly larger than the uncontrolled pre/post pooled effects size for individual MCT ($g = 1.57$), though smaller than the effect reported in subgroup analyses for g-MCT ($g = 2.45$) by Normann and Morina (2018), however this latter figure was substantially influenced by an outlier. Both findings from the current study and those in the Normann and Morina (2018) review use a combination of controlled and uncontrolled studies and rely on effect sizes calculated from change scores, which may overestimate within-group effects (Fu & Holmer, 2016). The current study, however, included more studies and larger studies and appeared less at risk from outliers, suggesting our findings might present a more accurate estimate of the effect

over time. Normann and Morina (2018) do not report the effect at follow up for MCT delivered solely in an individual or group setting. This study reported a very large pre/follow-up effect on primary outcomes ($g = 1.74$) which was slightly larger than the pre/follow-up effect found for MCT delivered in any format ($g = 1.57$) by Normann and Morina (2018).

Our pre/post effect for g-MCT intervention groups were similar in magnitude to uncontrolled pre/post effects seen in individual CBT ($g = 1.67$), however our pre/follow-up effects were much larger than those reported for individual CBT ($g = 0.22$; (Norton & Price, 2007). Group CBT has been shown to have large uncontrolled pre/post effects on symptoms of anxiety ($d = 0.87$), depression ($d = 0.95$), and repetitive negative thinking ($d = 1.62$; (Dugas et al., 2003) though our effects appeared higher on primary outcomes. A meta-analysis of g-ACT showed only moderate effects on symptoms of anxiety ($g = 0.52$) and depression ($g = 0.47$) despite these being a pooled effect of both uncontrolled and controlled effects (Ferreira et al., 2022). Caution should be used in the interpretation of within-group pre/post and pre/follow-up effects; these are uncontrolled effects and thus it is not possible to determine what proportion of these effects are due to the treatment.

4.3 Controlled effects of g-MCT against active control conditions

Due to the small number of studies utilising the conditions we were not able to conduct a meta-analysis comparing g-MCT against a waitlist control ($k = 1, n = 10$) or to no treatment ($k = 1, n = 15$). However, it was possible to compare g-MCT to active control conditions (i.e. group Behavioural Activation, CBT benchmark data). There was a small to moderate significant benefit of g-MCT above active control conditions in the change from pre- to post-treatment in primary outcome measures ($g = 0.39$) suggesting g-MCT reduced symptoms of depression and anxiety more than the active control conditions. Despite showing moderate effects at follow-up ($g = 0.70$) this was not statistically significant, likely reflective of the fact that few studies were available for such comparisons resulting in low statistical power. Normann and Morina (2018) found a larger advantage of MCT over CBT control conditions ($g = 0.69$ at post-treatment and $g = 0.37$ at follow-up), and this was significant at both time points; their analysis included individual therapy as well as group studies. In a meta-analysis of 34 studies into the efficacy and acceptability of g-CBT in patients with depression, Okumura and Ichikura (2014) compared g-CBT to low- and medium-intensity individually-delivered psychosocial

interventions. They found that g-CBT showed no advantage over either low- or medium intensity interventions, but the numbers of studies included in each analysis was low (two and seven, respectively). In a large meta-analysis of g-CBT for depression in adolescents, g-CBT was demonstrated to be superior to control conditions at both post-treatment ($d = 0.28$) and follow-up ($d = 0.21$) (Keles & Idsoe, 2018). It should be noted that the analysis by Keles and Idsoe (2018) consisted of both active and passive control conditions combined, making direct comparisons with our findings challenging as we compared to active control conditions.

With regard to other group therapies, meta-analyses have found that g-ACT was significantly better than control conditions at reducing depression ($g = 0.30, p = 0.041$) but not anxiety at post-treatment (Ferreira et al., 2022) with a second study showing that g-ACT is not statistically different from active controls at reducing general distress (Prudenzi et al., 2021); general distress was measured through a variety of validated measures including the General Health Questionnaire (Goldberg & Hillier, 1979) and symptom measures such as those used within the current study. The findings from the current research suggest g-MCT may compare favourably to other group therapies. It is worth noting that comparing controlled effects is challenging as the control conditions are not always equitable. Therefore, further studies randomising participants to receive either g-MCT or other evidence-based group therapies are needed to confirm this.

4.4 Secondary outcomes and g-MCT

Secondary measures of anxiety, depression, and repetitive thinking reduced substantially in g-MCT intervention groups, with large pre/post effects. This suggests that g-MCT may have a broader effect than just the primary outcome within studies, potentially adding weight to the argument that MCT is a transdiagnostic treatment. This would have substantial and important implications for clinical practice. Anxiety and depression rarely occur in isolation (Brown et al., 2001) with 67% of depressed patients also presenting with an anxiety disorder, and 63% of those with an anxiety disorder also presenting with a depressive disorder (Lamers et al., 2011). Transdiagnostic treatments, those which focus on common underlying maintenance factors across disorders, could be beneficial for people with comorbidities. Total metacognition score, as well as both positive and negative subscales showed large reductions in g-MCT intervention groups, consistent with the idea that this may be an important mechanism driving change and in line with the S-REF model underpinning MCT (Wells & Matthews, 1994, 1996).

4.5 Heterogeneity, inconsistency, quality, and possible sources of bias

In all but one comparison heterogeneity between studies was high and significant and inconsistency was high suggesting effect sizes differed more than random variability between studies would suggest. It is not known what is driving this variability in effects, thus caution should be used when interpreting these results. No one study appeared to substantially alter the pooled effect at either time point and the removal of two potential outliers did not substantially change the pooled effect. There was some tentative indication that registration status of therapists may be associated with larger effects. Specifically, the pre/post effect on primary outcomes was larger in studies with a member of the research team on the MCT register and bordered on statistical significance ($p = 0.051$). These comparisons consisted of a small number of studies which likely resulted in low statistical power. Effects were larger in studies which employed a short follow-up (1-3 months) compared to those which used a longer follow-up (6-12 months), suggesting there is some decrease in intervention effect over time, although both uncontrolled pooled effect sizes were very large and there was no statistical difference between them. There were some limitations with the categories created for subgroups. For example, registration status was defined as being on the MCT register at the time of writing for this study which may not accurately reflect registration status at the time of the study being conducted. Secondly, the member of the team with registration status may not be the member of the team proving therapy or supervision. Further studies could be conducted to understand the moderating variables on the effects of g-MCT in an attempt to understand the variance observed in this study.

Overall study quality was fair. This could be improved in future through more transparent reporting and through more RCT designs comparing g-MCT to active control conditions. Research bias was a potential concern as six studies included the treatment originator either delivering or supervising the administration of g-MCT which is a source of potential bias. However, this also a potential means of safeguarding treatment integrity and adherence. There is also a possible risk of publication bias within the body of evidence, and it is important that future studies should publish smaller and non-significant findings where applicable to allow for more accurate synthesis and greater confidence in meta-analytic findings.

4.6 Limitations

The current study is not without its limitations. Importantly, change in scores from pre- to post-treatment and pre-treatment to follow-up was used to calculate the measure of effect which can lead to an overestimation of the effects observed and are more likely to show a statistically significant finding (Fu & Holmer, 2016). Further, using change scores to calculate effects does not appear to resolve issues associated with baseline imbalances or regression toward the mean (Clifton & Clifton, 2019). This review utilised an adjusted effect size that attempts to account for repeated measures when calculating within-group effects; while these adjustments are recommended (Morris & DeShon, 2002) they require a correlation coefficient which was not available. In order to overcome this, a correlation coefficient based on previous studies was imputed, which might introduce a degree of error into the calculations that varies by measure and population. Applying a correction was deemed more appropriate than not correcting for repeated measures as a lack of correction may have led to an overestimation in effect sizes. Further, despite calculating controlled effects for g-MCT against active control conditions, this consisted of a combination of randomised and non-randomised studies, meaning caution should be used in its interpretation.

This review only included peer-reviewed journal articles meaning that some studies which delivered g-MCT have not been included (i.e. grey literature). This may have led to publication bias as smaller or negative findings are less likely to be published by the authors or accepted by journals for publication leading to a possible overestimation in the size of the effect found in this study. Further, we only included papers published in the English which can also increase the risk of publication bias through undesired findings being published in alternative languages (Nuñez & Amano, 2021).

4.7 Strengths

This review has a number of strengths. The review was comprehensive, including every published study that has delivered g-MCT with the aim of reducing psychopathology symptoms. A wide range of presenting problems were represented in the study as well as studies with children, adolescents, and adults. Furthermore, the samples included in the review had considerable levels of comorbidity and complexity which may be more representative of a clinical population.

A strength in this study was the rigorous approach to inclusion criteria for review and meta-analysis. There are a number of studies evaluating 'metacognitive therapies' but they do not directly target the same mechanisms. It is important that methods that are alike are combined in evaluating the effects of specific treatment methods. Although it formed the largest study and compared g-MCT to active control conditions, we excluded Wells et al. (2021) from the meta-analysis. This is because it tested the effects of g-MCT when used as an adjunct to cardiac rehabilitation which often consisted of some CBT methods such as relaxation training and therefore the independent effects of MCT cannot be determined in this study design.

4.8 Future directions

Further large-scale RCTs comparing g-MCT with evidence-based active control conditions are needed to verify the findings of this paper. To improve the quality of studies being conducted, future research should list potential confounders a-priori and conduct statistical difference analysis across treatment arms, aiming to control for confounding factors in subsequent outcome analysis. Studies should go further in defining and monitoring potential adverse events and defining the characteristics of those who drop out to better determine whether this is happening systematically. Blinding procedures were rarely used and should be utilised more in future research to avoid researcher bias. Studies should utilise ITT with imputation methods to avoid overestimation of results.

5. Conclusion

In conclusion, this review and meta-analysis suggests very low drop-out and large reductions in both primary and secondary outcomes in g-MCT intervention groups. There is also preliminary evidence of superiority of g-MCT compared to other active treatments but further, larger RCTs comparing g-MCT to evidence-based active control conditions are required to strengthen conclusions. Should the effects found in this study be confirmed, g-MCT could offer efficient and effective treatment to clinically diverse groups.

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Paper Two | Qualitative Analysis of the Psychological Experiences Described by Burns, Plastics, and Reconstructive Surgery Patients from the Perspectives of the Cognitive and Metacognitive models

This paper has been formatted in line with the publication guideless of the Journal of Health Psychology (see Appendix 2.1), however APA referencing has been used for readability and consistency with the thesis and tables and figures have been placed in line with the text.

Abstract (excluding keywords and highlights): 295 words

Main text (including footnotes, tables, and in-text citations, excluding title page, figures, and references): 9,621 words

Qualitative Analysis of the Psychological Experiences Described by Burns, Plastic, and Reconstructive Surgery Patients from the Perspectives of the Cognitive and Metacognitive Models

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Abstract

Burns and other injuries requiring plastic and/or reconstructive surgery (BPRS) are serious, often unexpected, and increase the risk of psychiatric morbidity. No research explores the applicability of psychological models to BPRS patients. Cognitive behavioural therapy (CBT) is a gold-standard treatment in mental health but may be less effective in physical health settings, often requiring adaptations. Metacognitive therapy (MCT) shows initial promise in reducing symptoms of anxiety and depression in people with cancer and cardiac rehabilitation patients. The present research aims to explore the psychological experiences, that is the feelings, thoughts, and coping strategies, of BPRS patients in the wake of their injury, and to explore whether the underpinning concepts of the cognitive and metacognitive models can be elicited from these accounts. Eleven patients were recruited from a BPRS psychology service and semi-structured interviews were conducted about their post-injury psychological experiences. Data was analysed using Thematic Analysis. Patients described a range of emotions including low mood, anxiety, anger, guilt, and loss. All patients described how they engaged in repetitive negative thinking (worry, rumination) and engaged in a wide range of coping strategies, such as distraction and thought suppression. Concepts underpinning both the cognitive and metacognitive models were successfully elicited from BPRS patients' accounts. From the perspective of the cognitive model, there were examples of all ten pre-specified types of distorted thinking and patient talk fit problem-specific cognitive models. The application of the metacognitive model noted that patients engaged in the cognitive attentional syndrome (i.e. repetitive negative thinking, inflexible attention, and maladaptive coping strategies) and endorsed both positive and negative metacognitive beliefs. The subsequent implications of the application of the models to clinical practice is discussed. The metacognitive model may offer potential theoretical benefits in clinical practice which should be investigated in further research in this population.

Keywords

1. Introduction

Around 175,000 people attend Accident and Emergency departments and 16,000 people are admitted for specialist burns care each year in the UK (National Burn Care Review Committee, 2001). Additionally, 48,000 injuries are treated in major trauma centres (National Audit Office, 2010) and over five thousand women undergo breast reconstruction following mastectomy each year in England (Jeevan et al., 2009). Burns and other injuries that require plastic reconstructive surgery (BPRS) are associated with higher healthcare use, increased morbidity and mortality, and poorer quality of life (Attoe & Pounds-Cornish, 2015; Mason et al., 2017). Mental health conditions such as depression, anxiety, and post-traumatic stress disorder (PTSD) are common after serious injuries and are more prevalent in BPRS patients than in the general population (Bich et al., 2021; Ter Smitten et al., 2011). Approximately 28% of burn injury patients received at least one psychiatric diagnosis post-injury (Ter Smitten et al., 2011) and prevalence of mental health disorders range from 30-70% after reconstructive surgery (Heron-Delaney et al., 2013; Kaminska et al., 2015; McKechnie & John, 2014; Sahu et al., 2017).

The National Burn Care Review Committee (2001) highlight the need for routine screening and psychological support as part of aftercare but there are currently no specific recommendations for treatment beyond the general problem-specific guidelines. Cognitive behavioural therapy (CBT) is the most widely recommended and effective treatment for most mental health conditions, including depression, anxiety, and PTSD (National Institute for Health and Care Excellence [NICE], 2009, 2018, 2020). CBT is based on cognitive theory (Beck, 1963, 1964, 1976) which states that negative automatic thoughts (NATs) are triggered by situations and events and are anchored in beliefs that individuals hold about themselves, other people, and the world around them. These beliefs are influenced by past experiences and can either be intermediate rules and assumptions about how to live, or deeply entrenched core beliefs. Cognitive distortions are biased patterns of thinking that maintain NATs and reinforce core beliefs. The cognitive model aims to identify and modify NATs through challenging their validity and reality-testing beliefs.

Cognitive therapy (CT) and CBT have been shown to be very effective in reducing a wide range of psychopathologies in the general population. In a review of reviews Butler et al. (2006) identified 332 trials of CBT consisting of 9995 participants and concluded that the mean effect size across a range of disorders when compared to no-treatment, wait list, or

placebo controls was large ($ES = 0.95$) and that CT/CBT was superior to supportive or non-directive therapy depression ($ES = 0.84$) and for generalized anxiety disorder ($ES = 0.71$), although these latter two comparisons only consisted of two studies in each category due to it being a rare control condition in studies. More recently, a meta-analysis (Watts et al., 2015) showed medium to large effects favouring CBT over treatment-as-usual (TAU) control conditions for both anxiety ($g = 0.69$, $n = 1,318$) and depression ($g = 0.70$, $n = 5,054$). Likewise, a meta-analysis of 22 studies (Andrews et al., 2010) showed that computerised CBT (iCBT) for anxiety and depressive disorders had a large advantage above a range of pooled control conditions ($d = 0.88$).

Neither CT nor CBT has been trialled with BPRS patients as a unified group. There has been research into the efficacy of these treatments in reducing symptoms of anxiety and depression in people with a range of comorbid physical health conditions; a population that may share some characteristics with BPRS patients, such as having to deal with an injury, condition, or unexpected event and the physical and psychological consequences of this. Effect sizes range considerably between meta-analyses of CBT in this population. One meta-analysis of twenty randomised-controlled trials (RCTs) examining CBT for distress in breast cancer patients found CBT had only a small superiority ($d = 0.31$) when compared to no treatment or standard care control conditions (Tatrow & Montgomery, 2006). A smaller study found much larger short-term reductions in anxiety ($d = 1.99, k = 4$) and depression ($d = 1.20, k = 4$) when compared to usual care conditions, most commonly consisting of medical management (Osborn et al., 2006). One possible explanation for the variability in findings within cancer patients comes from Greer et al. (2010) who suggest the participants in some studies "may more closely resemble the general population than patients with advanced disease undergoing palliative treatment" (p. 3). In a systematic review and meta-regression of randomised-controlled trials (RCTs) Dickens et al. (2013) aimed to identify characteristics of psychological interventions that improve symptoms of depression in cardiovascular disease (CVD) patients; 64 treatment comparisons were identified. They found a small advantage of CBT above control conditions for reducing depression in CVD patients ($d = 0.23$), which increased when only high-quality trials were pooled, but remained small ($d = 0.31$). Similar small magnitude advantages of CBT above control conditions have been shown for anxiety ($d = 0.34$) and depression ($d = 0.35$) in patients with CVD (Reavell et al., 2018), although this meta-analysis excluded studies which used a purely CT

approach or third-wave CBT-based treatments. A recent systematic review and meta-analysis of internet-delivered CBT (iCBT) for a range of chronic health conditions conducted by Mehta et al. (2019) combined effects observed across 25 studies including people with tinnitus ($k = 6$), fibromyalgia ($k = 3$), pain ($k = 7$), rheumatoid arthritis ($k = 3$), cardiovascular disease ($k = 2$), diabetes ($k = 1$), cancer ($k = 1$), a 'heterogeneous chronic disease population' ($k = 1$), and spinal cord injury ($k = 1$), and found small advantages of iCBT above control conditions in reducing anxiety ($SMD = 0.45$) and depression ($SMD = 0.31$).

The mechanisms behind why CBT appears to show smaller advantages above control conditions in reducing anxiety and depression in populations with comorbid physical illness than those seen in the general population is unknown. One possible explanation is that the cognitive model may not address distressing NATs that relate to clinically relevant concerns (Greer et al., 2010); "classic CBT techniques, such as cognitive restructuring, are inadequate or even inappropriate for patients with realistic fears related to the cancer diagnosis and treatment" (p. 3). McPhillips et al. (2019b) conducted a qualitative analysis of the emotional distress described by cardiac patients who screened positive for symptoms of depression or anxiety echoed this suggestion, finding that although CBT offered a framework that could be utilised in formulating their distress, there were challenges in categorising some distressing thoughts as realistic or not.

In an attempt to address the issue that mental health outcomes after CBT are worse for people with comorbid physical health conditions such as long-term conditions (LTC) and medically unexplained symptoms (MUS), than those without (Delgadillo et al., 2017), adaptations have been made to CT/CBT. Adaptations to CBT include using in-session materials specific to the condition the person is living with, liaising with physical health staff to incorporate relevant information, and providing therapists with additional training in motivational interviewing, Acceptance and Commitment Therapy (ACT), and pacing techniques. A systematic review suggests that there is some preliminary evidence to suggest that making adaptations to CBT may improve outcomes in the short-term (Sanders et al., 2020) although the authors acknowledge that the evidence base is currently small. One study by Kellett et al. (2016) compared the mental health outcomes in a primary care mental health service between those with and those without LTC/MUS. The proportion of patients with LTC/MUS reaching reliable recovery was lower than that for patients without LTC/MUS, although it could be argued that the definition for reliable

recovery could be harder to achieve for those with LTC/MUS. Uncontrolled effect sizes from pre- to post-treatment for people with LTC/MUS were small ($d = 0.25 - 0.35$) and were not reported for those without LTC/MUS.

While CBT has been consistently shown as more effective than control conditions in reducing symptoms of psychopathology in people with comorbid health concerns, the size of this superiority is smaller than those seen in the general population. While there have been suggestions of adapting CBT for use within this population, the evidence base is currently small and appears to also show smaller effects than in people without physical health concerns. There is a suggestion that the reason behind the small effect of CBT is that classic cognitive restructuring techniques are insufficient when concerns are realistic in nature. This raises a question of whether key concepts underpinning a purely cognitive model can be elicited from BPRS patients, a population potentially faced with realistic concerns regarding their injuries.

An alternative approach to treating psychopathology is Metacognitive Therapy (MCT; Wells, 2009). MCT is based on the metacognitive model (Wells, 2009; Wells & Matthews, 1994, 1996) and has developed through a theory-driven, cognitive science approach and has been argued as marking a paradigm shift in psychotherapy (Capobianco & Nordahl, 2021). The metacognitive model (Wells, 2009; Wells & Matthews, 1994, 1996) states that psychological distress is maintained by a style of thinking called the cognitive attentional syndrome (CAS). The CAS is characterized by repetitive negative thinking (such as worry and rumination), inflexible attention, and unhelpful coping strategies. The CAS is driven by an individual's metacognitive beliefs, which are the beliefs held about thinking. Metacognitive beliefs can be either positive (e.g. worrying helps me cope, worrying helps me be prepared), or negative (e.g. worrying is harmful and uncontrollable). Metacognitive beliefs have been found to be positively and significantly associated with psychological distress across a range of physical illnesses (Capobianco et al., 2020; Lenzo et al., 2019). Unlike the cognitive model, the metacognitive model does not challenge the content of individuals' thoughts but instead regulates the CAS and challenges patients' metacognitive beliefs. No meta-analyses have been conducted for MCT in treating psychopathology in people with comorbid physical health conditions but there is some preliminary evidence showing promise. For example Fisher et al. (2019) in a single-arm trial showed large uncontrolled pre/post effects ($d = 0.98 - 1.66$) in reducing a range of measures of psychological distress in cancer patients. A much larger randomised-

controlled trial of 332 cardiac rehabilitation patients with elevated symptoms of depression and/or anxiety (Wells et al., 2021) compared people receiving group MCT as an additive therapy on top of treatment as usual (TAU) with people receiving just TAU. The TAU in this study was Cardiac Rehabilitation, an educational group consisting of relaxation skills and some cognitive therapy elements. It found a moderate advantage of MCT+TAU over TAU alone ($d = 0.52$).

The cognitive and metacognitive models offer different approaches to conceptualising and treating psychological distress. Previous research in BPRS patients has explored manifestations of particular emotions following BPRS injuries (Kornhaber et al., 2018) and how these relate to the development of specific psychiatric outcomes, such as PTSD (Macleod et al., 2016). Less is known about the psychological sequalae experienced by BPRS patients and whether current therapeutic models are suitable for treating BPRS patients. As such, the first aim of this study was to explore and understand the psychological experiences of BPRS patients. By psychological experiences we mean feelings, thoughts, and coping behaviours. The second aim was to explore whether concepts underpinning the cognitive and metacognitive models can be elicited from BPRS patients' accounts of their psychological experiences since their injury.

2. Methods
2.1 Ethical approval

This research was conducted as part of the thesis requirements of the Doctorate in Clinical Psychology of the first author. Ethical approval was gained from Greater Manchester Central Research Ethics Committee North West (REC reference: 21/NW/0050; IRAS ID: 289258, see Appendix 2.3).

2.2 Patient and public involvement

Members of the University of Manchester's Community Liaison Group (CLG) were consulted during the planning stage of this study. They provided valuable feedback on patient-facing documentation and the interview topic guide[5].

2.3 Sample

Participants were recruited from the BPRS Psychology service at Wythenshawe Hospital in Manchester, UK. Inclusion criteria for the study was that patients must be: 1) under the

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[5] A detailed description of CLG involvement and feedback can be found in Paper Three, Page 118

management of the BPRS Psychology team[6]; 2) aged 18 or older; 3) at least one month post BPRS injury; 4) competent in English language skills (able to read, understand, and complete questionnaires in English). Patients were excluded if they met one or more of the following criteria: 1) had a cognitive impairment which precluded the ability to provide informed consent or the ability to participate; 2) were acutely suicidal; 3) were actively experiencing a psychotic episode; 4) had a current drug or alcohol dependence; 5) had ongoing deliberate self-harm; 6) had dementia or learning difficulties. There were no restrictions placed on the size or type of the injury, and no upper limit to how long ago the injury occurred.

2.4 Materials
2.4.1 Demographics questionnaire

A questionnaire (see Appendix 2.8) was created for the purposes of this study and included: age, sex, relationship status, highest level of education, current employment status, current living arrangements, current and past mental health background (i.e. current mental health rating on a visual analogue scale, past and present treatment), and details of their BPRS injury.

2.4.2 Symptom Outcome Measures

In order to gain an understanding of symptoms of anxiety and depression at the time of the interview and to help describe the sample, participants were required to complete a range of symptom measures (see Appendix 2.9).

Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001). The PHQ-9 is a nine-item measure designed to assess depression in primary care settings. Each item corresponds to DSM-IV criteria and is scored between 0 (not at all) to 3 (nearly every day). Total scores range from 0-27 representing mild (5–9), moderate (10–14), moderately severe (15–19), or severe depression (20–27). The scale demonstrates good reliability and validity (Cameron et al., 2008).

Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006). The GAD-7 is a brief seven-item scale to assess generalised anxiety disorder in primary care. Each item is scored between 0 (not at all) to 3 (nearly every day) with total scores between 0-21 representing

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[6] A definition of this is described in more detail in Paper Three (page 117/118) as well as ethics amendments (appendix 2.4) to clarify study inclusion criteria

mild (5-9), moderate (10-14), and severe anxiety (15-21). The scale demonstrates good reliability and validity (Rutter & Brown, 2017).

Impact of Events Scale – Revised (IES-r; Weiss, 2007). The IES-R is a 22-item measure designed to assess symptoms of PTSD. Patients are asked how distressing they have found each item in the previous seven days and are scored between 0 (not at all) and 4 (extremely). Total scores range from 0-88 with scores of 24 or more indicating PTSD is a concern and scores of 33 or above indicating probable PTSD. The IES-R has been shown to have good reliability and validity in burns victims and motor vehicle accident survivors (Beck et al., 2008; Sveen et al., 2010).

2.4.3 Interview Topic Guide

An interview topic guide (see Appendix 2.10) was developed for this study. It covered the following sections: 1) introductory questions intended to build rapport with the participant; 2) information about the index event; 3) emotional reaction since the index event[7]; 4) adjustment since the index event and thoughts regarding the concept of post-traumatic growth, and; 5) experiences of psychological support and thoughts about what should/could be offered in the future. Each section had a number of questions and optional prompts. The latter were used flexibly based on the amount of information the participant spontaneously gave. The wording relating to asking about "anxiety or low mood" was used as a placeholder and to offer continuity if prompt 3a[8] was used. The wording of subsequent questions and prompts were changed to reflect the primary concerns that the participant shared in their spontaneous answer to question 3a (i.e. anger, insecurity, worry, grief, etc.).

2.5 Procedure

Clinicians at the BPRS Psychology team routinely asked service-users about research involvement. Interested patients completed a Consent to Contact form to allow the research team to contact potential participants to discuss the study further, screen for eligibility, and arrange a time to complete informed consent. Verbal consent was provided and recorded over university approved video-conferencing software.

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[7] The section "emotional reaction since index event" covered questions around concepts such as feelings, content and engagement in thoughts, and coping behaviours.

[8] Prompt 3a suggested the interviewer ask "has this made you feel anxious, low in mood?" if the participant did not provide a spontaneous answer to the question "can you tell me how you've been feeling since your injury?".

Participants were given the option of completing the questionnaires over videocall, telephone, or on their own and returning completed forms by email.

Following the completion of questionnaires, the researchers outlined the main aims of the study and what areas the interview would cover. The lead author (JTB) conducted nine interviews with a further two being conducted by another trainee clinical psychologist (Fiona O'Donovan). Interviews were conducted in a conversational style over video conferencing software due to the COVID-19 pandemic limiting face-to-face research activity. All participants were reminded that the questions were optional, that there were no right or wrong answers to any of the questions, and that they could take a break from the interview or withdraw from the study at any time without giving a reason. An interview guide using open questions and prompts was used to facilitate the interviews (see Appendix 2.10). Each participant was asked about their BPRS injury and mental health since the injury, which constitutes this study. Participants were also asked about their thoughts about the concept of posttraumatic growth, adjusting to life after their injury, and their opinions on any psychological care they had received to date, and what ideal care might look like for someone in their position; this data was beyond the scope of the current research and is not reported here. Prompts were used to elicit further information relevant to the cognitive and metacognitive theories.

Interviews were audio/video recorded and a transcript generated using the built-in function of the video conferencing software. Transcripts were reviewed and corrected against the recording by JTB and anonymised. NVivo (QSR International Pty Ltd, 2018) was used to manage the data during analysis.

2.6 Data analysis plan

JTB familiarized themselves with the data by listening to recordings and reading the transcripts several times. Interviews were analysed using thematic analysis (TA; Braun & Clarke, 2006) by JTB. To explore the psychological experiences of BPRS patients, analysis followed the six phases of TA (Braun & Clarke, 2006) and themes were identified through inductive coding and discussed with LC.

To assess whether the key concepts of the cognitive or metacognitive models could be elicited from the BPRS patients' accounts of their psychological experiences a more deductive approach was used. JTB, LC and AW identified key aspects of both the cognitive and metacognitive models a-priori to use as a framework. For the cognitive model, ten

cognitive distortions were prespecified as codes whereas for the metacognitive model misdirected attention/control (i.e. hypervigilance, worry), and meta-beliefs (both positive and negative) were prespecified codes.

3. Results

3.1 Participant Overview

In total, seventeen people gave consent to be contacted by the research team. All were eligible to take part and fourteen (82%) went on to provide informed consent to take part in the research. Three patients withdrew following consent, resulting in eleven patients taking part in the interview. Reasons provided for not taking part in the interview after providing informed consent were: too busy to take part ($n = 1$); unable to find a time that suited both researcher and participant ($n = 1$); no reason provided ($n = 1$). Table 6 provides an overview of participant characteristics. Those who took part in the interview were between 24-70 years old ($mean = 44.45, SD = 10.10$), predominantly White British ($n = 10, 91\%$), female ($n = 9, 82\%$), and worked full time ($n = 6, 55\%$). Seven people (64%) reported a burn injury: five were thermal burns (four due to fire, one contact), one was a chemical burn, and one a laser burn from a cosmetic procedure. The remaining four (36%) participants reported plastic reconstructive surgery as their primary intervention. Three had a deep inferior epigastric perforators flap (DIEP) surgery with full breast reconstruction, and one having reconstructive surgery following a traumatic injury. Of the eleven people who took part in the interview, seven (64%) reported that the event took place more than one year ago, and four (36%) reported the event occurred six months to one year ago. Interviews lasted on average 63.68 minutes ($SD = 18.19$).

Patients' mental health is summarised in Table 7. The sample most commonly rated their mental health as 7 out of 10 ($range: 4 - 9$). Scores for depression ($mean = 8.45, SD = 4.76$), anxiety ($mean = 7.91, SD = 4.59$) and PTSD ($mean = 29.64, SD = 21.99$) were all around the clinical cut-off scores for the respective measures. A majority of patients ($n = 8, 73\%$) were currently receiving mental health support

Table 6 | Summary of demographic and physical health information for interviewed participants

ID	Age (gender)	Relationship	Education[a]	Employment	Living	Ethnicity	Injury type	Time frame	Comments
01	70 (f)	Married	University degree	Retired	Homeowner	White British	Burn	> 1y	Thermal burn to face
03	48 (f)	Married	University degree	Full time	Homeowner	White British	Reconstructive	> 1y	DIEP surgery
04	62 (m)	Separated/ divorced	GCSEs, GCEs, or O-levels	Full time	Homeowner	White British	Burn	> 1y	Thermal burns to face and arms
05	29 (m)	Single	Postgraduate	Student and part time	Homeowner	North African / British	Burn	6m - 1y	Chemical burn – face, head/neck
06	34 (f)	Single	University degree	Full time	Homeowner	White British	Burn	> 1y	Laser burn to face

07	53 (f)	Married	University degree	Part-time (14.5)	Homeowner	White British	Reconstructive	6m - 1y	DIEP surgery
08	48 (f)	Married	A-levels/BTECH	Full time	Homeowner	White British	Burn	6m - 1y	Thermal burn to lower body
10	47 (f)	Married	University degree	Full time	Privately renting	White British	Reconstructive	> 1y	DIEP surgery
12	24 (f)	Single	A-levels/BTECH	Unemployed	Living with Family	White British	Reconstructive	6m - 1y	Traumatic injury to arm
13	24 (f)	Single	A-levels/BTECH	Full time	Living with Family	White British	Burn	> 1y	Contact burn to legs
14	50 (f)	Single	A-levels/BTECH	Unemployed	Living with Family	White British	Burn	> 1y	Thermal burn

a = highest level of education attained at time of providing consent

Table 7 | Summary of mental health information for interviewed participants

ID	Diagnosis	Self-Perceived Mental health Status[a]	Current support	Past support	PHQ-9	GAD-7	IES-R			
							INT	AVD	HYP	Total
01	None	8	None	None	2	1	5	4	1	10
03	None	4	Therapy	Therapy	5	7*	6	6	2	14
04	None	9	None	None	0	3	0	1	0	1
05	None	5	Therapy	None	12*	7*	13	20	15	48*
06	Depression Anxiety	NA	Therapy Medication	Therapy Inpatient	10*	12*	12	9	8	29
07	None	7	Therapy	Therapy Medication	10*	6	12	4	5	21
08	None	7	Therapy Medication	Therapy Medication	11*	12*	24	14	21	59*
10	None	7	Therapy	Therapy	15*	9*	NA	NA	NA	NA
12	None	7	Therapy	None	5	3	20	21	17	58*

13	PTSD	7	None	Therapy	10*	11*	14	18	5	37*
14	Depression Anxiety PTSD	5	Therapy	Therapy	13*	16*	23	10	16	49*

a = Visual analogue scale of current mental health at time of providing consent; NA = missing information; PHQ = Patient Health Questionnaire-9; GAD = Generalised Anxiety Disorder-7; IES-r = Impact of Events Scale-revised; INT = intrusions subscale of IES-r; AVD = avoidance subscale of IES-r; HYP = hypervigilance subscale of IES-r; * above clinical cut-off: PHQ-9 ≥ 9; GAD-7 ≥ 7; IES-r ≥ 33.

3.2 Understanding Patients' Psychological Experiences Following a Burn or Reconstructive surgery

Three themes were identified when aiming to understand the psychological experiences of BPRS patients. These were: (1) the broad range of feelings, (2) the level of engagement in repetitive negative thinking and the diversity of concerns that patients describe, and (3) the various coping strategies patients used as ways to control their thoughts and feelings.

3.2.1 Theme one: the broad range of feelings

Patients experienced a range of feelings including "anger, guilt, sadness, and insecurity" (P06). A pattern did not emerge between the type of BPRS injury and feelings experienced and all patients described experiencing a range of feelings.

Low mood ($n = 9$) and anxiety ($n = 8$) were the most common feelings described. Patients described feeling "incredibly low and very tearful" (P03), that they felt they were different, felt isolated or alone, and that "nobody really understood" (P10) what they were going through. They described feeling anxious, which was described as being fuelled by a sense of "vulnerability and fear" (P01) since their injuries.

Patients commented about the anger they experienced following their injury ($n = 7$). Patients were angry "that [it] happened" (P12) in the first place, at their lack of control over the situation, and at the extent and consequences of their injuries (P12: "I'm angry […] I can't use my arm and can't go back to work"). One patient also spoke about how anger kept them focussed on the accident: "I was really angry all the time because most of the time I used to just think about the accident, it was all I thought about" (P12).

More than half of the patients described feeling guilty in the aftermath of their injury ($n = 6$). Patients reported feeling guilty about the "ripple effect through a family" (P14) who "all suffer too" (P07). Other patients, such as P06 said they felt "guilty for getting upset" about their injury because "in comparison to what happens to some people, it's absolutely nothing".

Although less common, patients also described feeling as though they had changed since their injury and feeling grief and loss ($n = 4$) about who they used to be as a person (P08: "you do, kind of, mourn the person that you used to be").

3.2.2 Theme two: the engagement in repetitive negative thinking and the diversity of concerns

All patients described engaging in repetitive negative thinking, namely rumination and worry. Both worry and rumination focused on a range of concerns. Rumination commonly focused on why the event happened, their role in the event, and what it meant about them as people. Alternatively, worry predominantly focused on what others thought of them and their injuries, about the healing process of their injuries, and whether they would regain function, or get back to what they could do prior to their injury.

3.2.2.1 Rumination

All patients reported engaging in rumination ($n = 11$). This was primarily focussed on why the event had happened to them, that they "must of done something wrong" (P12) or questioning what they had done to "deserve this" (P03). Other concerns were around what could have happened "if the burns had gone any further" (P04), and what the potential consequences of that would be. Patients that had opted for surgical interventions to prevent or remove cancer reported an inner conflict between justifying why they made the decision to have the operation and questioning it (P10: "I still kind of think 'what have I done to myself?', which is bizarre when I know why I've done it"). Patients described how they were "constantly thinking [and] dwelling" which led to feelings being "bottled in" (P03). Although rumination was intended to reduce arousal, patients commented that it often had the opposite effect making them "feel worse" (P12) and that it led to a "spiralling that happens in my mind" (P05).

3.2.2.2 Worry

All patients reported engaging in worry ($n = 11$). Patients' worrying covered a wide range of concerns. The majority of BPRS patients ($n = 7$) shared worries about their appearance, however, these manifested in different ways. Some shared worries about what they looked like after their injury (P01: "how can I live looking like this?") and how others' perceived them, saying "you can see them looking at it" (P05) and concerns that "no one's ever gonna find me attractive" (P06). However, P03 and P07 who had both had the DIEP surgery to prevent or remove cancer both spoke about how it was the fact people "can't see that there's anything wrong" (P03) that led to worrying about being "knock[ed] into" (P03) as there was a fear this could cause pain and delay healing.

Almost all patients ($n = 10$) described worrying about their injury (i.e. whether it would heal, level of functioning, engagement in future activities). P14 worried their "physical changes" would stop them escaping "a fire in the pub or the club". P12 shared that for months after an injury to their arm, they worried that it was "never gonna work again" and P01 recalled worrying about whether they would "be able to get back to work" and whether they were "ever going to run again". Patients also worried about the likelihood of a similar accident or injury happening again in the future and "catastrophising about what might happen now to me" (P08).

Patients who had the DIEP surgery reported misinterpreting bodily symptoms which led to worry that their cancer was returning. P07 described worrying whether a twinge in their back was "normal back pain" or "a tumour in my spine"). P03 worried about the effects of activities would have on them; if their stomach hurt, they would worry they had "done something to damage" themselves. These concerns were not shared by burn patients.

3.2.3 Theme three: the various coping strategies used to control thoughts and feelings

Patients used a range of coping strategies in order to modify negative thoughts and attempt to control their thoughts and feelings. Distraction techniques (i.e. keeping busy, focussing on other tasks, watching television) were used by most patients ($n = 9$) to keep their "minds occupied" as a means of "not thinking about my accident" (P04). Others engaged in exercise in an attempt to keep themselves physically busy to avoid distressing thoughts. Some ($n = 8$) went further and engaged in active thought suppression, either trying to "ignore" thoughts (P08) or push them away. Other patients ($n = 6$) dealt with distressing thoughts by trying to replace them by "think[ing] of something positive" (P12).

Patients also spoke about avoidance ($n = 9$) and the range of reasons that motivated this. P01 avoided loud noises and the smell of smoke because it "brought it all back" (i.e. thoughts and feelings of their accident). P05 avoided going to new, busy, or unfamiliar places because of fear of being attacked again and P03 spoke about "stepping aside massively to try and stay away from people" because of a fear of the pain and potential damage it could cause to their healing injuries. Patients also noted that they covered up more in front of their partners or family members and avoiding mirrors because of not liking how they looked; P14 spoke of their heart "beating through my chest" when they "caught a glimpse" of themselves in the mirror.

Fewer patients spoke about being hypervigilant ($n = 4$), however it played an important role in feeling safe for those that did engage in it. P05 described being "very careful of where I step […], who I speak to, [and] what I speak about" for fear of being attacked and that it helped them to prepare to "escape" if needed. P14, too, spoke of "constantly being on my guard for the next thing".

3.3 Can the underpinning concepts of the cognitive and metacognitive models be elicited from BPRS patients' accounts of their psychological experiences since their injury?

The second aim was to explore whether concepts underpinning the cognitive and metacognitive models can be elicited from BPRS patients' accounts of their psychological experiences since their injury.

3.3.1 The cognitive model and BRPS patients' accounts

Ten cognitive distortions were identified a-priori in collaboration with the co-authors. Table 8 provides an overview of the cognitive distortions selected and the number of patients who evidenced that distortion. Cognitive distortions were identified in every patient, with most patients exhibiting multiple distortions.

Catastrophising often related to the permanence of the current situation, patient's abilities, or appearance, and was closely linked to the injury or event. For example, P01 questioned whether they would "look anywhere near normal again", and P06 voiced similar concerns, stating "what if I don't ever look how I want to look?". P08 recalled sitting near a fire and thinking "it's going to explode". In a similar way to catastrophic thinking, overgeneralisation was often related directly to the injury or event. P06 "won't be going for a beauty treatment again" as this was the setting their burn occurred in and they were "not keen" on a laser treatment recommended by BPRS surgeons citing that lasers were "why I've got [the injury] in the first place". Patients who were taking part in the research after surgery to remove or prevent cancer reported overgeneralising the frequency people talked about cancer with "somebody always on the telly […] or somebody in your group or who's got [cancer]" (P07).

BPRS patients often reported thinking that they knew what other people thought of them (mind reading; $n = 10$). This was almost always related to concerns about patients' appearance. Burns patients often spoke about how distressing it was that their injury was visible: P01 said "what they will think of my face" and that "people can see there is a problem", P12 recalled thinking "people were looking at my scars", and P13 assuming

people thought about them as "the girl with the burn scars". On the other hand, those who had had surgery that wasn't visible feared that "people can't see that there's anything wrong" (P03) and would not know to steer clear, otherwise contact could exacerbate their injuries and delay healing.

Imperatives are a fixed idea of how oneself or others should behave, and examples of this distortion often related to self-blame: "I must be a terrible person for this to have happened to me" (P01), "if I hadn't of done that, then it wouldn't have happened" (P12), and "it's my fault" (P13). Those who had the DIEP surgery seemed more likely to think in this way due to the elective element of the surgery; for example, P07 said "I feel like I've done this to myself" and P03 saying it was "my fault that this has happened".

Some of the concerns shared seemed unrealistic and clear examples of cognitive distortions. For example, "you start assuming that everyone [is] out there to get you" from P05 is a clear example of overgeneralisation. However, there were numerous examples of where concerns may have reflected the patients' clinical reality. Several patients voiced concerns about other people noticing their injury and reacting to it. For example, a concern from P01 that other people could see their burn injury and the mask they wore to help it heal were true as it was "in your face, literally" (P01). P10 stated that they "just looked different", while perhaps not as obvious as they thought, this could be considered objectively true after their DIEP surgery removing breast tissue. Further, P07 had concerns that their "risk of ongoing cancers is pretty high" may be justified; they had been diagnosed with breast cancer on three occasions despite not meeting the criteria for any clinical risk factors and the risk of recurrence is higher in those who have already been diagnosed, around 30% for breast cancer (Colleoni et al., 2016). There were also concerns about the implications of physical changes, for example P14 shared a concern that they "wouldn't be able to get out fast" if there was a fire in a pub or club which may be justified due to the extent and impact of their injuries on mobility.

Some statements made by patients could be interpreted in a number of ways and could be categorised as more than one cognitive distortion. For example, when talking about their injured arm, P12 says "it's never gonna work again", which was coded as an overgeneralisation, but could easily have been interpreted as catastrophic thinking, a prediction, or even not a distortion at all if this was clinically true. Similarly, P01 discounted the positive aspect of their scar healing as being objectively "good" but then

also labels herself as a "Scarface". It was at times hard to determine which cognitive distortion best 'fit' the statement being made.

Table 9 demonstrates that BPRS patients' accounts exhibit thoughts consistent with symptoms of a range of problem-specific models. At times, people spoke about content that may fit into a number of these models. For example, P01 exhibited distressing cognitions pertinent to both PTSD and Social Anxiety (i.e. re-experiencing and avoidance, and strong opinions about what other people think of them; see Table 9), however, they did not score above the clinical threshold on any measure at screening and reported never receiving any psychiatric diagnoses. Similarly, P08 exhibited thoughts that would indicate the use of numerous problem-specific models including PTSD, depression, and GAD (see Table 9). They were hypervigilant of threat, avoidant of items that reminded them of their accident, were distressed by worries about a range of concerns, and reported having little hope about coping with events when they felt low in mood.

Concepts underpinning the cognitive model can be elicited from BPRS patients' accounts of their psychological experiences since their injury. There were multiple examples of every type of pre-specified cognitive distortions and multiple cognitive distortions in each patient's account. Additionally, patient talk could be categorised into disorder-specific models (e.g. social anxiety, health anxiety, PTSD, depression). Some concerns appeared to be based on the patient's clinical reality, making it hard to determine whether these were examples of biased thinking and some patient talk appeared to fit more than one problem-specific model.

Table 8 | The cognitive model with examples from interviews

Subtype	*n*	Description	Example from interviews
NATs	11	Spontaneous thoughts that occur in everyday cognition	"If somebody knocks into me then I know that's really going to hurt" **(P03)** "It's not fair" **(P07)** "I'm a lost cause" **(P13)** "I look grotesque" **(P14)**
Catastrophising	10	Negative predictions about the future, with no consideration of other possible outcomes	"Would I look anywhere near normal ever again?" **(P01)**
Overgeneralisation	10	Reaching a negative conclusion that goes beyond the present situation	"You start assuming that everyone's out there to get you" **(P05)**
Dichotomous thinking	10	A situation is viewed in only two categories	"I've not had real cancer" **(P03)**
Mind reading	10	Belief that others are thinking negatively about oneself, without considering more positive possibilities	"they're not really interested" **(P07)**
Labelling	8	A negative label is assigned to oneself and/or others, without consideration of other evidence	"I'm a bit of a basket case psycho those days" **(P07)**

Imperatives	7	A fixed idea of how oneself or others should behave and, when these expectations are not met, a negative outcome is overestimated	"I must be a terrible person for this to have happened to me" **(P03)**
Discounting the positives	7	Positive experiences or qualities do not count	"It is extremely good outcome in terms of burns, but it's still to me a Scarface" **(P01)**
Magnification/minimisation	6	When a person or situation is evaluated, the negative is magnified and/or the positive is minimized	"In comparison to what happens to some people, it's absolutely nothing" **(P06)**
Prediction/fortune-telling	5	Predicting a negative outcome without realistically considering the actual odds of that outcome	"Life isn't going to be worth living looking like this" **(P01)**
Emotional reasoning	5	Something is regarded as true because it is felt strongly, evidence to the contrary being ignored	"I feel like an idiot" **(P07)**
Intermediate	9	Rules, attitudes, and assumptions that people have about themselves, others, and the world around them	"I need to be proactive and look after my health" **(P07)**
Core	10	Peoples' beliefs about themselves, others, and the world around them that are deeply entrenched and regarded as absolute truths	"I'm a walking example of a burns patient" **(P01)**

NAT = Negative Automatic Thought

Table 9 | Problem-specific CBT models

Problem-specific model	Clinical criteria	IDs	Description	Evidence from interviews
PTSD	05 08 12 13 14	01 05 08 12 13 14	A sense of current, serious threat arising from: 1) negative appraisals of the trauma, and 2) memory disturbances with strong associative memories. Often resulting in episodes of re-experiencing the trauma (e.g. flashbacks), hypervigilance, and avoidance (Ehlers & Clark, 2000)	*Re-experiencing* "The bangs and the noises and you think "it's all happening again" **(P01)** "The more stronger the flashback, the more real the sensations feel to me" **(P05)** "I dream about someone or something that was associated with it" **(P12)** "I panicked, and I freaked out, I saw it and I just went into meltdown" **(P13)** "I'd doze off in the day and wake up screaming" **(P14)** *Hypervigilance* "I was very… very wary of where I go… I need to be extremely careful of who I'm speaking with, who's walking towards me, what's behind me, what's the setting, can I escape somehow?" **(P05)** "I'm very much more nervous and anxious around things" **(P08)** "Because of what's happened and constantly being on my guard for… for the next thing" **(P14)**

				Avoidance
				"I won't go near the little camping stove because that's what it that blew up" **(P01)**
				"I couldn't even use the oven because the heat would make me physically shake" **(P08)**
Depression	05 06 07 08 10 13 14	05 06 07 08 10 13 14	Negative Automatic Thoughts driven and maintained by negative beliefs about the self (Beck, 1963, 1964). Termed the Cognitive Triad thoughts tend to group into: 1) thoughts of being inadequate, 2) trying leads to failing, and 3) no hope for the future (Beck, 1976)	"I think when I do let them happen [negative thoughts] it possibly makes me feel worse" **(P06)** "I've been so down […] you do lose hope, you definitely do lose it" **(P14)** "I don't think you'll ever, ever fully get to point where you go "oh everything's brilliant" you know?" **(P06)** "I'm really not able to cope with it" **(P08)**
Social Anxiety	NA	01 03 07 12 13	Misinterpretation of own thoughts and concerns about appearance and	"What will they think of my face" "do they not know who I am or is it so bad that they are just too embarrassed to talk to me?" **(P01)**

			social functioning that forms a strong impression of how they appear to others and seeing social situations as a threat (Clark & Wells, 1995)	"I'm always doing this [touching silicone tape over scar] when I'm talking to people because I'm almost doing it to make them know I'm aware that that's there"; "no one's ever gonna find me attractive […] I'm never going to find me attractive" **(P06)** "People were looking at my scars" "people would see me differently because of what happened" **(P12)** "I do feel I'm going to get judged a lot" **(P13)**
GAD	03 05 06 08 10 13 14	01 03 05 08 10 13 14	A heightened preoccupation with threat coupled with an underestimation in their ability to cope with it results in a cycle of worry and an intolerance of uncertainty (Borkovec & Costello, 1993; Butler et al., 1987)	"What didn't help was not knowing what I was going to look like […] would I look anywhere near normal ever again?" **(P01)** "I'm constantly worrying or thinking about this" **(P05)** "Catastrophizing about what might happen now to me"; "you're consistently wanting your brain to just stop doing that but it's on a roll, it kinda just… it runs away with itself" **(P08)** "Worrying too much or something will lead to the worst catastrophe" **(P13)**

NA = Not applicable as not assessed

3.3.2 The metacognitive model and BPRS patients' accounts

All aspects of the CAS (i.e. repetitive negative thinking, inflexible attention, threat monitoring) could be elicited from BPRS patients' accounts of their psychological experiences post-injury. It was also possible to elicit a range of maladaptive metacognitive beliefs which BPRS patients stated interfered with regulation of their thoughts and feelings.

As noted under research question one theme two (Repetitive Negative Thinking) patients all engaged in rumination and worry. Patients ruminated on why the event had happened, their role in it, and what it meant for them as a person. The content of worries were many and varied; there was repetitive engagement in worries about appearance, what other people thought about them, their injury (i.e. whether it would heal, level of functioning, engagement in future activities), and about what kind of threat bodily sensations might represent. This engagement in the CAS was described as an attempt to "deal with it" (P05), however patients described it having the opposite effect and generating "a lot of questions that I don't have answers for" (P06). Others acknowledged, too, that the process was "stopping [them] from moving on" (P14) and led to their minds "spiralling" (P05).

Patients described experiences that may indicate a lack of flexibility in their attention. Patients described feeling unable to shift their attention away from negative thoughts or feelings. Patients described how the persistent focus on threat (or pain) meant that their distress was maintained; "it's constantly there physically, so it's been constantly there psychologically as well" (P10). This sometimes manifested in avoidance and hypervigilance as noted under research question one, theme three (Coping Strategies).

Patients ($n = 9$) endorsed two common maladaptive negative metacognitive beliefs: worrying is uncontrollable, and that it is harmful or dangerous. Patients noted that they often felt out of control of their thinking, stating that "there wasn't much I could do about it" (P05), and that their brain "runs away with itself" (P08). P06 said "once I start worrying about one thing, then I'll start worrying about something else, and something else" and that it "just happens at random" highlighting that they "don't feel particularly in control". This sentiment was echoed by P13, saying "my thoughts are in control". Patients also spoke about how worrying was "seriously dangerous" and that it "destroys your mind" (P01). Two patients noted that they believed that excessive worrying could "lead to

suicide" (P01) and that their neighbour had "worried [themselves] to death" (P01). Both P06 and P14 shared that they believed worry to be "destructive" and P06 added it was "almost like a form of self-harm". As in some of these examples above, some patients worried about worry itself (meta-worry), with P13 saying that "worrying too much" can make the thing more likely to happen and will "lead to the worst catastrophe".

Patients also spoke about positive metacognitive beliefs ($n = 8$) such as worrying being a helpful process that allowed them to be more prepared. P03 described worry as being "protective" and helping avoid "end[ing] up back in hospital". P05 said worry "has some kind of benefit" because it led to them "being extra-cautious and wary" which could help them avoid another potential attack. P13 believed that "worrying and analysing can also help me focus" and P07 expressed that "a little bit of a worry might help me get my thoughts into place".

The key concepts of the metacognitive model can be elicited from BPRS patients' accounts of their psychological experiences after their injury. There were multiple examples of all aspects of the CAS (i.e. repetitive negative thinking, inflexible attention, threat monitoring) as well as examples of both positive and negative metacognitive beliefs. Repetitive negative thinking encapsulates a diverse range of concerns shared by BPRS patients without having to reality-check the contents.

4. Discussion

The first aim of this study was to explore and understand the psychological experiences of BPRS patients. That is, the feelings, thoughts, and coping behaviours since their injury. The second aim was to explore whether concepts underpinning the cognitive and metacognitive models can be elicited from BPRS patients' accounts of their psychological experiences since their injury.

4.1 Summary of findings
4.1.1 Understanding the psychological experiences of BPRS patients

Patients described a broad range of feelings such as sadness, anxiety, anger, and grief and many patients described experiencing more than one in the aftermath of their injury. Repetitive negative thinking (i.e. worry and rumination) was common across all patients with the content varying considerably. There was a range of maladaptive coping strategies described as an attempt to control their thoughts and feelings. These included thought suppression, distraction, avoidance, and positive thinking in an attempt to

control thoughts and emotions. These results are in line with McPhillips et al. (2019a) who evaluated emotional distress in cardiac rehabilitation patients and found that patients experienced a range of worries, believed that worrying was uncontrollable and harmful, and utilised maladaptive coping strategies (i.e. reassurance seeking). Further, the use of strategies such as thought suppression and avoidance have been shown before in burns patients (Kornhaber et al., 2018) and have been posited at factors that may maintain distress and PTSD symptomatology in BPRS patients (Macleod et al., 2016).

4.1.2 Eliciting the key concepts of the cognitive and metacognitive models from BPRS patients' accounts

Concepts underpinning the cognitive and metacognitive models could be elicited from BPRS patients' accounts of their psychological experiences since their injury. The cognitive model makes a judgement as to whether the content of concerns is biased or distorted. There were multiple examples of all ten pre-specified cognitive distortions were found in BRPS patients' accounts. There were examples of thoughts concerns that may have either been examples of distorted thinking or based in clinical reality. BPRS patients' talk could be characterised as being consistent with symptoms of a range of problem-specific models.

The metacognitive model seeks to understand how much people engage in the CAS and to challenge the metacognitive beliefs that may drive this engagement. There were examples of all aspects of the CAS such as repetitive negative thinking (i.e. worry and rumination), inflexible attention, and unhelpful coping strategies. Positive and negative metacognitive beliefs were also readily accessible in the accounts BPRS patients' accounts.

These results are encouraging, suggesting that both the cognitive and metacognitive models could be applicable within the BPRS patient population – these models could be applied in future research to assess the acceptability, feasibility, and treatment efficacy of these approaches in this population.

4.2 Theoretical differences in the application of the models to clinical practice
4.2.1 The content of thoughts

The theoretical and conceptual underpinnings of the cognitive and metacognitive models could both be elicited from BPRS patients' accounts; however these models would approach clinical interventions differently.

The cognitive model relies on engaging in the content of thoughts. Some of the concerns reported by BPRS patients had a basis in clinical reality; topics such as appearance concerns, fear of cancer recurrence, and feeling at risk of another attack/accident could be realistic. Previous research into the relatively well-defined fear of cancer recurrence suggests that these concerns are often reported to a low to moderate degree, but that they are often considered "one of the top greatest concerns and the most frequently endorsed unmet need" (Simard et al., 2013). It has also been highlighted that a purely cognitive approach (e.g. using cognitive restructuring) may not adequately address these concerns (Greer et al., 2010). Behavioural aspects of CBT may be important (Turner & Knowles, 2020) and adaptations to CT/CBT have been suggested (Greer et al., 2010; Sanders et al., 2020), such as gaining additional information from treating physical health specialists and incorporating this into judgements about the likelihood of a worry happening and using acceptance-based approaches if this does not work. Research into these adaptations suggests that they are acceptable (Greer et al., 2012) and that they can be successfully implemented in primary care settings (Panchal et al., 2020) although it was described as "resource intensive" (p. 5). Further research is needed to determine the efficacy of adapting CBT for people with physical health concerns. A further theoretical downside to requiring personalisation and adaptation to a standard therapeutic model would mean that treating groups of people may be very challenging, although this could be a basis for future research.

The metacognitive model does not engage in the content of concerns (i.e. what people worry about) and instead focuses on the driving factors for *why* people worry, negating the need for reality testing concerns. This would mean patients would not have to share the content of their worries with practitioners, which could be a potential benefit. A recent paper suggested that cardiac patients were concerned about having to share their worries with practitioners (McPhillips et al., 2019a) and the BPRS population has high levels of trauma (Sahu et al., 2017; Ter Smitten et al., 2011) and making disclosures around this could in itself be distressing.

4.2.2 Problem-specific models

A feature of Beck's (1976) cognitive theory is the hypothesis that affective states can be discriminated based on the content of cognitions, referred to as the content-specificity hypothesis. In essence, it states that people with distinct emotional disorders will have distinct topics of content of their distressing cognitions. We found that many BPRS

patients accounts fit problem-specific models of distress, including concerns consistent with PTSD, social anxiety, depression, and generalised worry. This is encouraging and suggests these models may be of benefit to this population. Several patients, however, spoke about concerns that could be considered symptoms for multiple psychological presentations and each has distinct treatment approach based on cognitive content. For example, P01 shared concerns about their appearance and being judged by others as well as concerns about reexperiencing the event; this could fit into several distinct cognitive models and treatments (e.g. social anxiety and PTSD). The potential consequence of this in clinical practice is the requirement of therapists to be able to successfully determine a hierarchy of needs and target the most important need first. It is also possible that patients could require several distinct episodes of care to address all of their concerns. It is worth noting that this study did not set out with the intention to determine which problem-specific model would be most useful for BPRS patients and the interviews did not constitute a diagnostic interview. It is also worth noting that just because a patient shared concerns consistent with a particular presentation (e.g. social anxiety), it does not mean that they reached clinical threshold for this requiring treatment. Further research could utilise diagnostic interviews to clarify whether BRPS patients meet criteria for multiple diagnoses.

As MCT focusses on process rather than content, it is often referred to as being a transdiagnostic treatment; that is that the same model could be applied to different psychological presentations. This means there would not be a decision about which model to apply to whom and could open the possibility of group-based interventions across different presentations. These theoretical differences could be the basis for further research.

4.3 Limitations

Despite exploring psychological experiences there was no inclusion criteria pertaining to a minimum level of distress experienced (i.e. cut of score on an outcome measure), such as is the case in previous studies (McPhillips et al., 2019a, 2019b). While this approach allowed more people to participate and offered a more representative reflection of the BRPS psychology service being recruited from, it may have under-represented the distress and concerns that are held by this population. It should be noted, however, that despite some patients not scoring above clinical cut-off scores on any psychometric measure, they still spoke about challenging feelings, thoughts, and behaviours. This could be in part

due to not administering a wide enough range of measures (i.e. social anxiety). Administration of the MCQ-30 (Wells & Cartwright-Hatton, 2004) may have also been a useful addition to this study to determine the correlation between scores on problem-specific measures and metacognitive beliefs.

Our approach to interviewing and analysing data for two research questions in parallel may have influenced the findings, particularly pertaining to research question one. Through asking questions salient to the cognitive and metacognitive models, we may have overemphasised the cognitive components and processes of their experiences, however, it remains that our findings are in line with previous research that took a similar approach (McPhillips et al., 2019a, 2019b).

Much of the literature into effective treatments for psychological distress in people with comorbid physical health conditions uses CBT or CBT-based treatments with adaptations such as mindfulness or acceptance practices to address realistic concerns that are distressing (Greer et al., 2010). Indeed, Reavell et al. (2018) excluded studies that used purely CT approaches from their meta-analysis. The use of a pure cognitive model here may therefore not represent the routine clinical practice available to BPRS patients. Indeed, some research into CBT for Multiple Sclerosis suggests that it is the behavioural element of CBT that can be of particularly effective (Turner & Knowles, 2020).

The study has a relatively small sample size which could limit the generalisability of findings. Qualitative studies tend not to require sample sizes as large as those required in quantitative studies, and data saturation was reached with the sample that was recruited. It should also be noted that there was minimal diversity within the sample; most participants were White British women and, therefore, this may have restricted the breadth of beliefs and experiences captured.

4.4 Reflexivity

Qualitative studies are shaped by the researchers perspectives, and it is worth nothing that while members of the research team are experts in both the cognitive and metacognitive models this did include the originator of the metacognitive model and of MCT. The first author was aware of this throughout the process and the team worked to

acknowledge and account for this potential bias by grounding the research in the narratives of the patients' experiences and specifying aspects of both models a-priori[9].

5. Conclusions

The psychological experiences of BPRS patients are varied with a wide range of feelings, substantial engagement in repetitive negative thinking about a broad range of concerns, and a range of coping behaviours described in patients' accounts. It is encouraging that key concepts underpinning both the cognitive and metacognitive models could be elicited from BPRS patients' accounts of their psychological experiences post-injury. Some theoretical differences in how these models would then be applied in clinical practice raise questions that could be addressed in future research such as trials into the acceptability, feasibility, and treatment efficacy of CT/CBT and MCT in the BPRS population.

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[9] Reflexivity is discussed in greater detail in Paper Three, page 120/121

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Paper Three | Critical Reflection

Main text: 7,309 words

1. Introduction

The following paper contains a critical appraisal and evaluation of the research conducted within the present thesis, as well as a personal reflection on the process of undertaking the work. The paper will provide critical consideration of planning, implementation, and interpretation of the systematic review and qualitative study. The paper concludes with a reflection on how I have developed both personally and professionally throughout the process, and the implications this has for my future clinical practice and career.

Metacognitive therapy (MCT; Wells, 2009) is based on the self-regulatory executive function (S-REF) model (Wells, 2019; Wells & Matthews, 1994, 1996). The theory outlines that a maladaptive style of thinking, termed the cognitive attentional syndrome (CAS) maintains psychological distress. The CAS consists of worry, rumination, inflexible attention, and maladaptive coping strategies such as avoidance and thought suppression. The extent to which individuals engage in the CAS is linked to metacognitive beliefs. Metacognitive beliefs can be positive (e.g. "worry helps me to prepare") or negative. Negative metacognitive beliefs tend to focus on the uncontrollability of worry and the dangerousness of it (e.g. "worrying too much can be harmful"). MCT aims to reduce engagement with the CAS through modifying metacognitive beliefs and highlighting the control and flexibility an individual has over their attention. Unlike other approaches, such as cognitive therapy (Beck, 1963, 1964, 1976), MCT does not require the content of thoughts to be discussed or challenged, and might provide a more parsimonious approach to conceptualising patients' distress than other approaches (McPhillips et al., 2019). Metacognitive beliefs have been shown to be a more reliable predictor of psychological distress than the content of thoughts (Bailey & Wells, 2016; Bennett & Wells, 2010; Gwilliam et al., 2004; Myers et al., 2009; Myers & Wells, 2005).

One of the benefits of a theory and therapeutic treatment that focuses on transdiagnostic processes rather than problem-specific content, is that it allows for the ability to treat clinically diverse groups of patients with the same treatment manual, which could lead to more efficient service provision. MCT has been shown to be effective at reducing symptoms of anxiety and depression across a range of disorders (Normann & Morina, 2018; Normann et al., 2014). While MCT has predominantly been evaluated in individual, one-to-one, settings seven of the studies in the review by Normann and Morina (2018) tested MCT as a group treatment (g-MCT) and subgroup analyses found that g-MCT appeared to have a larger pooled effect size than studies that offered individual MCT.

However, these results must be interpreted with caution as there was substantial influence from an outlier. Since the 2018 meta-analysis by Normann and Morina there has been a growth in the number of studies evaluating g-MCT, as such the focus of Paper One was to determine whether g-MCT is an acceptable and effective approach for treating psychological distress.

Paper One is a systematic review and meta-analysis of sixteen studies delivering g-MCT. The studies consisted of nine (56%) uncontrolled (single-arm) trials, five (31%) randomised-controlled trials (RCTs), and two (13%) service evaluations. There was a variety of primary presenting problems treated with g-MCT (depression, generalised anxiety, mixed presentations of depression and anxiety, OCD, prolonged grief disorder, and tinnitus-related distress) and high levels of comorbidities (37-91%). A majority of the studies ($k = 14$) were conducted in adult samples, with one conducted in children (7-13 years) and one in adolescents (14-17 years). Studies varied in the number, frequency, and length of treatment sessions and in the provision of booster sessions. We found that drop-out at post-therapy was low (8%) suggesting that patients found this treatment acceptable, although this measure has shortcomings. A more useful measure of the average number of sessions attended was not consistently reported across studies. Fifteen studies included data to explore the pre/post change in primary outcomes and fourteen studies reported follow-up data. Large reductions in the primary outcome measures were seen between pre- to post-treatment and from pre-treatment to follow-up ($g = 1.72$ and $g = 1.74$, respectively). Four studies were included in a meta-analysis comparing the change from pre-to post-treatment for g-MCT and active control conditions, and three studies included in the pre-treatment to follow-up comparison. These found a small-moderate advantage of g-MCT above active control conditions at post-therapy ($g = 0.39$) and a larger but more variable effect at follow-up ($g = 0.70$), with the latter not reaching statistical significance. We conclude that larger RCTs comparing g-MCT to evidence-based active control conditions are required to strengthen conclusions.

Paper two was a qualitative evaluation of patients' psychological experiences following burns or another injury requiring plastic and/or reconstructive surgery (BPRS). The aims were to explore the psychological experiences experienced by BPRS patients and to explore whether concepts underpinning the cognitive and metacognitive models can be elicited from BPRS patients' accounts of their psychological experiences since their injury.

Eleven BPRS patients recruited from a BPRS psychology service were interviewed. Patients described a range of distressing feelings including low mood, anxiety, anger, guilt, and loss. All patients described how they engaged in repetitive negative thinking (worry, rumination), and the various coping strategies they used as ways to control their thoughts and feelings. Key concepts from the cognitive and metacognitive models could be elicited from BPRS patients' accounts. The cognitive model conceptualises distress as being maintained by distorted thinking styles; there were multiple examples of all ten pre-specified cognitive distortions in BPRS patients' accounts of their psychological experiences post-injury. Patients often engaged in more than one distorted thinking style and at times it was challenging to identify whether content was an example of distorted thinking due to the concern being based in the clinical reality for the patient. For example, concerns around appearance, fear of cancer recurrence, and feeling at risk of another accident could be realistic. Content of BPRS patients' accounts appeared to fit problem-specific models. Regarding the metacognitive model, patients engaged in talk characterised as the cognitive attentional syndrome and endorsed both positive and negative metacognitive beliefs. This encapsulated the broad range of content of thoughts and was irrespective of the realistic or distorted nature of such cognitions. Metacognitive beliefs were also clearly evident in the talk of patients. As such, MCT may offer a promising treatment option for BPRS patients and further research should be conducted to assess the feasibility and acceptability of delivering it to this population.

2. Paper one: systematic literature review
2.1 Topic selection

I initially set out to use my literature review to understand more about the population I was studying within my empirical paper, BPRS patients. I quickly learned that although these groups of people are often grouped together for physical and mental health treatments, they are often distinct groups within research. There appeared to be a wealth of research conducted in both populations aiming to describe the prevalence of psychiatric morbidity and predictors of diagnosis and outcomes post-injury or event (Bich et al., 2021; Butcher & Swales, 2012; Madianos et al., 2001; Smolle et al., 2017; Ter Smitten et al., 2011; Wisely et al., 2010), but very little information on what type of treatment would best suit them. Through scoping searches conducted within PsychInfo and PubMed, I found that there was a dearth of research on this topic, as noted by Cukor et al. (2015, p. 185): "despite the pervasive, well-documented challenges that often

follow burn injury, no published studies have reported on the efficacy of psychiatric outpatient treatment for burn survivors suffering from these diagnoses".

I refocussed my efforts on understanding more about the metacognitive model and MCT. I was aware of a review on the effectiveness of MCT (Normann & Morina, 2018) which provided an update to a previous review conducted several years earlier (Normann et al., 2014). It evaluated the effectiveness of MCT in reducing symptoms of anxiety and depression and found that MCT was acceptable, as defined by having a low drop-out rate at post-treatment, and that there were large reductions in symptoms of anxiety and depression at post-treatment and follow-up. There was preliminary evidence to suggest that the controlled effect at post-treatment and at follow-up was significantly larger than when compared to CBT control conditions. This review, however, focused only on studies with adult samples of ten or more and grouped together studies which delivered MCT individually and in a group setting. This last point limited the conclusions that could be drawn from g-MCT. Group interventions provide a significant number of benefits including reducing therapist-per-client time by up to 75% (Himle et al., 2003) and the environment in itself can be beneficial as it allows shared learning of experiences (Yalom & Leszcz, 1985). As such, I felt an investigation into the effectiveness of g-MCT would have important clinical utility

2.2 Search terms

A systematic search was conducted to identify all articles assessing g-MCT published in peer-reviewed journals in the English Language. Six electronic databases were included: PsychINFO, MEDLINE, Embase, Web of Science, CINAHL, and PubMed. Search terms were based on those used by Normann and Morina (2018) and agreed through discussion with LC and AW. The search string "(metacognitive OR meta cognitive) AND (therapy OR trial OR intervention OR treatment OR psychotherap*) AND (group)" was used.

2.3 Inclusion and exclusion criteria

Selection of inclusion and exclusion criteria was guided by previous research (Normann & Morina, 2018; Normann et al., 2014) and the study aims. In order to determine whether g-MCT was acceptable, and to conduct a meta-analysis to assess efficacy of g-MCT we kept the inclusion criteria broad while maximising the quality of studies included. Our inclusion criteria differed in important ways from past research. First, we only included studies that had been published in a peer-reviewed journals. The benefit of this was that

there was a certain degree of quality and accountability attributable to the peer-review process. The potential cost of this was the risk of publication bias, in that some negative findings may not have been published by authors or accepted by journals. Normann and Morina (2018) included grey literature and included unpublished findings from studies delivering g-MCT in their analysis, which makes direct comparisons more challenging. Secondly, we included non-adult samples. This allowed us to conclude that less research has been done with a non-adult population, but that effects appear similar to those in adults; these studies were not outliers. One limitation to our inclusion criteria was that we only included studies in the English language, which can increase publication bias as non-significant findings may be published in non-English language journals (Nuñez & Amano, 2021).

There was more judgement than anticipated to determine whether some papers should be included in the review. Some were simple to determine, for example a 'metacognitive therapy' for Attention Deficit Hyperactivity Disorder (ADHD) which combined behavioural and cognitive principles to address impairments in time management, organization, and planning skills in a group setting (Solanto et al., 2008; Solanto et al., 2010) was not metacognitive therapy as described by Wells (2009). Further examples include 'meta cognitive-behavioural therapy' (Dehkordi et al., 2017) which does not consist of metacognitive therapy but employs psychoeducation to increase awareness of cognitive processes in Bipolar Disorder, and an integrative approach (Cheli et al., 2019) consisting of some aspects of metacognitive therapy, but also aspects of compassion-focussed therapy, metacognitive interpersonal therapy, and narrative exposure therapy. A study which utilised metacognitive therapy but delivered initial sessions individually and others in a group setting (Farahmand et al., 2014) was also excluded for not being solely a group intervention. Other reasons that were easy to determine included two studies, one for using performance on a cognitive task as the primary outcome (Bayegan et al., 2021) and the other not reporting raw or summary data (Esbjørn et al., 2015) as it was a case report of the first four participants recruited to a larger trial that was included (Esbjørn et al., 2018). Studies that re-analysed study data were also not included due to not wanting to duplicate representation of participants (Dammen et al., 2016; Lassen et al., 2021; McEvoy et al., 2015; Walczak et al., 2021).

It was more challenging to determine whether other studies should be included. For example, studies relating to 'metacognitive training' (Moritz et al., 2013; Moritz &

Woodward, 2007) were not included as, despite the researchers themselves referring to the therapy as a metacognitive approach, the method of change is primarily through raising awareness of cognitive biases and challenging the content of thoughts, which is a process of CBT and not the focus of Wells' MCT (Capobianco & Wells, 2018).

2.4 Contacting authors

It was not necessary to contact authors for further data as all studies included in the review published the required summary and variance statistics (i.e. means and standard deviations of primary outcome measures at applicable timepoints). However, contact was made with authors to determine the level of training in MCT at the time of their research. Responses were often vague, and the information provided was subjective (i.e. that researchers claimed to have training that could not be verified by the treatment originator). Ultimately, this information was not included in the review and a more objective way of categorising researcher training was found. This method required searching for members of a studies research team on the MCT-Institute website register of qualified therapists. While this approach is more objective it does have a short-coming: the information pertains to the time of searching and not the time the research was conducted. However, it was felt that this compromise was acceptable and broadly tallied with the responses received directly form the researchers who responded to requests for information.

2.5 The aim of meta-analysis

Most studies included in Paper One were single-arm trials (i.e. there were no control groups). I decided to calculate a pooled within-group effect of g-MCT, however, the choice of which effect size to calculate was more challenging than I had anticipated. Most studies reported a Cohen's d (Cohen, 1988) effect size ($\frac{M1-M2}{Pooled\ SD}$). This approach is appropriate when the means are from independent groups, however, it does not account for repeated measures when both mean scores are within the same sample, and this introduces error (Cuijpers et al., 2017). There is little agreement on how repeated measures should be accounted for (Westfall, 2016), or whether they should be undertaken at all. One option is to use a change score, but this requires the standard deviation of the change scores (SD_{change}) which was not reported by any study and requires the full dataset to compute. Morris and DeShon (2002) offer a solution by suggesting that an estimate of the SD_{change} can be calculated using the correlation in the

scores at the two time points being included in the effect size and that an estimate of this correlation can be used if it not reported in the study. Normann and Morina (2018) had access to data which allowed them to calculate a conservative value of the correlation coefficient ($r = 0.5$). For the purpose of this review, the same value was used. The software Comprehensive Meta-Analysis (CMA; Borenstein et al., 2013) allows for computation of this adjusted within-group effect size utilising the correlation coefficient. A further adjustment for small sample sizes is then made to make this an adjusted Hedges' g. For between-group comparisons, the same software was used to enter the same level of data (i.e. means and standard deviations at two time points, and a correlation coefficient) for both an intervention and control condition to calculate an effect size, which was then pooled. A positive effect size in favour of g-MCT and negative if in favour of the control condition.

One issue with using a non-standard approach is that, although it may be more robust, it makes comparisons more challenging. While using an estimate for the correlation coefficient was not ideal, it was deemed better than not applying any correction.

2.6 Quality assessment

Quality assessment is an important aspect of a systematic review (Higgins et al., 2019). There are a number of tools available to assess the risk of bias within studies, however many of them are set up to assess only one type of study design. The Downs and Black (1998) and the Effective Public Health Practice Project (EPHHP; Thomas et al., 2004) were both considered, and the Downs and Black (1998) checklist chosen due to its applicability across different study designs.

The final question on the Downs and Black (1998) Checklist was adapted for use within the study. This question related to statistical power ("*Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*") which was changed to ("*Was a power calculation conducted?*"). This change was made to acknowledge that many of the studies included for review were early-stage trials (i.e. small single-arm trials, feasibility studies) which are often not powered sufficiently to make judgements of treatment efficacy. The rewording of this last question allows for studies to be statistically underpowered as long as this is stated, to better aid interpretation of the findings. I found that only four studies conducted and reported a power calculation. Although there is an argument for not

completing a power calculation for feasibility trials (Lancaster et al., 2004), I chose to retain the question as clear reporting aids interpretation.

Inter-rater reliability and test-retest reliability is often poor in quality appraisal (Oremus et al., 2012). In order to overcome this, I enlisted the support of a colleague (Fiona O'Donovan) who was completing a linked project. We completed the quality assessment together for 20% of included papers. Disagreements were discussed with project supervisors and an agreed consistent approach was used for the remainder of the papers that were assessed separately. Inter-rater reliability for the remaining papers rated independently was rated as having 'considerable' agreement (Cohen's Kappa = 0.80).

An important decision was regarding the scoring and reporting of the QA results. One option was to compare studies' score against the total possible for the checklist (28), or to compare it to the total possible for the type of study by removing scores for items that were not applicable (i.e. questions about whether patients were randomised to conditions, when there was only one group in the trial). One represented a strict, absolute measure of quality and the other a more nuanced criterion. I opted to compare attained score against total possible for the type of study as studies such as single-arm trials would have been penalised multiple times (i.e. for not randomising, not blinding, not recruiting both groups at the same time or from the same population), which could have over-emphasised the difference in quality of papers.

2.7 Interpretation of results

Narrative synthesis of the studies that had conducted g-MCT was relatively straightforward; there were differences in population demographics, primary presenting problem, how this was assessed, the primary outcome measure, and how g-MCT was conducted – the number, length, and frequency of sessions, and whether booster sessions were offered. The initial meta-analyses comparing within group effects pre- to post- treatment and pre-treatment to follow-up, and between group effects of g-MCT compared to active controls at both these time points were relatively simple to interpret. The aspect that required most judgement and interpretation, and ultimately caution to not mislead the reader through misrepresentation of findings, was heterogeneity and inconsistency. Heterogeneity is defined as "variability in the intervention effects being evaluated in the different studies […] and is a consequence of clinical or methodological diversity, or both, among the studies" (Higgins et al., 2019, Chapter 10.10.1, para 1). We

found high and statistically significant levels of heterogeneity and high inconsistency in all but one comparisons. This suggested the "intervention effects [were] more different from each other than one would expect due to random error (chance) alone" (Higgins et al., 2019, chapter 10.10.1, para 1). We concluded that further research into the moderating variables of g-MCT could be conducted.

It was challenging to decide on what subgroup analyses should be conducted. We had anticipated at the planning stage that there would be enough studies to assess the results based on presenting problem. Although only two studies are needed for a meta-analysis (Cheung & Vijayakumar, 2016), as some studies did not collect follow-up data, not all categories could be represented at each time point, therefore many of the groups would have been very small and statistically underpowered. We had also considered whether to conduct adult vs non-adult sample comparisons but felt combining one sample of children and one sample of adolescents may not be similar enough to be appropriate to combine. It was decided by the research team that we would only investigate two subgroup comparisons – one based on MCT registration status, and one on follow-up length.

No subgroup comparisons were statistically significant, unsurprising given the small number of studies included and the low statistical power that will have resulted. However, interesting patterns emerged that could help inform future research – there did appear to be a large difference between studies that did and did not have registered MCT therapists on the research team, and one comparison bordered on significance ($p = 0.051$).

2.8 Clinical implications and future directions

Results from the review suggest that g-MCT appears to be acceptable, although better reporting and more consistency with g-MCT provision would allow a more confident appraisal of this. The meta-analysis showed very large uncontrolled pre/post and pre/follow-up reductions in symptoms of both primary and secondary outcome measures in intervention groups receiving g-MCT. There is also preliminary evidence to suggest a superiority of g-MCT against active control conditions. This holds great promise for the application to clinically diverse populations, such as in physical health settings, where people are grouped based on their physical injuries rather than the psychological presenting problem. Should further studies show that g-MCT is an acceptable and

effective group treatment, it could help to reduce pressure on services by offering an efficient use of therapist time and increase patient treatment choice.

3. Paper two: empirical paper
3.1 Developing the research topic

Initially, the aim was to understand how BPRS patients found receiving a g-MCT intervention and what their experiences of it were. However, this was not feasible as it would have resulted in waiting until the end of a linked project and therefore was undeliverable given the time constraints of the thesis. An alternative design and research question was decided upon early in the process. I wanted to pursue the exploration of what type of psychological support might best suit BPRS patients. The aim, therefore, was to explore and understand the psychological experiences of BPRS patients and whether the cognitive and metacognitive models could be applied to their accounts.

3.2 Why the cognitive and metacognitive theories?

The Cognitive model of mental health posits that the content of one's thoughts maintain psychological distress (Beck, 1963, 1964, 1976) through patterns of distorted, or biased, thinking styles. As a result, cognitive therapies aim to challenge the content of thoughts by means such as challenging whether they are realistic concerns and to explore whether there are alternative perspectives to take. Cognitive behavioural therapy (CBT) is unarguably one of the most significant developments in clinical psychology and its efficacy and effectiveness have been proven repeatedly (Butler et al., 2006; Cuijpers et al., 2013; Cuijpers et al., 2019) and much of the National Institute of Clinical Excellence's (NICE) guidelines suggest CBT as the recommended intervention (NICE, 2009; 2018, 2020). It is also considered the gold-standard for treatment by many.

There are potential limitations to applying the cognitive model to the accounts BPRS patients' gave of their psychological experiences post-injury. There is evidence to suggest that while CBT is effective at reducing anxiety and depression in people who also have comorbid physical health conditions, the size of this effect and the margin to which it is superior to control condition appears smaller than those seen in the general population. Most research suggests that CBT may only demonstrate small advantages over control conditions for the reduction of anxiety and depression in people who also have comorbid physical illnesses and injuries (Baumeister et al., 2011; Dickens et al., 2013; Tatrow & Montgomery, 2006; Tully et al., 2021). Some studies do show larger advantages of CBT

over control conditions (e.g. Osborn et al., 2006) but have been criticised for recruiting participants that "may more closely resemble the general population than patients with advanced disease" (Greer et al., 2010, p. 3). Further, Greer et al. (2010) states "classic CBT techniques, such as cognitive restructuring, are inadequate or even inappropriate for patients with realistic fears" (p. 3). McPhillips et al. (2019) found that the content of thoughts of a group of cardiac patients may not be as open to challenge due to there being evidence to support them; worrying thoughts that you may have another heart attack are based on facts that subsequent heart attacks are more likely. The first potential limitation to applying the cognitive model to the accounts of psychological experiences following a BPRS injury is that they too may have a number of concerns based on clinical reality, which may be distressing but not distorted in nature.

The second potential limitation with applying the cognitive model to BRPS patients is that it suggests the content of thoughts is specific to the disorder (the content specificity hypothesis). This has led to the development of problem-specific models for different presentations, such as for generalised anxiety disorder (Borkovec & Costello, 1993; Butler et al., 1987), panic (Beck, 1989; Clark, 1986), social anxiety (Clark & Wells, 1995), health anxiety (Warwick et al., 1996; Warwick & Salkovskis, 1990), PTSD (Ehlers & Clark, 2000), and depression (Beck, 1976). Therapists need to be aware of, trained, and competent in a wide range of interventions to support clients, especially if the client group is clinically diverse. It made sense that a population who are grouped based on physical treatment would result in very different psychological and emotional reactions, suggesting that there could be a wide breadth of presentations within this population. A transdiagnostic approach could be better placed and more efficient in this type of setting.

Instead of focussing on the content of thoughts, the metacognitive theory states that individuals become entangled in a style of thinking characterized by worry, rumination, and inflexible attention that maintains distress (Wells, 2009; Wells, 2019; Wells & Matthews, 1994, 1996). Metacognitive therapy (MCT), can be seen as a transdiagnostic approach and has been shown to be effective in reducing symptoms of anxiety and depression across a wide range of psychological presentations (Normann & Morina, 2018) and in both mental and physical health settings (Fisher et al., 2019; Wells et al., 2021; Wells et al., 2020). Other benefits of MCT include spending less time discussing the content of thoughts, which can be distressing for clients. There is also research to suggest that metacognitive beliefs play an important role in maintaining distress in people with

comorbid physical health conditions (Brown & Fernie, 2015; Capobianco et al., 2020; Cook et al., 2015; Donnellan et al., 2016; Fisher & Noble, 2017; Lenzo et al., 2019; Maher-Edwards et al., 2012).

The metacognitive model could, therefore, have some hypothetical benefits over the cognitive model and thus it made sense to determine whether it was possible to elicit key concepts underpinning each of the models from BPRS patients' accounts of their psychological experiences post-injury.

3.3 Why Burns and Plastics patients?

Despite research showing BPRS patients having high psychiatric morbidity after the event (Bich et al., 2021; Kaminska et al., 2015; Ter Smitten et al., 2011), less is known about models of therapy that might be effective (Cukor et al., 2015). Further, many recommendations for treatment appear to be 'imported over' from mainstream adult services without consideration of specific nuances in the type of distress that this population faces.

3.4 Methodology

Qualitative research is an important aspect of intervention research (O'Cathain et al., 2013) and thus can give valuable insights into which models of understanding may be best suited, and therefore, what models of therapy might be worth exploring. Past qualitative research in this area has investigated the expressions of particular emotions, such as guilt, shame, and blame (Kornhaber et al., 2018), the impact of challenges such as living with visible scars (Jones et al., 2017; Martin et al., 2017), or the manifestation of psychiatric diagnoses in survivors (Macleod et al., 2016). These offer valuable insights into lived experience, but do not inform how to approach the task of supporting the mental health needs of this population.

3.5 Recruitment process

Study participants were recruited from the BPRS Psychology team at Wythenshawe Hospital. In accordance with the ethics application, participants were first approached by a clinician within the BPRS Psychology team to determine whether they would be interested in taking part in research and given an overview of the research projects being offered. Participants could then provide their consent to be contacted by the research team to discuss study participation further. This approach worked well but was not

without limitations. Clinicians were asked to be impartial in their approach to asking potential participants about taking part in research, however this proved an unexpected challenge. Clinicians would report not approaching some patients or deeming others not eligible for the study despite this not being part of their role. I attended weekly team meetings with the BPRS Psychology team to provide information about the study, and any support and guidance to the recruiting team. Clinicians were protective of their patients' rights, often motivated to not approach them about research as they worried the process would be too distressing.

The initial inclusion criteria did not capture all of the people that we had intended. For example, there were people who had experienced a BPRS injury within the psychology service but were not in the process of having active therapy; they tended to be in contact with an outreach or support group. An ethics amendment was made (see Appendix 2.4) to allow this group of patients to be represented within the research. Thus, we clarified and broadened the entry criteria to include anyone "open to the BPRS psychology team" – which included those under the support group, a 'burns camp' group, and people involved in outreach services. These patients gave a longer-term perspective of living with a BPRS injury.

3.6 Feedback from the Community Liaison Group

The study aim required participants to reflect on and discuss their psychological experiences since their event or injury that had required treatment under the BPRS team. We were concerned that this could become distressing for participants and wanted to ensure that this did not become overwhelming or was unnecessarily distressing. We sought feedback from the University of Manchester Community Liaison Group (CLG), a group of mental health service users who offer consultation to the Doctorate training programme. We sent them all participant-facing documents and the interview topic guide. Feedback was positive and the CLG member applauded the construction of a narrative through the interview schedule which should help to alleviate distress – initial questions on medical care set the scene and context, questions about mental health, questions about adjustment and growth, and finally what they have found useful or would like to see implemented in future psychological care offered to people in their position. A distress management protocol was developed; however no escalation was required.

3.7 Interview process
3.7.1 Logistical considerations

The Covid-19 pandemic shaped many aspects of this research. The most significant change was the requirement to conduct all research activity remotely. This meant discussing the study with potential participants over the phone, providing the Participant Information Sheet and Consent Form (see appendix 2.6 and 2.7, respectively) electronically, taking informed consent and holding research interviews using video conferencing software. A plan was developed in the case that face-to-face research was permitted during the course of the research. This plan allowed for personal choice in where the interview could take place (either at an NHS site or at home) as it has been suggested that the location of interviews can substantially change the content of what people discuss (Elwood & Martin, 2000), however this was not possible throughout the course of the research and all interviews were held online. While online interviews were not a first choice, they did allow for greater flexibility in where and when interviews took place. A possible benefit of conducting interviews online is that it increased access to the study for those who would otherwise not have been able or willing to meet somewhere (Saarijarvi & Bratt, 2021), but the necessary IT equipment and internet infrastructure could also have limited participation (Krouwel et al., 2019) – particularly to older or less financially well-off populations (Yoon et al., 2020). On reflection, this could have accounted for some of the lack of representation of marginalised populations in the study.

There were challenges to conducting the research online. The first was the barrier that technology created – the ability to detect non-verbal cues on camera is limited, especially when all that is in shot is the patients head, as is common for videocalls. I ensured that my own camera showed a relatively wide-angle to provide greater context. There was also a risk of the technology failing unexpectedly; while this only happened a few times it interrupted the flow of the conversation. Risk management was another important consideration with conducting the interviews online, which was deemed 'lone working' by the University and thus their lone-worker policy was adopted. The distress management plan also included an escalation procedure which covered the possibility that a client could terminate the call while distressed, although fortunately this was not needed.

3.7.2 Conducting interviews

I was anxious prior to conducting the initial interview. Despite understanding the theory of conducting the interview, I was nervous to put it into practice and worried about either not finding the 'right' information, not knowing what to say, or being met with significant distress. As a result I stuck quite rigidly to the interview schedule in initial interviews, often giving prompts and examples when none were needed. None of the feared events happened, however the first interview was very long and required a second part that was arranged later in the day to ensure we had spoken about all the topics. As the interviews continued, I learnt to trust in the process and in the individual participants to share what was most important to them. As a result, I was able to feel more comfortable asking the broader, more open questions, referring more generally to "feelings since the event" or asking about their "mental health" rather than feeling I had to provide an example or prompt. This allowed people to bring their own language to the interviews and I used this in subsequent questions to gain a deeper understanding of the key elements they brought spontaneously. Despite being an emotionally charged topic, I thoroughly enjoyed the opportunity to listen to people's experiences and was struck by the honesty with which they spoke and the resilience I observed. Research has shown that people take part in qualitative research for a range of reasons, both individual (i.e. introspective or economic interest) and collective (i.e. representation and informing change; Sheridan et al., 2020). I was heartened that despite the topic being sensitive and potentially distressing, several participants thanked me for the opportunity to take part and spoke about how the process had been of benefit to them.

3.7.3 Reflexivity

I attempted to approach interviews with minimal assumptions about what I might find, although this is never truly possible. My previous clinical and research background has been entirely quantitative. Despite my best efforts, I could not shake the feeling that I needed to find an objective truth. This exacerbated a feeling that I did not know what I was doing – something very common within trainee psychologists (Jones & Thompson, 2017). A worry had been that I would not be able to identify the themes from the content, but it was interesting to get a sense of themes emerging as I gathered more perspectives. I was particularly struck at the variety of the content of thoughts – the topics people ruminated on and worried about – but the consistency in the reasons why people engaged in this type of thinking and the common underlying beliefs. I had to be

careful not to become too biased and to be aware of my position and wider context within the research team. It is worth noting that members of the research team were experts in both the cognitive and metacognitive models and included the originator of the metacognitive model and of MCT. I aimed to be as grounded as possible in the narratives of the patients' psychological experiences. Specifying aspects of the cognitive and metacognitive models a-priori helped to maintain an objective position.

I feel it important to acknowledge that I started this research thinking of myself as an outsider looking in (Hellawell, 2006). I do not have personal experience or know of other people who have experience of severe burns or injuries requiring plastic reconstructive surgery. While not known to the research participants, I do have an experience of a close family member experiencing a serious and unexpected medical event which has substantial lasting effects. I have seen the devastating and long-lasting impact a single moment can have on the life of an individual and the network of people around them and am, myself, diagnosed with a condition that could change my life at any time without warning. It was impossible for this to not shape my approach to interviews and my interpretation of the data. I benefitted from the more critical and objective stance that came with being an outsider of the BPRS group, specifically from being able to be better placed to identify biases the group may have (Dwyer & Buckle, 2009). On reflection, I also hope that I benefitted from a specific 'valid acknowledgement' that comes from being an insider (Brannick & Coghlan, 2007). I learnt to recognise that, to an extent, I was occupying 'the space in-between' (Woods, 2019).

3.8 Data analysis

Due to conducting research interviews through video conferencing software, I utilised the built-in transcription function. I had planned to spend time immersing myself within the data by listening back to the recordings and ensuring that the transcription was accurate. I overestimated the capabilities of the transcription and found that, at times, it was a simpler process to transcribe whole sections myself. This process was lengthy and effortful but led to a deeper understanding of the data. I found that listening to the interviews gave space for reflection that was not possible in the moment; identifying the emotions behind what was being spoken about as much as the explicit content and being able to better acknowledge my own emotional reactions.

The analysis and write-up for this study was an iterative process, which I have not been as reliant on in past research. I had to relinquish the use of a linear framework of execute, analyse, write up and come to terms with going back and forth between the data, interviews, and write-up. This process of checking quotes against their wider context, re-coding, and re-naming themes allowed me to determine the best way to present the findings with a narrative that flowed between themes and broader research questions. I read around the process of qualitative research to be aware of some of the common pitfalls. I worried that I was simply writing topic summaries rather than identifying novel themes (Braun & Clarke, 2022). I believe I was able to achieve a balance between inductive themes for research question one and a more deductive and objective approach for research question two.

3.9 Clinical implications and future directions

This study found that the model that underpins a gold-standard treatment of psychological distress, the cognitive model, can be applied to the accounts of psychological experiences BRPS patients describe. There are some theoretical shortcomings in applying this model to clinical practice, that have been noted in similar populations and warrant further research. These are that some concerns raised are based in clinical reality and that there appeared to be some overlap in the problem-specific models that patient talk could be categorised as. Some of these concerns have been addressed in research investigating the adaptations that have been made to CBT to suit this population, however, these adaptations can be resource intensive and the level of individualisation required would make delivering interventions in a group very challenging.

The metacognitive model could also be applied to the psychological experiences described by BPRS patients. There were examples of patient speak characterising all aspects of the CAS and metacognitive beliefs were readily accessed. The CAS could in theory account for the broad range of concerns raised and as thoughts are not routinely challenged in MCT, clinical practice would not require reality-testing. This suggests that MCT may be applicable to BPRS patients and future research should focus on understanding whether MCT is feasible and acceptable, before assessing efficacy at reducing symptoms of depression and anxiety.

4. Reflections

4.1 Reflections on the findings

Although I had completed systematic reviews in the past, this was my first experience of conducting a meta-analysis. I anticipated the process to be relatively straight-forward with a clear set of agreed procedures and analyses. However, the process required more subjective judgements and the analysis itself required more interpretation than I had anticipated. This has made me reflect on meta-analytical procedures and, while I understand why they are at the top of the research evidence pyramid, they are far from fool-proof and require a critical eye to interpret the findings and to determine whether the methodology was suitable and reported findings justified in line with the results.

The process of research in paper two surprised me more than the findings. I thoroughly enjoyed conducting the qualitative interviews and found interpreting the results enjoyable and interesting. I found it difficult to code each section of the interview responses because it was difficult to determine which cognitive distortion best fit a concern. This was frustrating until I realised that it told me something about the model and was, in itself, an interesting piece of data. The metacognitive model was easier to code, and I was genuinely struck by how consistently people reported very similar metacognitive beliefs despite a wide range of content in the worries and ruminations.

4.2 Personal reflections

My involvement in this research project has had a lasting impact both personally and professionally. While I was initially cautious about taking on a qualitative project when I have had no previous experience of this methodology, I am proud that I took it on and am grateful for those around me who supported me through the journey. I believe that many of the skills that are required to conduct high quality qualitative interviews are key to developing a strong therapeutic alliance. I have learnt to step back, allow a reflective space to emerge, and to allow the client the time and space to take the conversation where they need it to go while holding a framework in mind. I have improved my active listening skills and know this will be invaluable to me moving forward as a clinician. The qualitative process, particularly the analysis, has taught me to slow down and notice what is not said, and how something is said, just as much as the content itself. I have found that the skills developed through this research has informed and strengthened my clinical practice, particularly during my specialist placement using Psychodynamic Interpersonal Therapy (PIT).

Supervision has allowed me to be guided but not led, and to develop confidence in my ability to make decisions and follow research through to the end. It has been challenging and there have been times where I have questioned my own ability to see it through. Despite the initial struggles with identifying a topic for my literature review and how to distil the vast amount of information from qualitative interviews, I feel I have created a useful piece of research that contributes to and informs clinical practice.

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Appendix
Appendix 1.1 | Publication Guidelines

Author guidelines for the publication Clinical Psychology Review can be found here

NIHR | National Institute for Health Research

Citation

Joe Taylor-Bennett, Fiona O'Donovan, Lora Capobianco, Adrian Wells. Group metacognitive therapy: a systematic review. PROSPERO 2022 CRD42022311694 Available from:
https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022311694

Review question
What is the evidence that Group Metacognitive Therapy is an acceptable and effective treatment for people presenting with psychological symptoms?

Searches [1 change]

The following databases will be searched: PsycINFO, MEDLINE, PubMed, Embase, CINAHL, Web of Science.

Searches will consist of search terms associated with the following key phrases: "group", "metacognitive", and "therapy".
Search results will be limited to results published in the English language and, where possible, peer-reviewed journal articles.

Types of study to be included
Inclusion: interventional studies that provide a Group MCT intervention to a population of people of any age that present with elevated symptoms of anxiety and/or depression. A number of interventional studies will be acceptable (e.g. randomised controlled trials, feasibility and acceptability trials, benchmarking studies, non-randomised interventional studies, pilot studies etc.

Exclusion: qualitative research, reviews (e.g. systematic reviews or meta-analyses), grey literature (dissertations/theses not published in a peer-reviewed academic journal), studies published in a language other than English, studies not reporting original data on delivering a Group MCT intervention.

Condition or domain being studied
Improvements in psychological symptoms or wellbeing; the exact outcome measure reported may differ from study to study due to the potential for a range of presenting problems being treated. The most relevant outcome measure to the presenting psychological problem being treated will be selected. An effect size will be reported where available and one calculated were possible.

Participants/population
Inclusion: any group of individuals of any age that present with elevated symptoms of anxiety and/or depression who have been offered Group MCT (or are within a control arm).

Exclusion: Any non-clinical population (i.e. not presenting with elevated symptoms of anxiety and/or depression) or a population presenting with another primary concern (i.e. psychosis).

Intervention(s), exposure(s)
Inclusion: Group Metacognitive Therapy (Group MCT) as developed by Adrian Wells

Exclusion: Individual MCT, any element of MCT that are being examined in isolation (i.e attentional training).

Comparator(s)/control

A control group is not a necessary requirement for inclusion within this review, it will include any study that

offers Group MCT to a group of people who present with elevated symptoms of anxiety and/or depression. Where a control group is included, there are no restrictions on what this could be and could include waiting list controls, benchmark data, treatment as usual, or another intervention.

Main outcome(s)

The main outcome for the review will be the treatment effect size between pre- and post-treatment (or follow-up) using the outcome measures used within the studies included for review. There will not be a pre-specified list of accepted outcome measures but is likely to consist of measures of psychopathology such as the Beck Depression Inventory, the Penn State Worry Questionnaire, the Hamilton Anxiety and/or Depression Scale, etc. This will be guided by the most relevant measure for the presenting problem being treated.

Measures of effect

Hedges g will be utilised as an effect size measure - similar to Cohen's d it is based on the standardised mean difference, but applies a correction factor for small samples.

Additional outcome(s)
Not applicable

Data extraction (selection and coding) [1 change]

Following the systematic search of the pre-defined databases, JTB will screen the article titles/abstracts and make judgements against the inclusion/exclusion criteria. Following this, JTB will retrieve and review the full texts of the remaining articles and make a judgement against the inclusion/exclusion criteria. Any uncertainty will be discussed with the rest of the research team to reach a conclusion. All articles deemed to be included in the review will be discussed with the research team and any discrepancies of opinion will be resolved by AW.

For each included study, the following information will be extracted where available:

• author, date published, DOI

• study aims/hypotheses

• study design

• psychological disorder treated

• comparison conditions (if applicable)

• sample characteristics (i.e. size, gender distribution, mean age, co-morbidity information)

• intervention information (i.e. number and length of therapy sessions, size of therapy groups, drop-out rates at the end of the intervention, attendance statistics)

• follow-up time from the end of the intervention (if applicable),

• statistical procedures used to analyse data,

• primary outcome measures (deemed as most relevant for presenting disorder treated),

• key findings (e.g. effect size of intervention)

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• means and standard deviations for pre- and post-treatment and any follow-up time points, where applicable.

Risk of bias (quality) assessment

If appropriate and possible, the GRADE approach will be used to make a judgement about the overall quality of the evidence base. Quality of individual papers will be assessed using a tool such as the Risk of Bias tool developed by The Cochrane Collaboration, or the EPHPP Quality Appraisal Tool for Quantitative Studies.

Strategy for data synthesis [1 change]

A narrative review of the findings of the review will be conducted. This will consist of information summarising study characteristics, patient characteristics, information pertaining to the deliverance of Group Metacognitive Therapy (e.g. number of sessions, length of sessions, number of attendees, etc), outcome variables, follow-up, quality assessment, treatment effects (e.g. within-group effect sizes).

If possible and appropriate, a random-effects model meta-analysis will be conducted. To be included in any such meta-analysis, studies would have to utilise a randomised-controlled design to account for confounding variables which would not be controlled for in observational or quasi-experimental design studies. Between-group effect sizes will be calculated for the primary outcome measure between the Group MCT condition and a waitlist control or active treatment control (at end of treatment and at longest follow-up time available) respectively; these would be analysed separately. Hedges g will be used for effect sizes and values of 0.2, 0.5, and 0.8 will be used to indicate a small, medium, or large effect. If there are a small number of studies, a discussion will be held with the wider research team to determine whether a meta-analysis is appropriate to conduct. Similarly, discussions on inclusion into a meta-analysis will be held to determine whether to include any pilot study or acceptability/feasibility trial which utilised a randomised controlled design as these studies may not

Where there are a minimum of 10 studies available which allow for any between group effect size calculations, publication bias will be investigated using visual inspection of funnel plots (looking for asymmetry indicative of publication bias and heterogeneity will be calculated using the I² statistic, where 25, 50, 75% interpreted as referring to low, moderate and high levels of heterogeneity (Higgins et al., 2019). If a meta-analysis is possible and appropriate,

Analysis of subgroups or subsets

If appropriate and possible, subgroup analyses will be conducted. This could consist of subgroups of populations (e.g. studies conducted in children, adolescents, and adults), and presenting complaint (e.g. transdiagnostic studies, depression, generalised anxiety disorder).

Contact details for further information

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Organisational affiliation of the review

The University of Manchester

Review team members and their organisational affiliations

Mr Joe Taylor-Bennett. The University of Manchetser
Dr Fiona O'Donovan. University of Manchester; Greater Manchester Mental Health NHS Foundation Trust
Dr Lora Capobianco. University of Manchester; Greater Manchester Mental Health NHS Foundation Trust
Professor Adrian Wells. University of Manchester; Greater Manchester Mental Health NHS Foundation Trust

Type and method of review

Meta-analysis, Narrative synthesis, Systematic review

Anticipated or actual start date

27 February 2022

Anticipated completion date

30 September 2022

Funding sources/sponsors

This review is being conducted as part of a Clinical Psychology Doctorate (ClinPsyD) program at the University of Manchester. No funding or sponsorship has been obtained for this review specifically.

Conflicts of interest

Language
English

Country
England

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Cognitive Behavioral Therapy; Humans; Metacognition

Date of registration in PROSPERO
24 February 2022

Date of first submission
18 February 2022

Stage of review at time of this submission [4 changes]

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
24 February 2022
02 March 2022

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11 March 2022
01 April 2022
19 June 2022

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Appendix 1.3 | Search strategy

#	Query	Results
	APA PsychInfo	
1	metacognitive	9236
2	meta cognitive	826
3	therapy	458778
4	trial	119600
5	treatment	738164
6	psychotherap*	206831
7	intervention	309097
8	group	682254
9	1 OR 2	9868
10	3 OR 4 OR 5 OR 6 OR 7	1228299
11	8 AND 9 AND 10	743
12	limit 11 to english language	667
13	limit 12 to peer reviewed journal	454
	OVID MEDLINE	
1	metacognitive	2657
2	meta cognitive	233
3	therapy	5343214
4	trial	1218387
5	treatment	4773987
6	psychotherap*	90530
7	intervention	614351
8	group	2749268
9	1 OR 2	2860
10	3 OR 4 OR 5 OR 6 OR 7	8293238
11	8 AND 9 AND 10	315
12	limit 11 to english language	306
	Embase	
1	metacognitive	4017
2	meta cognitive	420
3	therapy	8563790
4	trial	2367485
5	treatment	7663743
6	psychotherap*	116283
7	intervention	1116853
8	group	4424711
9	1 OR 2	4340
10	3 OR 4 OR 5 OR 6 OR 7	13081818
11	8 AND 9 AND 10	602
12	limit 11 to english language	567
13	limit 12 to (article OR article in press)	392

	CINAHL Plus	
1	metacognitive	1,425
2	meta cognitive	129
3	therapy	1,558,933
4	trial	255,361
5	treatment	1,207,821
6	psychotherap*	43,910
7	intervention	320,368
8	group	663,911
9	1 OR 2 OR 3	1,535
10	4 OR 5 OR 6 OR 7 OR 8	2,368,988
11	9 AND 10 AND 11	202
12	Limit 11 to: English language	186

	PubMed	
1	Metacognitive	3,626
2	meta cognitive	302
4	therapy	5,711,045
5	trial	1,322,573
6	treatment	5,432,891
7	psychotherap*	135,783
8	intervention	743,876
9	group	3,437,340
10	1 OR 2	3,631
11	3 OR 4 OR 5 OR 6 OR 7 OR 8	9,291,534
12	9 AND 10 AND 11	451
13	Limit 12 to English language	443

	Web of Science	
1	metacognitive	10,281
2	meta cognitive	1,263
4	therapy	2,839,002
5	trial	1,305,106
6	treatment	5,439,869
7	psychotherap*	180,602
8	intervention	903,162
9	group	4,090,309
10	1 OR 2 OR 3	11,302
11	4 OR 5 OR 6 OR 7 OR 8	8,352,427
12	9 AND 10 AND 11	818
13	Limit 12 to English AND published articles	708

Checklist for measuring study quality

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
   If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described ?*
   In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*
   Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
   A list of principal confounders is provided.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*
   Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
   In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
   This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*
   This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

yes	1
no	0

External validity
All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
   The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. *Was an attempt made to blind study subjects to the intervention they have received ?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls ?*
Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*
Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

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For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
    For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
    For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*
    Studies which state that subjects wererandomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
    This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*
    If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
    Sample sizes have been calculated to detect a difference of x% and y%.

	Size of *smallest* intervention group	
A	$<n_1$	0
B	n_1-n_2	1
C	n_3-n_4	2
D	n_5-n_6	3
E	n_7-n_8	4
F	n_8+	5

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Appendix 1.5 | Full quality appraisal data

Quality assessment scores according to the Downs and Black (1998) Checklist

Study	Reporting										External validity			Internal validity - bias							Internal validity - confounding						Power	Overall[b]
	1	2	3	4	5[a]	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Rees and Koesveld 2008	1	1	1	1	1	1	1	0	0	1	1	NK	NK	0	0	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Fair
van der Heiden et al 2013	1	1	1	1	1	1	1	0	0	1	1	NK	NK	0	0	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Fair
Dammen et al 2015	1	1	1	1	1	1	1	0	1	1	1	NK	NK	0	0	1	1	1	1	1	NA	NA	NA	NA	1	1	1	Good
McEvoy et al 2015	1	1	1	1	1	1	1	0	0	1	NK	NK	1	0	NK	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Fair
Papageorgiou and Wells 2015	1	1	1	1	0	1	1	0	1	1	1	NK	NK	0	NK	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Fair
Zemestani et al 2016	1	1	1	1	1	1	1	0	1	1	0	NK	NK	0	NK	1	1	1	1	1	1	NK	1	NK	1	1	0	Fair
Capobianco et al 2018	1	1	1	1	2	1	1	1	1	1	1	NK	NK	0	NK	1	1	1	1	1	1	1	1	0	1	1	0	Good

Study																													Rating[b]
Esbjørn et al 2018	1	1	1	1	1	1	1	0	1	0	NK	NK	NK	0	1	1	1	1	0	1	NA	NA	NA	NA	1	1	0	Fair
Papageorgiou et al 2018	1	1	1	1	2	1	1	0	0	1	1	1	1	0	NK	1	NA	1	1	1	1	0	0	0	1	1	0	Fair
Callesen et al 2019	1	1	1	1	1	1	1	0	0	1	1	NK	1	0	NK	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Good
Ferraro et al 2019	1	1	1	1	1	1	1	0	0	1	NK	1	1	0	NK	1	1	1	1	1	NA	NA	NA	NA	0	1	0	Fair
Haseth et al 2019	1	1	1	1	1	1	1	0	0	1	1	NK	1	0	NK	1	1	1	1	1	NA	NA	NA	NA	1	1	0	Good
Wenn et al 2019	1	1	1	1	2	1	1	0	0	1	NK	0	1	0	NK	1	1	1	0	1	1	1	1	NK	1	1	1	Good
Thorslund et al 2020	1	1	1	1	0	1	1	0	0	0	0	0	1	0	NK	1	1	NA	1	1	NA	NA	NA	NA	NA	1	0	Fair
Wells et al 2021	1	1	1	1	2	1	1	1	0	1	1	NK	NK	0	1	1	1	1	1	1	1	1	1	1	1	1	1	Good
Zahedian et al 2021	1	1	1	0	2	1	1	0	1	1	NK	NK	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	Good

All questions scored 0 (does not meet criteria) or 1 (meets criteria), NK = not known or not able to determine, NA = not applicable except where indicated otherwise; a = question was scored 0 (does not meet criteria), 1 (partially meets criteria), 2 (meets criteria); b = overall rating according to proportion of total score of applicable questions: Poor (0-53%), Fair (54-70%), Good (71-92%), Excellent (93-100%)

Appendix 1.6 | PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	11
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	12
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	13/14
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	14
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	15
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	14
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	14, 123/124
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	15
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	15
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	15
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	15
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	15/16
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	16/17
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	16/17
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	16/17
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	16/17
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	16/17
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	17
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	17
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	15/16
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	15/16

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	17/18
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	18/19
Study characteristics	17	Cite each included study and present its characteristics.	22-24
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	32, 128/129
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	22-24
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	32
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	33-41
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	40/41
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	40
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	32
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	33/34
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	46-50
	23b	Discuss any limitations of the evidence included in the review.	49
	23c	Discuss any limitations of the review processes used.	49
	23d	Discuss implications of the results for practice, policy, and future research.	50
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	14, 118-122
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	118-122
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	NA
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	6/7
Competing interests	26	Declare any competing interests of review authors.	6/7
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	NA

Appendix 2.1 | Publication guidelines

Author guidelines for the publication Journal of Health Psychology can be found here

University of Manchester
Clinical Psychology Doctorate

Large Scale Research Project
PROPOSAL SUBMISSION PROFORMA

Trainee name: Joe Taylor-Bennett

Title of project: Qualitative analysis of emotional distress in burns and reconstructive surgery patients from the perspectives of Cognitive Behavioural and Metacognitive theories

Is this LSRP linked to another LSRP?   **Yes**

If so, please provide name(s) of other trainee(s):

Fiona O'Donovan

Primary academic supervisor: Prof. Adrian Wells
Other academic supervisors: Dr. Lora Capobianco
NHS Clinical Collaborators: Dr. Julie Wisely

Statement on minimum standards expected for a ClinPsyD thesis:

a.   *The research thesis is expected to be an original piece of empirical work of relevance to clinical psychology, demonstrating the candidate's ability to apply scientific principles and undertake rigorous investigation. It should be of a **quality** comparable to publications within peer-reviewed professional / academic journals, make a distinct **contribution** to the knowledge of the subject and show evidence of **originality**.*

b.   *The work done for the thesis must not have been submitted in fulfilment of the requirements of any other degree, and it must be the candidate's own work. If the candidate is working in a team or analysing previously collected data the candidate's personal contribution must be substantial and clearly defined. The criterion of acceptability is that the candidate is making a substantial independent contribution to the study. Although research supervisors are required to offer guidance and advice to trainees throughout, ultimate responsibility for decisions relating to the conduct and completion of this work rests with the trainee.*

c.   *The ClinPsyD programme supports a pluralistic approach to research. The candidate is free to choose from a range of approaches and paradigms as long as the research methods are appropriate to the research questions or hypotheses being investigated.*

Checklist for submission with proforma

- Letters of support from service leads/managers (NOT clinical collaborators unless they have the authority to confirm local approval and access to potential participants) indicating willingness to support research where recruitment involves input from external agencies (e.g., clinical services, charitable organisations, schools etc.)
  - Appendix 1
- Interview schedule
  - Appendix 2

BRIEF SUMMARY OF PROPOSAL IN LAY TERM

Please provide a summary of the proposed study including background information, aims, methods and implications in lay terms.
276/300 words maximum. Please include measures of readability (e.g., Flesch Indices.)

Painful and disfiguring injuries can be the result of burns or surgery to remove cancer. They can be serious, unexpected, and require repeated medical treatment. These injuries can have a negative effect on a person's mental health. Anxiety, low mood, and trauma are common difficulties. A quarter to two-thirds of burns and plastics patients require mental health support.

There are different types of mental health support for burns and plastics patients. The most common is cognitive behavioural therapy (CBT). CBT may not be that effective for patients who experience distress after a physical injury. New and more effective therapies are needed. One promising therapy is Meta-cognitive therapy (MCT). MCT is a recent, evidenced-based, therapy. It has shown to be effective in mental health settings.

MCT has not yet been applied to burns and plastics patients so we don't know if it is suitable for these people. The first step is to understand the emotional distress that these patients experience. We can then compare how well CBT and MCT models explain this distress.

This research will recruit burns and plastics patients who are referred to a psychology service. They will be seeking support for the distress causes by their injuries. These people will be invited to an interview. Interviews will last approximately an hour.

The study will help us to understand peoples' mental health after a physical injury. It will inform which model best explains their distress. It will help with knowing if MCT might be useful for these people. MCT could then be tested to see if it reduces distress for these people. This might lead to new treatments for patients with burns and physical injuries.

Flesch readability score: 60.1

INTRODUCTION / SUMMARY OF CONTEXT
Provide a brief summary of the relevant literature.

397 /400 words maximum

Painful and disfiguring injuries (i.e. burns, surgical removal of cancer) can have a negative effect on a person's mental health. They can be serious, unexpected, require repeated medical treatment, and are associated with increased anxiety, low mood, and trauma. Wisely et al (2007) screened 57 consecutive patients admitted to a UK regional burn centre and found that 63% required some level of psychological input following a burn injury. In addition to burns, patients with disfiguring injuries that require reconstructive plastic surgery such as surgical removal of cancerous tissue experience significant psychological distress. Kaminska et al (2015) found that rates of depression and anxiety in women were around 38% following mastectomy, and this was significantly higher than in women who had received non-surgical interventions.

The need for routine screening and psychological input throughout hospital care and through community services is highlighted as a necessary aspect of care (British Burns Association 2018; NICE, 2018), however, there are no specific recommendations for treatment. CBT is widely offered within the NHS and is likely to constitute much of the treatment. However, CBT has shown to have limited efficacy in treating psychological distress in patients with physical injuries. One reason may be that CBT requires patients to distinguish between realistic and unrealistic thoughts - something that becomes difficult when thoughts relate to diagnosed physical health problems (McPhillips et al., 2019).

One treatment that may be better suited at treating psychological distress in patients with physical injuries is metacognitive therapy (MCT; (Wells, 2009). MCT focusses on transdiagnostic processes that maintain psychological distress and has been shown to be more effective at treating anxiety and depression than CBT in mental health settings (Normann & Morina, 2018). MCT is being evaluated in physical health settings with promising outcomes (Fisher et al., 2019; Wells et al., 2018). For example, Fisher et al. (2019) evaluated MCT in a population of adult cancer survivors experiencing emotional distress and found that 52% of patients met criteria for recovery 6 months post-treatment.

MCT has not yet been investigated in patients with burns and physical injuries. As such, the aim of the current study is to explore the emotional distress of burns and plastics patients referred to a psychology service to understand whether the CBT or MCT theoretical framework

better conceptualises this and to provide service-user data that can be used to support subsequent trials of MCT with this client group.

CONTRIBUTION TO BE MADE BY THE PROPOSED RESEARCH
What is the gap in the literature that the proposed research aims to address?
*What **novel** and **significant** contribution to the knowledge base would be made by your proposed research?*

190/250 words maximum

MCT has been shown to be superior to CBT in mental health settings (Normann & Morina, 2018), and has been shown to be an acceptable treatment in physical health settings (Fisher et al., 2019; Wells et al., 2018). This research would be the first time that the MCT conceptual framework has been applied to the emotional distress of people who have experienced significant injuries or required reconstructive plastic surgery.

This study will investigate the experiences of burns and plastics patients in order to understand their emotional distress and determine which theoretical framework best conceptualises this. O'Cathain and colleagues (2013) highlight the importance of using qualitative methods to assess the "fit" between theory and interventions. Recently, this method has been applied to a population of cardiac rehabilitation patients with the finding that MCT offers a superior fit over CBT in conceptualising emotional distress (McPhillips et al., 2019).

This research is the first step in understanding how MCT might help conceptualise emotional distress in a burns and plastics population. The approach could potentially see more effective care and more time- and cost-effective solutions due to the group and transdiagnostic format of treatment.

147

AIMS AND RESEARCH QUESTIONS OF THE EMPIRICAL STUDY

Briefly state the principal and subsidiary aims of the research and the research questions to be investigated

51/150 words maximum

Principal aim

To understand the emotional distress experienced by burns and plastics patients.

Subsidiary aim

To understand how the CBT and MCT theoretical frameworks map onto the emotional distress of burns and plastics patients, and which gives a better "fit" to inform which may be beneficial as a choice for intervention.

STUDY DESIGN

Provide an outline of the design to be used (e.g. correlational, group comparison, etc.), stating dependent/target and independent/predictor variables where appropriate

54/100 words maximum

This study is a qualitative evaluation of patients' emotional distress following burn injuries and/or plastic reconstructive surgery.

Burns and plastics patients who are referred to the psychology service working within a burns centre and identifying themselves as needing support with emotional distress following a burn injury and/or reconstructive surgery will be invited to interview.

STUDY HYPOTHESES

State, in formal terms, the hypotheses to be tested and how these relate to the research aims

53/200 words maximum

This is an exploratory study so there are no hypotheses. The main study questions are: 1) what is the nature of psychological distress experienced by burns and plastics patients; 2) What are the psychological needs identified by these patients; 3) How are distress and needs explained by the CBT and the MCT models.

PARTICIPANTS

Describe the types of participants (service users or students, age and sex ratios if appropriate, inclusion / exclusion criteria). Provide an estimate of the number of eligible, potential participants who would have to be screened in order to attain your sample size, accounting for any possible drop outs. Please explain what these estimates are based upon, and justify any calculations provided.

147/300 words maximum

This study will recruit burns and reconstructive surgery patients who are referred to psychology due to their emotional distress.

Participants will have sustained an injury requiring treatment from either burns or plastics services at Wythenshawe Hospital, will be help-seeking, and been referred to the psychology team.

Inclusion criteria:

- Outpatients at the Adult Burns Centre in Wythenshawe Hospital;
- Age 16 or older (in line with normal clinical practice of the burns service);
- At least one month since the occurrence of the injury;
- A competent level of English language skills (able to read, understand and complete questionnaires in English).

Exclusion criteria:

- Cognitive impairment which precludes informed consent or ability to participate;
- Acute suicidality;
- Active psychotic disorders;
- Current drug or alcohol dependence;
- Individuals engaging in active deliberate self-harm;
- Dementia or learning difficulties;

- Concurrent psychological intervention for emotional distress.

There will be no restrictions based on the size of the injury.

RECRUITMENT STATEGY
Describe the proposed recruitment strategy.

154/300 words maximum

Potential participants will be recruited from burns and reconstructive surgery patients who are referred to the psychology department at Wythenshawe Hospital. Patients on any existing waiting list will also be approached for participation.

The psychology team receives referrals from the Wythenshawe Burns Centre and the plastic surgery team (including surgeons, junior doctors, nurses, and physiotherapists). The referrals are for outpatients of the burns and plastics service at Wythenshawe Hospital who the clinician feels would benefit from an assessment of psychological and support needs, generally following a traumatic accident or injury. The patient may be experiencing psychological distress as a result of the accident or injury, or have difficulties related to body image adjustment given a change in appearance or function.

A feasibility and acceptability study of group MCT is recruiting from the same population – any potential participants for this study will be approached to take part in this study, prior to any psychological intervention.

POWER CALCULATION/EXPECTED NUMBER OF PARTICIPANTS
Please describe your power or sample size calculation, or the expected number of participants if qualitative research.

91/150 words maximum

The psychology department within the Burns Centre at Wythenshawe Hospital normally has a waiting list of around 3-4 months and receives around 10 new referrals a month from the burns and plastics teams. While this is disrupted due to the Covid-19 pandemic, it is expected to return to normal by the time recruitment for this study begins.

We anticipate that 10-15 participants will be required to obtain a range of views. Recruitment will continue until data saturation has been reached, defined as when no further themes are observed in additional interviews.

MEASURE(S)
List the measures that will be used in the study, the rationale for using them, any validation work that may be required and any training required to use them.

13/400 words maximum

An interview schedule has been developed to guide the interview. See Appendix 2.

PROCEDURE
Describe the study procedure, in replicable detail.

329/400 words maximum

Once all relevant ethical authorisations are in place, recruitment will begin. Eligible individuals will be provided with participant information sheets outlining the purpose of the research, any potential risks and benefits of taking part, information about data collection, management, and storage, and researcher contact details. Informed consent will be gained from participants using a consent form. This information will be provided in person, emailed or via the post depending on individual preference. If working remotely, a teleconferencing or telephone appointment can be arranged to discuss the study and provide relevant information and forms. Confidentiality, and the limits of confidentiality, will be discussed at this stage and throughout.

A convenient date, time, and location will be agreed upon for the interview to take place. This will be a private location to ensure confidentiality and ideally a neutral setting such as University.

The interview topic guide will be followed to guide the interview, although allowing space for new, important topics to emerge as relevant. The interview will be audio recorded on an encrypted device and participants will be allocated a unique identifying code should they wish to withdraw consent.

The interview will be transcribed by the researcher as soon after the interview as possible to allow analysis to occur alongside subsequent interviews. Interviews will continue to the point of data saturation and the topic guide will be updated alongside interviews.

Taking part in this research will involve discussing emotional distress and emotionally difficulty and sensitive information. The wellbeing of participants is paramount and will be discussed in advance of the interview as well as monitored throughout. Procedures for dealing with distress occurring within the interview will be outlined in the study protocol and will outline when to stop the interview and having services to signpost to for support. Should any concerns about safety occur, confidentiality may have to be broken to safeguard the safety of the participant - this would be discussed in advance at the time of gaining informed consent.

DATA ANALYSIS

Provide an outline of the procedures to be used in data analysis in relation to each hypothesis/aim.

148/400 words maximum

Data will be analysed in line with previous studies of this nature, for example McPhillips and colleagues (2019) who conducted a similar study with cardiac patients. Interviews will consist of open questions with follow-up closed questions to probe and clarify responses. Interviews will be audio-recorded and transcribed verbatim.

Analysis will follow the principle of template analysis (Crabtree & Miller, 1992) with main principles of CBT and MCT providing a template. For CBT, Negative Automatic Thoughts, cognitive distortions, and negative core beliefs will be identified and code (Beck, 1979). MCT will focus on coding elements of perseverative thinking such as worry and rumination, as well as metacognitive beliefs. Rather than using the analysis to further develop these principles, the analysis will be with the aim to assess the "fit" of each therapeutic model – whether CBT or MCT could better explain the emotional distress that burns and plastics patients describe.

DIFFICULTIES

Please include a list of the potential challenges or difficulties that this research presents you with and describe how these will be managed. Include practical pitfalls and potential confounds.

204/300 words maximum

Potential difficulty: Recruitment could be lower or slower than anticipated. This could occur due to process delays (such as gaining appropriate ethical approval) or finding that fewer people are opting into the study after being referred to the psychology team. Either scenario could leave inadequate time or insufficient numbers of people for qualitative interviews following the group MCT intervention.

Proposed solution: In response to the above difficulty, recruitment could shift from relying on referrals to the psychology team to active advertisement of the study. This could include posters advertising the study being shown in communal areas of relevant hospital departments. Advertising would aim to recruit anyone who was experiencing psychological difficulties following a burns injury or plastic reconstructive surgery, regardless of whether they had been referred to the psychology team. The remaining eligibility criteria would still apply.

Potential difficulty: Due to the Covid-19 pandemic, it is possible that qualitative interviews are not able to take place in person.

Proposed solution: Qualitative interviews would take place over teleconferencing software such as Zoom or Microsoft Teams. Careful considerations will be made with regard to adapting the protocol and procedures to account for differences with online/remote working (e.g. managing safety/distress remotely; procedure for internet cutting out etc.).

CONTINGENCY PLAN

Include details of contingency plan and when this would be implemented (i.e. stop-go criteria for main study and dates this will be determined). More detailed contingency plans would be required for 'high-risk' projects, e.g. recruiting from 'difficult to engage' populations. Please note that the contingency plan should have a revised research question and alternate design to the original study. The contingency plan must contain more than recruitment extensions for the original study.

276/300 words maximum

The Covid-19 pandemic has had a number of direct and indirect implications for this research project. First, the impact on the number of people who are experiencing burn injuries and the number of people involved in accidents requiring reconstructive surgery has reduced significantly in line with a reduction in the number of people in work and travelling regularly. Second, outpatient clinics at Wythenshawe Hospital were cancelled and staff redeployed, disrupting existing referral pathways and the professional connections which maintained these. This is beginning to return and the psychology team are rebuilding and reinstating referral pathways. Discussions with NHS clinical collaborators suggest that the expectation of recruiting 10-15 patients is feasible. Recruitment is planned to commence in January 2021 (pending ethical approval) and run through to September 2021. Recruitment rates will be monitored closely, and the following contingency plans enacted if 5-10 people are recruited for interview by September 2021:

- Recruitment to shift from psychology referrals to any burn and reconstructive surgery patient who is actively help-seeking. The study could be actively advertised in public areas of the relevant departments and professional connections will be made with relevant clinical staff in these departments
- Recruitment can be extended to December 2021, giving an additional three months of recruitment.

If by September 2021, fewer than 5 people have been recruited for the study, the following contingency plans will be implemented:

- Existing interviews will be analysed using Interpretive Phenomenological Analysis (IPA), which offers a very rich account of individual's experience of an event, and requires fewer participants
- The research question will narrow to exploring the individuals' experience of their burn injury or reconstructive surgery and their psychological distress following this.

COSTS

Estimate the research costs (e.g., cost of tests/measures, travel, photocopying, service user consultation costs, foot pedals, recorders etc.) and provide an itemised budget. All trainees have an allocated budget of £400 for their LSRP. Sums slightly larger than this can be requested if justified, but these are at the discretion of the Research Sub-Committee and cannot be guaranteed. Trainees should therefore ensure that a meaningful project can still be conducted should funding be limited to £400.

88/300 words maximum

Expenditure	Cost
Trainee travel *(to be covered by trainee)*	--
Participant reimbursement for qualitative interviews (15-20 interviews x £10)	£150-200
Voice recorder (e.g. Olympus LS-P4)	£114
BPS DCP conference attendance	£49
Total	**£<400**

PATIENT AND PUBLIC INVOLVEMENT (PPI)
Describe the potential utility and benefit of the proposed research project to service users and their supporters. If you have had any discussion or consultation with service users, please describe these activities and how exactly they have informed your proposal. Please describe any PPI throughout the research process.

264/400 words maximum

The proposed research project will have utility for key stakeholders. The greatest benefit may be seen for individuals in emotional distress following a burn injury or plastics treatment. If the group based MCT intervention is feasible and acceptable, future research could determine how effective this intervention is in this population. This has the potential to alleviate psychological distress within a cohort that may have sustained traumatic and life-altering and injuries. A reduction in psychological suffering within this group could also have a knock-on beneficial effect on patients' family members and carers. Further, from a services perspective, this group MCT program could allow more individuals to receive psychological input in a more time- and cost-effective manner than the currently prevalent one-to-one therapeutic interventions. In that vein, this intervention could reduce waiting lists and waiting times for patients.

Consultation for the proposed study had been sought from the University of Manchester's Community Liaison Group (CLG).

Due to the recent developments with Covid-19, the possibility of timely liaison with the University CLG group is unlikely. This will be pursued and may have to occur via videoconferencing and at a later date than was intended. The further down the line with regards to conducting the research, the more limited impact discussions can have on shaping design, procedure, and documents. Liaison will be pursued in alternative methods of communication with the CLG, for example email or video conferencing.

Liaison will be sought from an increased number of sources, such as:
- Manchester Burns Advisory Group
- Peer Support Programme based at Wythenshawe Burns Centre
- Katie Piper Foundation
- Dans Fund for Burns

DISSEMINATION STRATEGY

Please outline your plans to disseminate the findings from your research including dissemination via academic publications and conferences AND to wider stakeholders such as clinicians, service users and/or the wider public.

79/300 words maximum

The dissemination strategy will be as follows:

- Publication of systematic review and empirical study in academic journals.
- Presentation of findings at in-house postgraduate research conference.
- Presentation of findings at relevant conferences attended by the researcher, academic supervisors or clinical collaborators (e.g. BPS DCP conference).
- Findings disseminated amongst relevant third sector organisations (e.g British Burns Association) with plain language summaries.
- A lay summary of the findings will be provided to all participants who volunteered to take part in the study.

KEY REFERENCES

Provide up to 10 (max) key references

British Burns Association. (2018). *National Burn Care Standards and Outcomes 1st Edition*. Retrieved from https://www.britishburnsassociation.org/wp- content/uploads/2018/11/BCSO-2018-FINAL-v28.pdf

Beck, A. T. (1979). *Cognitive therapy and the emotional disorders*. Penguin.

Crabtree, B. F., & Miller, W. F. (1992). A template approach to text analysis: developing and using codebooks.

Fisher, P. L., Byrne, A., Fairburn, L., Ullmer, H., Abbey, G., & Salmon, P. (2019). Brief metacognitive therapy for emotional distress in adult cancer survivors. *Frontiers in psychology*, *10*.

Kaminska, M., Kubiatowski, T., Ciszewski, T., Czarnocki, K. J., Makara-Studzińska, M., Bojar, I., & Staroslawska, E. (2015). Evaluation of symptoms of anxiety and depression in women with breast cancer after breast amputation or conservation treated with adjuvant chemotherapy. *Annals of Agricultural and Environmental Medicine*, *22*(1).

McPhillips, R., Salmon, P., Wells, A., & Fisher, P. (2019). Qualitative Analysis of Emotional Distress in Cardiac Patients From the Perspectives of Cognitive Behavioral and Metacognitive Theories: Why Might Cognitive Behavioral Therapy Have Limited Benefit, and Might Metacognitive Therapy Be More Effective? *Frontiers in psychology*, *9*, 2288.

Normann, N., & Morina, N. (2018). The efficacy of metacognitive therapy: a systematic review and meta-analysis. *Frontiers in psychology*, *9*, 2211.

O'Cathain, A., Thomas, K., Drabble, S., Rudolph, A., & Hewison, J. (2013). What can qualitative research do for randomised controlled trials? A systematic mapping review. *BMJ open*, *3*(6).

Wells, A. (2009). *Metacognitive therapy for depression and anxiety*. Guilford Press.

Wells, A., McNicol, K., Reeves, D., Salmon, P., Davies, L., Heagerty, A., Doherty, P., McPhillips, R., Anderson, R., & Faija, C. (2018). Improving the effectiveness of psychological interventions for depression and anxiety in the cardiac rehabilitation pathway using group-based metacognitive therapy (PATHWAY Group MCT): study protocol for a randomised controlled trial. *Trials*, *19*(1), 215.

Wisely, J., Hoyle, E., Tarrier, N., & Edwards, J. (2007). Where to start?: Attempting to meet the psychological needs of burned patients. *Burns*, *33*(6), 736-746.

Appendix 2.3 | Study approval documentation

2.3.1 NHS Ethics approval letter

NHS
Health Research
Authority

North West - Greater Manchester Central Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 1048 007

> **Please note:** This is an
> acknowledgement letter from the REC
> only and does not allow you to start
> your study at NHS sites in England
> until you receive HRA Approval

01 April 2021

Professor Adrian Wells, Professor of Clinical & Experimental Psychopathology
University of Manchester
Oxford Road
Manchester
M23 9LT

Dear Professor Adrian Wells

Study title:	**Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories**
REC reference:	21/NW/0050
Protocol number:	N/A
IRAS project ID:	289258

Thank you for your letter of 26 March 2021. I confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 March 2021.

Documents received

The documents received were as follows:

Document	Version	Date
Interview schedules or topic guides for participants [Interview schedule]	2	26 March 2021
Other [Distress Management]	2	26 March 2021
Other [Summary of HRA and REC amendments]	1	26 March 2021
Participant consent form [Consent Form]	2	26 March 2021
Participant information sheet (PIS) [Participant Information Sheet]	2	26 March 2021

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)		04 February 2021
Interview schedules or topic guides for participants [Interview schedule]	2	26 March 2021
IRAS Application Form [IRAS_Form_09022021]		09 February 2021
Letter from sponsor [Letter from sponsor]		04 February 2021
Letters of invitation to participant [Information leaflet]	2	16 February 2021
Non-validated questionnaire [Background questionnaire]	1	20 November 2020
Other [Certificate of Liability Insurance]	1	02 July 2020
Other [Certificate of Public Liability insurance]	1	02 July 2020
Other [Lone working]	1	15 January 2021
Other [Participant debrief sheet]	1	16 November 2020
Other [Signposting]	1	25 January 2021
Other [Clarifications re age limit and data access]		16 February 2021
Other [Distress Management]	2	26 March 2021
Other [Summary of HRA and REC amendments]	1	26 March 2021
Participant consent form [Consent to Contact]	1	06 November 2020
Participant consent form [Consent Form]	2	26 March 2021
Participant information sheet (PIS) [Participant Information Sheet]	2	26 March 2021
Referee's report or other scientific critique report [Peer review evidence]	1	24 August 2020
Research protocol or project proposal [Study protocol]	1	19 October 2020
Summary CV for Chief Investigator (CI) [CI brief CV]	CI CV	29 January 2021
Summary CV for student [JTB brief CV]	1	29 January 2021
Summary CV for student [FOD brief CV]	1	29 January 2021
Summary CV for supervisor (student research) [LC brief CV]	1	29 January 2021
Validated questionnaire [Symptom questionnaires]	1	05 February 2021

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID:	**Please quote this number on all correspondence**

Yours sincerely

Elaine Hutchings

Elaine Hutchings
Approvals Officer

2.3.2 HRA approval letter

Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Professor Adrian Wells
Professor of Clinical & Experimental Psychopathology
University of Manchester
Rawnsley Building
Manchester Royal Infirmary
Oxford Road
Manchester
M23 9LT

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

09 April 2021

Dear Professor Wells,

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

Study title:	**Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories**
IRAS project ID:	**289258**
Protocol number:	**N/A**
REC reference:	**21/NW/0050**
Sponsor	**University of Manchester**

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

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

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

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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

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

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
- Registration of research
- Notifying amendments
- Notifying the end of the study
The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

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

Your IRAS project ID is **289258**. Please quote this on all correspondence.

Yours sincerely,
Laura Greenfield

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Lynne Macrae, The University of Manchester*

2.3.3 Trust confirmation of Capacity and Capability

NHS
Greater Manchester
Mental Health
NHS Foundation Trust

Mr Joe Taylor-Bennett
2nd Floor Zochonis Building
University of Manchester
Brunswick Street
Manchester
M13 9PL

Research & Innovation
1st Floor, Harrop House
Bury New Road
Prestwich, Manchester
M25 3BL

Tel: 0161 271 0607
Email: researchoffice@gmmh.nhs.uk
Date: 14 May 2021

Confirmation of Capacity & Capability at GMMH

Re: Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories
IRAS Reference: 289258
Research & Innovation Reference: x529
Sponsor: University of Manchester
GMMH Study Lead: Oliver Murray

Dear Mr Taylor-Bennett

On behalf of Greater Manchester Mental Health NHS Foundation Trust, I am pleased to confirm Capacity and Capability for the above research to commence at our site.

Approved Documents
Protocol Version 1 dated 19/10/2020 is recognised as the most current to date.

The documents approved for use at this Trust are as listed in the Health Research Authority Letter dated: 09/04/2021.

Any subsequent, relevant amendments are additionally approved to date.

Metrics and Recruitment

First Participant Target	Total Target Recruitment	Recruitment Target Date
13/06/2021	10-15	28/02/2022

Recruitment Updates
To help R&I monitor the progress of the study, and recruitment activity within GMMH, please record your recruitment data on the attached spreadsheet. We ask all study teams to complete this on a monthly basis and return it to researchoffice@gmmh.nhs.uk by the 01st of each month.

We will then update our study database, R-PEAK, and report on trust-wide recruitment to the R&I Committee.

Study Staff
The CV and relevant training of the PI has been reviewed.

C&C Letter Template non-
portfolio & non-interventional studies
version 02 05/08/2020

Page 1 of 2

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Conditions of Approval

The following conditions apply to this approval:

a) The study is conducted in compliance with all the relevant legislation and the relevant GMMH Policies and R&I SOPs. These can be found on the R&I website: www.gmmh.nhs.uk/standard-operating-procedures-sops-and-guidance-documents

b) All staff working on the study have the appropriate training and experience and have responsibilities formally delegated to them. A Research Passport is required for non-GMMH staff that require access to GMMH services or facilities.

c) Serious Breaches of GCP or the protocol will be notified to Research & Innovation within one working day of awareness.

d) All relevant documents will be maintained and will be made available to R&I personnel, to facilitate compliance checks, formal audits and regulatory inspections.

e) You will notify R&I of any subsequent protocol amendments.

f) You will promptly inform R&I of the end of the study and share a copy of the end of study notification.

I wish you every success with the study.

Yours sincerely,

Mark Dawson
Research Initiation and Delivery Manager (Operations)

2.3.4 Proof of Sponsor Green Light

From: **MHS Ethics Applications** FBMHethics@manchester.ac.uk
Subject: IRAS 289258 – Sponsor Green Light
Date: 6 May 2021 at 10:22
To: Joe Taylor-Bennett joe.taylor-bennett@postgrad.manchester.ac.uk
Cc: Adrian Wells adrian.wells@manchester.ac.uk, Fiona O'Donovan fiona.odonovan@postgrad.manchester.ac.uk

PLEASE ONLY FORWARD THIS EMAIL FOLLOWING CONFIRMATION OF CAPACITY & CAPABILITY AT SITES

Dear Joe,

Congratulations on getting HRA approval.

<u>**Summary of what is in place for your study**</u>

- Your study has been added to the list of University-sponsored studies (the reference number is listed on your letter of sponsorship)
- Your study is covered by the University's insurance policies (subject to policy terms and conditions)
- Your study has a favourable ethical opinion
- Your study has HRA approval
- The final versions of the study documents have been submitted to the sponsor
- You have met the University's requirements for restarting face-to-face activities with research participants*

<u>**Can the study start?**</u>

I am happy to confirm the green light for your study to start, please forward this email confirmation to the Trust(s).

* Important information about face-to-face (F2F) activities with research participants for studies with a restart checklist:

- Sponsor Green Light is being issued for your study to start however **F2F/in-person contact can only take place if permitted by the University's guidance <u>at the time of the planned contact</u>**. You can find the current guidance here: <u>COVID-19 Research FAQs</u> webpage and <u>University's guidance.</u> Updates to the University's COVID-19 guidance applies to all studies, including those with a restart checklist and/or issued with sponsor green light; the guidance must be implemented even if this means suspending or pausing F2F contact.

- It is the CI's responsibility to (1) determine whether F2F activity is permitted under University guidance and (2) ensure the guidance is monitored for changes. Decisions about undertaking or suspending face-to-face activities should be documented (e.g. email) and retained in the study file.

Before the research starts at each site, there must be confirmation from that site that the study can start. In England, confirmation of capacity and capability should be received and in the other UK nations, R&D approval should be in place before the study starts at a site.

<u>**What happens next?**</u>

Annual Progress Reports	Your **Annual Progress Report** will need to be submitted on the anniversary of your ethical approval (http://www.hra.nhs.uk/research-community/during-your-

	research-project/progress-reporting/). This is a **condition of ethical approval** and we will remind you of this closer to the time. For research with HRA Approval which were not required to be reviewed by a NHS REC (i.e. **UREC or HRA only studies**), progress reports are also required to be submitted annually to the HRA. Please note: If your study was approved by a **proportionate NHS REC** then Annual Progress Reports are not required. Additionally, for all studies which are of a **two year timeframe or less** Annual Progress Reports to the **NHS REC/HRA** are not required.
Annual updates to insurance certificates	You will need to download the insurance certificates from the insurance policies pages of staffnet annually. Please visit: https://www.staffnet.manchester.ac.uk/insurance/insurance-policies/ (see Liability cover section and clinical trials, if applicable).
Amendments	You should inform the sponsor of any proposed changes to the study before the change is implemented. All amendments must be sent to fbmhethics@manchester.ac.uk for approval <u>before</u> they are submitted to the REC/HRA. Further details can be found in the 'Amendments' folder of the governance pack: www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/sponsorship-approval/
Incident reporting	Please take time to familiarise yourself with the reporting requirements for your study. The University has an SOP for the reporting of any research related incidents which includes a reporting form (http://documents.manchester.ac.uk/display.aspx?DocID=23493). In the event that there are any issues or incidents, please complete the incident form and **contact us as soon as you become aware of a problem**. The HRA requirements for safety reporting are outlined on their website: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/. **For incidents involving data (including potential breaches), please follow the University's reporting procedures in the first instance:** http://www.staffnet.manchester.ac.uk/igo/data-protection/report-data-protection-incident/
Ending/Extending Your Study	You will receive a reminder from us approximately one month before your study is due to end in line with the information you have given in your IRAS application. It will contain information on the next steps, and what we require if you wish to extend your study. For further information on the HRA requirements for notifying the end of study please see: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/
Keep up to date	· **FBMH research office research governance team (our team)** Website: http://www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/

Twitter @FBMH_ethics

> · **The University research governance, ethics and integrity team:**
>
> Website: http://www.staffnet.manchester.ac.uk/services/rbess/governance/
> Twitter: @RGEIUoM
>
> · **Health Research Authority (HRA):**
>
> Website: http://www.hra.nhs.uk/

If there are any questions or you are unsure of any of the above please let us know, otherwise, best of luck with your research!

Best wishes,

Scott.

Have you downloaded our new Governance Pack? For information on our processes from initial application through to Ending your study, and everything in between (Amendments/Sponsor Green Light/Training for Researchers) including guides and templates, please use the link below:

www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/sponsorship-approval/

Dr Scott Bannister
Research Governance Support Officer
Faculty of Biology, Medicine and Health
Room 5.011 Carys Bannister Building | Dover Street
Tel: (+44) 161 306 0677, or MS Teams (9am-4pm - voicemail outside of these hours)

Manchester Academic Health Science Centre
driving research in
Health Innovation **Manchester**
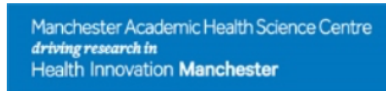
Website: **FBMH Research Governance Website**
Twitter: **@fbmh_ethics**

2.3.5 Service letter of support

NHS
Manchester University
NHS Foundation Trust

Department of Burns, Plastics and Reconstructive Surgery
Burns Centre
Wythenshawe Hospital
Southmoor Road, Manchester M23 9LT

Dr Julie Wisely
Consultant Clinical Psychologist
Telephone: 0161 271 0766

18th May 2020

Joe Taylor-Bennett

Trainee Clinical Psychologist

Division of Psychology and Mental Health

The University of Manchester

2nd Floor Zochonis Building

Brunswick Street

Manchester

M13 9PL

Dear Joe

I confirm that you have my support to recruit clients referred to the Manchester Adult Burns and Plastic's Psychological Therapies Service and to conduct your study with the support of my team. The academic supervisor for your projects is Professor Adrian Wells and I am acting in the capacity of field supervisor.

Yours sincerely

Dr Julie Wisely
Consultant Clinical Psychologist
Clinical Lead Burns and Plastics Psychological Therapies Team

Appendix 2.4 | Ethics amendment summaries

2.4.1 Substantial amendment

Amendment Tool	For office use
v1.5 25 Mar 2021	QC: No

Section 1: Project information

Short project title*:	Understanding emtional distress in burns and plastics patients
IRAS project ID* (or REC reference if no IRAS project ID is available):	289258
Sponsor amendment reference number*:	Substantial amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	20 August 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	The main changes that this amendment will make to the study is: 1) to allow the clinician to take verbal consent to pass on details of potential participants to the research team and to document this on the Consent to Contact Form (and to document this within the local notes); 2) to change the inclusion/exclusion criteria for the study to allow for people currently within psychological therapy to take part in the study; 3) to clarify the recruitment process (e.g. who is responsible for undertaking eligibility screening); 4) To correct the name of a service that refers to the psychology team we are recruiting from (from "Burns Centre at Wythenshawe Hospital" to "The Burns, Plastics, and Reconstructive Surgery Team at Wythenshawe Hospital"); and 5) to add in contact details for the clinical collaborator for the study which were missed out in error. It is not anticipated that these changes would significantly alter the design methodology or otherwise affect the scientific value to the study. No scientific critique has been obtained in this regard.

Project type (select):	● Specific study
	○ Research tissue bank
	○ Research database

Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	● Yes	○ No

What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	● NHS/HSC REC
	○ Ministry of Defence (MoDREC)

Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes	● No

	England	Wales	Scotland	Northern Ireland
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	●	○	○	○

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	● No
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	● No
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	● No
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	● No
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	● No
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes	● No
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	● No
Did the study involve children OR does the amendment introduce this?:	○ Yes	● No
Did the study involve NHS/HSC organisations prior to this amendment?:	● Yes	○ No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	● No

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	●	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Participant Procedures
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of participants
Further information (free text - note that this field will adapt to the amount of text entered):	Verbal consent can be given to the clinician who is requesting Consent to Contact andt they can document this on the Consent to Contact Form. Roles and responsibilities for judging study eligibility have been clarified (this is the responsibility of the research team and not the psychology team).
Applicability:	England Wales Scotland Northern Ireland

Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study
Further information (free text - note that this field will adapt to the amount of text entered):	Change to the inclusion/exclusion criteria to allow people who are currenlty in psychological therapy to take part in the study.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 3	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that will have additional resource implications for participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Change to the Consent to Contact Form to reflect the changes outlined in the Change 1 above. Version numbers and dates have been updated.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 4	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	Changes to the protocol include reflecting the changes outlined in changes 1 and 2. Additional changes include correcting the name of the referring service from "Burns Centre at Wythenshawe Hospital" to "Burns, Plastics, and Reconstructive surgery Team at Wythenshawe Hospital". Contact deatils for the NHS collaborator, Dr Julie Wisely, have also been added to the research Key Contacts page at the top of the document (these were missed from the original in error). Version numbers/dates have been updated.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]*:	Lynne MacRae
Email address*:	FBMHethics@manchester.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

<div style="text-align:center;">**Lock for submission**</div>

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

| | Review bodies | | | | | | | | | | | | | | | | | | |
| | UK wide: | | | | | | England and Wales: | | | | Scotland: | | | | Northern Ireland: | | | | |
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	Y					Y				Y									A
Change 2:	N					(Y)				(Y)									A
Change 3:	N					(Y)				(Y)									A
Change 4:	N					(Y)				(Y)									A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y									
Notification only:	N					N				N									
Overall amendment type:	Substantial																		
Overall Category:	A																		

2.4.2 Non-substantial amendment

Amendment Tool	For office use
v1.5 25 Mar 2021	QC: No

Section 1: Project information

Short project title*:	Understanding emotional distress in Burns and Plastics patients
IRAS project ID* (or REC reference if no IRAS project ID is available):	289258
Sponsor amendment reference number*:	Non-substantial amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	01 October 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	1) changing reference from "Zoom" to "University of Manchester approved videoconferencing software" to allow for a broader range of applications(e.g. Teams) and better access to the study. 2) Including option for interview to take place over the phone and be recorded by an appropriate device. 3) Change incusion criteria to be anyone open to Burns and Plastics Psychology service, regardless of whether they are a current outpatient of the Burns, Plastics and Reconstructive surgery team at Wythenshawe Hospital - this will allow people under outreach and support services who are still in emotional distress from their injury to be included in the study. 4) Change to allow alternative methods of qualitative analysis. 5) Updated interview schedule to include more prompts. 6) remove all references to the email address joe.taylor-bennett@nhs.net.

Project type (select):	● Specific study			
	○ Research tissue bank			
	○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	● Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	● NHS/HSC REC			
	○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		● No	

	England	Wales	Scotland	Northern Ireland
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	●	○	○	○

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		● No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		● No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve children OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve NHS/HSC organisations prior to this amendment?:	● Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		● No	

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	●	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource at participating organisations - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	Refer to "University of Manchester approved videoconferencing software" rather than "Zoom" to allow use of different platforms such as Teams. Add option of carrying out interview over the phone and recording it.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

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Change 2	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study
Further information (free text - note that this field will adapt to the amount of text entered):	Change incusion criteria to be anyone open to Burns and Plastics Psychology service, regardless of whether they are a current outpatient of the Burns, Plastics and Reconstructive surgery team at Wythenshawe Hospital - this will allow a broader group of relevant people to be recruited to the study (e.g. support group attendees and people under outreach teams who may not have a consultant and be an "outpatient" of the Burns, Plastics and Reconstructive Surgery Team).

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 3	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	Change of wording to reflect Change 1 & 2 above and change 5 below in Study Protocol. Wording clarified to better reflect previous amendment (Substantial Amendment 1, 20/08/2021) in study procedure section - this previously had not been changed in line with recruitment changes aproved under substantial amendment 1).

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 4	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Change 1 above reflected in Participant Information Sheet. Added prompts to the interview schedule (no new or additional questions and no changes to questions). Changes to email address on Particiapnt Debrief Sheet and Consent to Contact Form.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 5	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Reworded the statistical analysis section of the study protocol to allow for a broader range of quantitative analysis to take place, based on the data extracted throughout the study. Previously this stipulated a "template analysis", but Thematic Analysis (TA) or Interpretative phenomenological analysis (IPA) may be the most appropriate and this will not be known until the data has been collected.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☑

Change 6	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Change to the Information Leaflet to reflect change to inclusion criteria (change 2 above).

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐

Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All	○ Some

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]*:	Lynne MacRae
Email address*:	FBMHethics@manchester.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

<div align="center">

Lock for submission

</div>

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	UK wide:						England and Wales:				Scotland:				Northern Ireland:					Category:
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	
Change 1:						(Y)				(Y)									C
Change 2:						(Y)				(Y)									A
Change 3:						(Y)				(Y)									A
Change 4:						(Y)				(Y)									C
Change 5:						(Y)				(Y)									C
Change 6:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		

RESEARCH PROTOCOL

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1) **RESEARCH TEAM & KEY CONTACTS**

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Clinical Collaborator	
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2) INTRODUCTION

Burns and injuries which require plastic reconstructive surgery are often serious, unexpected, and require prolonged medical treatment. The injuries can have a negative effect on a person's mental health leading to the development of anxiety, low mood, and post-traumatic stress symptoms. Between 20-67% of burns and plastics patients require mental health support.

The most common mental health support is cognitive behavioural therapy (CBT). Research shows that CBT may be not be that effective for patients who experience distress after a physical injury. CBT often relies on making distinctions between realistic and unrealistic thoughts and this becomes difficult if the concerns are around diagnosed conditions. New and more effective therapies are needed. One promising therapy is metacognitive therapy (MCT); a recent, evidenced-based, therapy. It has shown to be effective in mental health and physical health settings (i.e. cancer and cardiac patients).

MCT has not yet been applied to burns and plastics patients so we don't know if it is suitable for these people. The first step is to understand the emotional distress that these patients experience. We can then compare how well Cognitive and Metacognitive models explain this distress.

This research will recruit burns and plastics patients who are referred to a psychology service. They will be seeking support for the distress caused by their injuries. These people will be asked to complete some brief questionnaires and invited to an interview. Interviews will last approximately an hour.

The study will help us to understand the emotional distress experienced by burns and plastics patients. It will inform which model best explains their distress and whether MCT might be useful for these people. MCT could then be studied to see if it reduces distress for these people. This might lead to new treatments to support the mental health of people with burns and injuries requiring plastic reconstructive surgery.

3) BACKGROUND

Painful and disfiguring injuries (i.e. burns, injuries requiring plastic reconstructive surgery) can have a negative effect on a person's mental health. They can be serious, unexpected, require repeated medical treatment, and are associated with increased anxiety, low mood, and trauma. Wisely et al (2007) screened 57 consecutive patients admitted to a UK regional burn centre and found that 63% required some level of psychological input following a burn injury. The surgical removal of cancer is another example of patients who often have to receive plastic reconstructive surgery. Kaminska et al (2015) found that rates of depression and anxiety in women were around 38% following mastectomy.

The need for routine screening and psychological input throughout hospital care and through community services is highlighted as a necessary aspect of care (British Burns Association, 2001; NICE, 2018) but there are no specific recommendations for treatment. Cognitive behavioural therapy (CBT) is widely offered within the NHS and constitutes much of the treatment available, however, CBT has shown to have limited efficacy in treating psychological distress in patients with physical injuries. One reason may be that CBT requires patients to distinguish between realistic and unrealistic thoughts - something that becomes difficult when thoughts relate to diagnosed physical health problems (McPhillips et al., 2019).

Very few studies have explored the efficacy of CBT within the context of experiencing painful or disfiguring injuries such as burns or injuries requiring plastic reconstructive surgery, and none have explored the fit of this model in explaining the distress these people experience.

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An evidence-based model from mental health research called the Metacognitive model offers effective and predictable treatment for depression and anxiety. MCT has been shown to be superior to CBT in mental health settings (Normann & Morina, 2018), and has been shown to be an acceptable treatment in physical health settings (Fisher et al., 2019; Wells et al., 2020). This research would be the first time that the MCT conceptual framework has been applied to the emotional distress of people who have experienced significant injuries or required reconstructive plastic surgery.

This study will investigate the experiences of burns and plastics patients in order to understand their emotional distress and determine which theoretical framework best conceptualises this. O'Cathain and colleagues (2013) highlight the importance of using qualitative methods to assess the "fit" between theory and interventions. Recently, this method has been applied to a population of cardiac rehabilitation patients with the finding that MCT offers a superior fit over CBT in conceptualising emotional distress (McPhillips et al., 2019).

This research is the first step in understanding how MCT might help conceptualise emotional distress in a burns and plastics population. The approach could potentially see more effective care and more time- and cost-effective solutions due to the group and transdiagnostic format of treatment.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

To understand the emotional distress experienced by burns and plastics patients.

4.2 Secondary Question/Objective:

To understand how the Cognitive and Metacognitive theoretical frameworks map onto the emotional distress of burns and plastics patients, and which gives a better "fit" to inform which may be beneficial as a choice for intervention.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

10-15 participants will be recruited. Participants will have had an injury or accident and will be open to the Burns, Plastics, and Reconstructive Surgery Psychology Team at Wythenshawe Hospital.

5.2 Study Procedures

Once all relevant ethical authorisations are in place, recruitment will begin.

Burns and plastics patients struggling with their mental health can be referred to psychology by clinicians in the Burns and Plastics team at Wythenshawe Hospital and other support services such as Support Groups and Burns Outreach groups. A member of the psychology team will approach these referrals to provide information about the study and ask whether they consent to be contacted by the research team.

The psychology team will be encouraged to hand out the Information Leaflet and Consent to Contact forms All individuals who consent to being contacted by the research team will have this this documented in their case notes and their contact information will be passed onto the research team. Verbal consent to being contacted can be taken by the clinician and this should be documented on the Consent to Contact from and documented on local notes.

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When the research team contact a potential participant, they will provide them with the Participant Information Sheet and Consent Form and offer a space to ask questions about taking part in the research. Eligibility will be checked. Verbal consent will be taken and recorded. A copy of the consent form will be completed by the member of the research team taking verbal consent, indicating that verbal consent was provided, the date it was provided on and that it was recorded. A copy of the Consent Form will be sent to the participant (via post or email), a copy uploaded to the University of Manchester P:Drive, and the original form retained in a locked cabinet in a locked office on Trust property. Consent Forms (both electronic and hard copy) will be retained for 2 years from the end date of the study. Confidentiality and the limits of confidentiality will be discussed at this stage and throughout.

Once informed consent has been taken, a convenient method, date, time, and location will be agreed upon for the interview to take place. Interviews can be conducted via University of Manchester approved videoconferencing software, over the phone, or in person at an NHS site or at the participants home. A Lone Worker document with escalation policy and a Distress Management document has been developed to assist in identifying and managing any risk with conducting qualitative interviews.

Questionnaires (PHQ-9, GAD-7, IES-R, background questionnaire) will be sent to the participant and can either be completed in advance of the interview and returned by email or can be completed at the start of the qualitative interview. The interview topic guide will be followed to guide the interview, although allowing space for new, important topics to emerge as is appropriate. If the interview is conducted over University of Manchester approved videoconferencing software, the interview will be recorded (audio and visual) with the video file being deleted at the earliest opportunity and the audio file transferred to the University's Research Storage Service (RDSS). Interviews conducted in person will be audio recorded on an encrypted device with the audio file uploaded to the RDSS and the original deleted from the device at the earliest opportunity. Participants will be allocated a unique identifying code with the pseudonymisation key stored away from research data on the University's P:Drive.

The interview will be transcribed. This will either be done automatically using transcription software and checked through by a member of the research team, or will be recorded using an appropriate device. If recorded on a device from a face-to-face interview, the researcher will transcribe the audio recording. Transcriptions will take place as soon after the interview as possible to allow analysis to occur alongside subsequent interviews. Audio files of the qualitative interviews will be deleted after transcription has taken place. Interviews will continue to the point of data saturation and the topic guide will be updated alongside interviews. Transcripts of interviews will be used to conduct qualitative analysis to address the research questions. Data collected via questionnaires will be used for descriptive purposes only for defining the cohort recruited.

Taking part in this research will involve discussing emotional distress and emotionally difficulty and sensitive information. The wellbeing of participants is paramount and will be discussed in advance of the interview as well as monitored throughout. A Distress Management document has been created to help the research team identify and manage risk associated with distress being caused throughout involvement in this study. The document outlines how to identify when distress may be occurring, when to pause or stop the qualitative interview and when and where to provide signposting information for support. Should any concerns about safety occur, confidentiality may have to be broken to safeguard the safety of the participant - this would be discussed in advance at the time of gaining informed consent.

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7) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

This study will recruit people who have either had a burn injury or who have had plastic or reconstructive surgery who have experienced emotional distress since this time. They must be open to the Burns, Plastics, and Reconstructive Surgery Psychology Team during the study.

Inclusion criteria:

• Open to the Burns, Plastics and Reconstructive Surgery Psychology Team;

• Age 18 or older;

• At least one month since the occurrence of the burn injury or plastic/reconstructive surgery;

• A competent level of English language skills (able to read, understand and complete

questionnaires in English).

6.2 Exclusion Criteria:

Exclusion criteria:

• Cognitive impairment which precludes informed consent or ability to participate;

• Acute suicidality;

• Active psychotic disorders;

• Current drug or alcohol dependence;

• Individuals engaging in active deliberate self-harm;

• Dementia or learning difficulties.

There will be no restrictions based on the size of the injury.

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6.3 Recruitment:

Potential participants will be recruited from burns, plastics, and reconstructive surgery patients who are open to the psychology department at Wythenshawe Hospital. Patients on any existing waiting list will also be approached for participation.

The psychology team at Wythenshawe Hospital receives referrals from the Burns, Plastics and Reconstructive surgery team at Wythenshawe Hospital, and other support and outreach services for people who the treating team feel would benefit from psychological assessment and/or intervention. A member of the psychology team at Wythenshawe hospital will approach referrals and anyone on a waiting list for psychological assessment/intervention. If the patient is willing to be contacted about taking part in the research, the psychology team member will complete the Consent to Contact form, in which the patient gives permission for personal information (e.g. contact details) to be passed on to a a member of the study team. This form can be completed by the clinician after verbal consent has been provided by the potential participant. All decisions about consent for information to be passed to the research team will be documented on the local system.

A member of the research team will then contact the potential participant, provide them with relevant information, check eligibility, and gain informed consent should they still be willing to take part in the study.

Participants will only be included in the study if they have sufficient levels of English language skills to enable them to read and understand the study information and participant information sheet. This is due to not having sufficient funding to cover the translation of study materials, and the issue of validity with regards to preforming qualitative analysis on transcripts of interviews.

6.4 Participants who withdraw consent:

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. Data that can be identified through the use of a participant identity number (as part of the pseudonymisation process), will be removed should a participant wish to withdraw from the study. It will not be possible to remove any data from the study after the pseudonymisation key is deleted at the end of the study. This is highlighted on the Participant Information Sheet and Consent Form where appropriate.

Due to the brevity of involvement within the research it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

8)   OUTCOME MEASURES

Recent research has shown that Cognitive Behavioural Therapy (CBT) may not be the most effective way to conceptualise the emotional distress of people who have experienced a physical health illness. This is because much of the CBT model requires distinctions to be made about how proportionate and realistic concerns are and that many of the worries facing this population are realistic. Research has shown that following a cardiac event, Metacognitive Therapy (MCT) provides a better conceptual framework than CBT. MCT focuses on transdiagnostic processes such as perseverative thinking styles like worry and rumination, rather than the content of these processes.

Understanding the emotional distress experienced by burns and plastics patients and which therapeutic framework better conceptualises this distress will allow a more fully informed decision about which therapies are provided to this patient group.

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Data gained from participants completing background and symptom questionnaires will be used for descriptive purposes only to define the sample of people recruited for qualitative interviews.

9) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Data will be collected from questionnaires and participant interviews. Data will be collected from participants who meet the eligibility criteria and have given recorded verbal informed consent.

All participants will receive a Participant Information Sheet which states the procedure for participation, limits of confidentiality, and data retainment processes. Contact information will be stored on a password protected word document on the University's P:Drive. These will be used to send participants a copy of the Participant Information Sheet, Consent Form, questionnaires, and to contact the participant with a summary of the research at the end of the project if they have stated that they would like to receive this. Once this has been done, this information will be permanently deleted.

Verbal consent will be taken and audio recorded. The audio recording of consent will be stored away from research data on the University's P:Drive. A Consent Form will be completed and signed by the researcher on behalf of the participant to indicate that verbal consent was taken and recorded, the date on which this was done. The original Consent Form will be stored in a locked cabinet in a locked office designated for the storage of research material. Two electronic copies will be made of the Consent Form with one being sent to the participant and the other stored on the University's P:Drive. Consent Forms and the audio recording of verbal consent will be stored for two years after the end of the study.

Participants will be allocated a unique study code which will be used to link data (questionnaires and transcript) without being immediately identifiable. A pseudonymisation key will be created and password protected. It will be stored away from research data (on the University P:Drive). It will be destroyed at the end of the study. While the Pseudonymisation key exists, it will be possible to identify and remove research data if participants with to withdraw from the study.

Participants will have the choice of sending back completed questionnaires via email or to complete the questionnaires over University of Manchester approved videoconferencing software with the researcher filling in the questionnaires on the participant's behalf based on their answers. These will be scanned and stored on the University RDSS and the original destroyed.

The qualitative interview will take place either in person, over the phone, or over University of Manchester approved videoconferencing software depending on restrictions in place due to Covid-19. If taking place by University of Manchester approved videoconferencing software, the meeting will be audio/video recorded. The video file will be deleted at the earliest opportunity with the audio file saved to the RDSS at the earliest opportunity. University of Manchester approved videoconferencing software's built-in transcription service will be utilised and the recordings will be reviewed to check for accuracy. If interviews are conducted in person, the researcher will audio record the interview with an approved encrypted audio recording device with the audio file saved to the RDSS at the earliest opportunity. Interviews will be transcribed and stored on the RDSS. After transcription, the audio files of qualitative interviews will be deleted.

Research data will be stored electronically on the University of Manchester's Research Data Storage Service (RDSS), which is a secure, backed up drive, which is only able to be accessed by the research team or those with legitimate interest at the discretion of the data custodian. Each participant will be given a unique code identifier which will be used to identify and link all documents for each participant. The database that links participants personal details to their data as well as documents containing personal

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information (e.g. Consent Forms, recording of verbal consent) will be password protected and sorted separately to the research data, on the University of Manchester's P: Drive.

Only quotes which cannot identify individuals will be used in reports of the research.

Access to participant information shall be restricted to the person's direct clinical care team and members of the research team with legitimate access at the discretion of the data custodian. Data can be used for future research at the discretion of the data custodian. Any data used for future research will not be identifiable and will not be combined with any other data which would allow participants to be identified. Information about this is outlined in the Participant Information Sheet and Consent Form.

Interviews conducted via University of Manchester approved videoconferencing software will be automatically transcribed using the built-in function meaning personal data will be processed by Zoom or Teams. This may mean that personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the European Commission to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

Data will only be available through restricted, shared areas on the secure University of Manchester computer systems (password and username secured). Participants will be informed of this on the participant information sheet and will be asked to consent to this at the time of consent to the study.

Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

10) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

Data collected through the Background questionnaire and the symptom questionnaires (PHQ-9, GAD-7, IES-r) are for descriptive purposes only and to help define the cohort of people recruited for qualitative interviews. They will not be analysed as part of this study.

Interviews will consist of open questions with follow-up closed questions to probe and clarify responses. Interviews will be audio/video recorded and transcribed verbatim. For interviews conducted on University of Manchester approved videoconferencing software, the transcription function will be utilised with the recordings listened back to, to ensure accuracy.

Analysis will be directed by the data that is generated from the interviews. It could follow the principle of template analysis (Crabtree & Miller, 1992) with main principles of CBT and MCT providing a template. For CBT, Negative Automatic Thoughts, cognitive distortions, and negative core beliefs will be identified and coded (Beck, 1979). MCT will focus on coding elements of perseverative thinking such as worry and rumination, as well as metacognitive beliefs. Rather than using the analysis to further develop these principles, the analysis will be with the aim to assess the "fit" of each therapeutic model – whether CBT or MCT could better explain the

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emotional distress that burns and plastics patients describe. An alternative methodology of analysis (such as Thematic Analysis or Interpretive Phenomenological Analysis) could also be implemented if it is deemed to suit the data better.

9.2 Sample Size:

We anticipate that 10-15 participants will be required to obtain a range of views. Recruitment will continue until data saturation has been reached, defined as when no further themes are observed in additional interviews.

11) DATA MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of the University of Manchester

12) PEER REVIEW

An internal panel from the Research Subcommittee for the Doctorate programme in Clinical Psychology at the University of Manchester have internally reviewed and approved the research.

13) ETHICAL and REGULATORY CONSIDERATIONS

13.1   Approvals

NHS Research Ethics Committee and Health Research Authority approval will be obtained before commencing research.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2   Risks

Time commitment is a potential burden for participants within this study. These will be explained to any potential participants during the recruitment phase. Participants will have the right to withdraw at any time and for any reason.

There is a potential for emotional distress to the participant. Although sensitively conducted qualitative interviews are unlikely to cause distress themselves, they might uncover distress that participants feel about their illness or other aspects of their lives. Participants will be informed via the patient information sheet and just prior to interview of the topics that will be discussed, that interviews will be recorded, that they may interrupt the interview at any time and that they do not have to answer any questions that they do not wish to. The researcher is trained and experienced in detecting distress and will be supervised. A Distress Management document outlines how to identify possible signs of distress and suggests ways the researcher could mitigate this, including offering to pause or stop the interview and when and where to signpost to supporting organisations. Where unmet needs associated with distress, or any other aspects of care are detected, these will be discussed with the supervisory team and then signpost the patient to the appropriate sources of help or information. Where there is any indication of risk of harm to the participant or another person, the responsible clinician will be urgently informed. Patients will be given contact details of the research team, relevant health professionals, PALS and those of the chief investigator if they want to discuss any aspect of the study further.

There is potential for the researchers to become distressed at the content of the interviews as participants will be asked about sensitive information. The researchers will have access to regular supervision and debriefing following interviews where any arising issues can be discussed and addressed.

Researchers will be lone working when conducting qualitative interviews. A lone working document has been created to support researchers to act safely and consistently at all times. When lone working in the community (NHS site or participant's home) researchers will collect relevant risk information prior to the visit. Researchers will collate the visit information (time, date, location, contact details etc.) and pass these to a monitoring colleague within the research team. The researcher will call in to the monitoring colleague when the visit has concluded to inform them that they are safe. The monitoring colleague will be informed when to expect this call and will follow an escalation procedure if they do not hear from the researcher. The researcher will also carry their NHS ID with them and ensure that they have two mobile phones (at least one with navigation and a torch function), and a copy of the distress management document, including signposting information. For interviews conducted online, the applicable aspects of the lone worker policy will be followed, and the same monitoring procedure will be followed.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

There is no external funding for the project. The study is being conducted as part of the fulfilment of the doctorate in clinical psychology programme at the University of Manchester for Mr. Taylor-Bennett.

16) PUBLICATION POLICY

This study will form part of a doctoral thesis. It will also be published in peer-reviewed scientific journals, and presented at conferences.

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18) REFERENCES

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Participant Information Sheet (PIS)

You are being invited to take part in a research study which aims to understand the emotional distress experienced by burns and plastic reconstructive surgery patients and whether the Cognitive or Metacognitive model better "fits" in describing it. The Cognitive theory states that the content of our thoughts can lead to emotional distress being maintained, whereas the Metacognitive theory puts more emphasis on thinking processes such as worry and rumination and our beliefs about these processes.

This study forms part of a Doctorate in Clinical Psychology being undertaken by the researcher. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➢ **Who will conduct the research?**

This study forms part of the requirements for a Doctorate in Clinical Research degree.

Chief Investigator (academic supervisor 1)
Prof. Adrian Wells, Professor of Clinical and Experimental Psychopathology, Division of Psychology and Mental Health, University of Manchester

Academic Supervisor 2
Dr Lora Capobianco

Co-investigator
Joe Taylor-Bennett, Trainee Clinical Psychologist; Student, Division of Psychology and Mental Health, University of Manchester

Co-investigator
Fiona O'Donovan, Trainee Clinical Psychologist; Student, Division of Psychology and Mental Health, University of Manchester

Sponsor
The University of Manchester

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

NHS Collaborators
Dr Julie Wisely, Consultant Clinical Psychologist, Greater Manchester Mental Health (GMMH) NHS Foundation Trust

Collaborating Institutions
GMMH NHS Foundation Trust

➤ **What is the purpose of the research?**

The aim of this research is to better understand the emotional distress experienced by burns and plastic reconstructive surgery patients. We are hoping to make a judgement about whether Cognitive or Metacognitive theories better explain your distress.

You are being approached to take part in this research because you have either had a burn injury or had plastic or reconstructive surgery and have experienced emotional distress since this time. We are hoping to interview 10-15 people to get a range of perspectives on the type of emotional distress people experience after such an injury.

➤ **What are the possible benefits in taking part?**

There are no direct benefits to taking part in this research, however taking part will help us to better understand the emotional distress experienced by this population of people and will help guide future research. It is possible that a result of this future research will help inform what therapies are provided to people in a similar position to yourself in the future.

➤ **Will the outcomes of the research be published?**

This research is being undertaken as part of a Doctorate in Clinical Psychology and findings will be written up as part of the thesis. Findings may also be published in academic journals and presented at research conferences. You will not be identifiable from any published quotes.

➤ **Who has reviewed the research project?**

This project has been reviewed and approved by an NHS research ethics committee and the Health Research Authority (HRA).

What would my involvement be?

➤ **What would I be asked to do if I took part?**

- If you choose to take part, you will be given a copy of the Participant Information Sheet and a Consent Form to keep.

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

- You will be asked to complete a number of brief questionnaires. These cover some background information about you (such as demographic information), and some symptom questionnaires. These will be used to define the group of people we have recruited for the study and will not be part of any statistical analysis.

- Take part in one interview.

- In the interview we would like to find out about a bit about you, what your injury was and how it occurred. We will ask you about what emotional distress you have been experiencing since your injury. We would also like to hear about your thoughts on how somebody 'should' deal with distress and what strategies you find useful. There are no right or wrong answers we want to hear about your experience. Your participation in the study will be kept anonymous. Please be aware that this is a potentially distressing topic. The interview will be conducted by members of the research team that have been trained in recognising and managing distress. Guidance has also been developed to help the researcher manage any potential distress in an effective and standardised way, which will include offering to pause or stop the interview and being able to provide information about support services.

- The interview will be recorded. The length of the interview will vary depending on how much you wish to talk about and how much time you can spare. The interview is likely to last between 40 and 60 minutes.

- The interview will be conducted by a member of the research team. The interview can take place either:

  - Online via University of Manchester approved videoconferencing software

  - Over the phone and recorded

  - Face-to-face (when permitted due to Covid-19 restrictions). This can take place at the Rawnsley Building (Manchester Royal Infirmary), the hospital where you receive ongoing care for your injury (facilities permitting), or your home.

- If during the interview you do not want to answer a question, or questions, this is fine, any question that you do not wish to answer can be passed over. Alternatively, the interview can be stopped so that you can take a break and/or a different time to finish the interview that is convenient to you can be arranged.

➢ **Will I be compensated for taking part?**

You will be provided with a "Love2Shop" voucher to the value of £10 as reimbursement for your time if you decide to take part in this study. This voucher will be sent to you electronically via an email address that you provide to us and can be used at many high street retailers and well-known brands.

➢ **What happens if I do not want to take part or if I change my mind?**

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It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. It will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data; this will happen at the end of the study and it may be possible to remove your data up to this point. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Recording of the interview is essential to your participation in the study, however, you are free to pause or stop this recording at any point and discontinue with participation in the study without giving a reason.

Data Protection and Confidentiality

> **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Demographic information
  - Age
  - Gender
  - Relationship/marital status
  - Highest level of educational qualification
  - Employment status
  - Current living arrangements
  - Ethnicity
- Information about your mental health
  - Any historical treatment for mental health problems
  - Details on your current emotional wellbeing
- Information about your physical injury
  - Type of injury sustained
  - When this occurred
- For an interview conducted in person: an audio recording of the interview
- For an interview conducted via University of Manchester approved videoconferencing software: an audio and visual recording of the interview
  - Please be aware that the video file will be deleted at the earliest opportunity, and the audio file stored securely and accessed to ensure accuracy with the transcription generated automatically by the built-in transcription software within the University of Manchester approved videoconferencing software.

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➢ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➢ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

➢ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

We will not tell anyone else what you have said. And we will not tell you anything that anyone else in the study has told us. All information collected for this study will be kept safely and securely on computer and/or paper records. **Professor Adrian Wells** will be the custodian of all study data. All information about you will be kept secure and confidential for 5 years after the end of the study. Any information which identifies you will be removed from the transcripts of the interview. Your name will not appear with any of the information you give us – you will be identified by a code with the link between you and the code used stored on a separate system in a password-protected document. The contact details that you provide for the research team to contact you will be stored separately from the research data on a secure system in a password-protected document. Your contact details will be destroyed at the end of the study, or after the research team has provided you with a summary of the research if you outline that you would like this.

There are some situations in which confidentiality must be broken:
- If, during the study, we have concerns about your safety or the safety of others, we will inform your GP/care team/family member.
- If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

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If your interview takes place online through University of Manchester approved videoconferencing software, the interview will be automatically transcribed using the built-in function. This will be checked through for accuracy by a member of the research team.

Your participation in this research will be recorded in University of Manchester approved videoconferencing software (Teams/Zoom) and your personal data will be processed by Teams/Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the European Commission to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.
Further privacy information:
- [Microsoft privacy statement](#)
- [Zoom privacy statement](#)

If your interview takes place in person, the audio recording will be transcribed by a member of the research team. If this is to be completed by anyone other than the research team, they will be reminded of the guidelines regarding confidentiality and they will be asked to sign a copy the Confidentiality Agreement (http://documents.manchester.ac.uk/display.aspx?DocID=41438). If they are a third-party they must be a UoM approved supplier as this ensures a confidentiality agreement is in place between their organisation and UoM. All personal identifiable information will be removed in the final transcript and the recording destroyed after 5 years.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your information will be shared in order to support additional research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of further qualitative analysis regarding other research questions and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

COVID-19 specific information

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

> ➤ **Are there any additional considerations that I need to know about before deciding whether I should take part?**

If you opt to take part in a face-to-face interview, rather than online, please be aware that this increases the possible risk of infection through travelling to and from the venue and through increased contact with researchers. Social distancing measures and other guidelines will be followed to reduce this risk where appropriate.

Please be aware that you should opt to take part online (via University of Manchester approved videoconferencing software) if you are in a vulnerable group or if you have symptoms.

> ➤ **What additional steps will you take to keep me safe while I take part?**

We have developed this study to be as safe as possible to take part in. We can conduct the study entirely remotely if necessary.

> ➤ **Is there any additional information that I need to know?**

If attending an interview in person, please adhere to all current government guidance (e.g. wear a face mask, maintain physical distancing requirements etc.).

> ➤ **Additional data use**

If you attend an interview in person the researchers would have an obligation to provide your contact details to NHS Track and Trace if it becomes necessary.

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

What if I have a complaint?

> ➤ **If you have a complaint that you wish to direct to members of the research team, please contact:**

Professor Adrian Wells, Chief Investigator, email: adrian.wells@manchester.ac.uk; Address: Manchester Mental Health & Social Care Trust Rawnsley Building, 3rd floor, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL

Dr Lora Capobianco, email: lora.capobianco@manchester.ac.uk; Address: Manchester Mental Health & Social Care Trust Rawnsley Building, 3rd floor, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

Joe Taylor-Bennett, Trainee Clinical Psychologist, Mobile: 07594 505654; email: joe.taylor-bennett@postgrad.manchester.ac.uk; Address: The University of Manchester, 2.01, 2nd Floor Zochonis Building, Brunswick Street, Manchester, M13 9PL

Professor Adrian Wells, Chief Investigator, email: adrian.wells@manchester.ac.uk; Address: Rawnsley Building, 3rd floor, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL

Dr Lora Capobianco, Chief Investigator, email: lora.capobianco@manchester.ac.uk; Address: Rawnsley Building, 3rd floor, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL

You can also contact your local Patient Advice and Liaison Service (PALS) on 0161 918 4047 to obtain independent advice about taking part in research.

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

Version 2; Date 26/03/2021
IRAS ID: 289258

Greater Manchester Mental Health
NHS Foundation Trust

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

Consent Form

If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (Version 3, Date 01/10/2021) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set; this will happen at the end of the study so may be possible up to this point. I agree to take part on this basis.	
3	I agree to the interviews being audio / video recorded.	
4	I agree that any data collected may be published in anonymous form in academic books, reports or journals.	
5	I understand that data collected during the study may be looked at by individuals from The University of Manchester, Greater Manchester Mental Health NHS Foundation Trust, or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
6	I agree that any anonymised data collected may be shared for use in future research.	
7	I understand that there may be instances where during the course of the interview information is revealed which means that the researchers will be obliged to break confidentiality, and this has been explained in more detail in the information sheet.	
8	I agree to take part in this study.	

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	Optional consent activities	Initials
1	Optional: I agree that the researchers may contact me in future about other research projects.	
2	Optional: I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the Privacy Notice for Research Participants.

_____   _____   _____
Name of Participant   Signature   Date

_____   _____   _____
Name of the person taking consent   Signature   Date

One copy of this form will be given to the participant for their records, one copy will be retained by the research team (original), and one copy will be made and retained in medical notes.

Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

Version 1 20/11/2020
IRAS: 289258

Understanding emotional distress in Burns and Plastics patients

Background information questionnaire

Participant ID :   Date :

This questionnaire collects some background information about you. Please read and answer every question. All information provided will be treated in strict confidence.

Part one: demographic information

1. Age ……………………………………

2. What gender do you identify as?

☐	Female
☐	Male
☐	Prefer not to say
☐	Other (please state) ………………

3. What is your current relationship status?

Single	☐
Married	☐
Living together	☐
Separated or divorced	☐
Widowed	☐
Other	☐

Understanding emotional distress in Burns and Plastics patients

4. What is your highest level of education?

No qualifications	☐	To end of year ....
GCSEs, CSEs, or O-levels	☐	
A levels/ BTEC	☐	
Trade/apprenticeship	☐	
University degree	☐	
Other	☐	Please specify..

5. What is your current employment status?

Full time employment	☐	
Part time employment	☐	If so, how many hours per week? ....
Home duties	☐	
Receiving benefits	☐	
Voluntary work	☐	If so, how many hours per week? ....
On maternity leave	☐	If so, please also indicate your employment status prior to your leave ....
Unemployed	☐	

6. What are you current living arrangements?

☐	Home owner
☐	Privately renting
☐	Social Housing
☐	Living in a care home
☐	Living in a hostel/shelter
☐	Homeless/no fixed abode

Understanding emotional distress in Burns and Plastics patients

7. Which ethnic group do you identify with? Please tick

White

- ○ English / Welsh / Scottish / Northern Irish / British
- ○ Irish
- ○ Gypsy or Irish Traveller
- ○ Any other White background

Mixed / Multiple ethnic groups

- ○ White and Black Caribbean
- ○ White and Black African
- ○ White and Asian
- ○ Any other Mixed / Multiple ethnic background

Asian / Asian British

- ○ Indian
- ○ Pakistani
- ○ Bangladeshi
- ○ Chinese
- ○ Any other Asian background

Black / African / Caribbean / Black British

- ○ African
- ○ Caribbean
- ○ Any other Black / African / Caribbean background

Other ethnic group

- ○ Arab
- ○ Any other ethnic group (please state)
  …………………………………..

Understanding emotional distress in Burns and Plastics patients

Part two: your mental health

8. Do you have a mental health diagnosis?

☐ Yes   ☐ No

Please state your diagnosis (if any)

……………………………………………………………………………………

9. How would you rate your current mental health? (please circle)

1……….….2…….…..3…….……..4…….……5…….….6……..….7…….….…8…..….…9…….…...10

Not at all good   Excellent

10. Are you receiving any current support for your mental health or psychological difficulties?

☐ Yes   ☐ No

If yes, what support are you receiving?

☐ Medication   ☐ Talking therapy   ☐ Inpatient admission

☐ Other (please specify) …………………………………………………………….….

11. Have you previously received any support for your mental health or psychological difficulties?

☐ Yes   ☐ No   ☐ N/A

If yes, what support did you receive?

☐ Medication   ☐ Talking therapy   ☐ Inpatient admission (how many?.........)

☐ Other (please specify) …………………………………………………………….…

Understanding emotional distress in Burns and Plastics patients

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Part three: your physical health

12. Have you recently had a burn injury which required medical treatment?

☐ Yes ☐ No

13. Have you recently had an injury which required plastic reconstructive surgery?

☐ Yes ☐ No

14. If you have answered "yes" to either questions 12 or 13 above, when did the injury occur?

☐ Less than 1 month ago
☐ Between 1-6 months ago
☐ 6 months – 1 year ago
☐ More than 1 year ago

15. Please briefly outline the type and extent of your injuries

……

……

……

……

Thank you for taking the time to fill in this form

Understanding emotional distress in Burns and Plastics patients

Patient Health Questionnaire (PHQ-9)

Name: _____ Date: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

For office coding: Total Score _____ = _____ + _____ + _____

Total Score _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

☐ Not difficult at all   ☐ Somewhat difficult   ☐ Very difficult   ☐ Extremely difficult

Generalized Anxiety Disorder Screener (GAD-7)

Over the *last 2 weeks*, how often have you been bothered by the following problems?	Not at all	Several Days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritated	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
	Add columns			
	Total Score			
8. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

When did the symptoms begin? _____

IMPACT OF EVENTS SCALE-Revised (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to _____
_____(event)
that occurred on _____(date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Total IES-R Score:_____

INT: 1, 2, 3, 6, 9, 14, 16, 20
AVD: 5, 7, 8, 11, 12, 13, 17, 22
HYP: 4, 10, 15, 18, 19, 21

Weiss, D.S. (2007). The Impact of Event Scale-Revised. In J.P. Wilson, & T.M. Keane (Eds.)
Assessing psychological trauma and PTSD: a practitioner's handbook (2nd ed., pp. 168-189). New York: Guilford Press.
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MANCHESTER
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Qualitative analysis of emotional distress in burns and plastic reconstructive surgery patients from the perspectives of Cognitive and Metacognitive theories

Interview Schedule

Principal aim

To understand the psychological sequela of burns and plastics patients.

Subsidiary aim

To understand the psychological needs of burns and plastics patients.

Note: How these interview guides will be used:

The following questions and prompts are designed as a guide only. The exact way in which questions and prompts will be used, their content and order, will be determined by the progress of the interview itself, and may be subject to change for subsequent interviews as a result of on-going analysis.

Topic guide

Thank you for agreeing to take part in this research study. We are interviewing people who have experienced either a burn injury or another injury that needed plastic or reconstructive surgery. We are hoping to get an understanding of what types of things are causing you emotional distress since the injury. We are doing this because we would like to be able to understand what types of concerns or worries people in your position have, how you cope with these things, and what types of goals you might have. Understanding these things could then allow us to make a judgement about whether the therapies that are currently on offer for this group of people is the most suitable, or whether it is worth exploring other psychological models. It is useful to interview a number of people to ensure that we hear a range of experiences.

This interview will have an open format: this means that I have some questions that I would like to ask, but that these are a framework, and what I really want is to hear what you feel is important, and about your experiences. There are no right or wrong answers, and you don't have to answer anything that you don't want to. It is important that you know that you can pause or end the interview at any time without giving a reason.

Anything that you tell me in the interview will be kept confidential, except for if you tell me anything which makes me have concerns for your or anybody else's safety (for example if you express thoughts or plans of harming yourself or someone else). In this case, I would need to contact your GP/care team/family member.

1. **Introductory questions**
   The first few questions are some introductory questions about yourself.

   Complete background questionnaire and symptom questionnaires here if not completed already.

   If completed, summarise to check that it is accurate.

   Prompt: include some general conversation to build rapport before starting the interview.

2. **Index Event**
   Thank you for completing/reviewing those questionnaires. I would now like to understand a bit more about the injury that led to you receiving medical support from the burns and plastics department.
   a. Can you tell me a little bit about your (burn injury or plastic surgery).
      Prompt: What kind of injury was it, when was it, how did it happen? What treatments have you had? Are you receiving any ongoing care? How do you feel your injury is healing? Are there things that are helpful/unhelpful for healing progress?

Note: Remind participant that they can provide as much or as little detail as they are comfortable.

3. **Emotional Reaction Since Index Event**
   The next few questions are about how you've been feeling since your injury/surgery. If you're uncomfortable answering any of the questions feel free to skip them.

   a. Can you tell me how you've been feeling since your injury?
      Prompt: Has this made you feel anxious, low in mood

   b. When you feel anxious or low in mood what goes through your mind
      Prompt: What kind of negative thoughts do you have?

   c. When you feel anxious or low in mood how do you cope with that?
      Prompt: do you avoid reminders, try not to think about things, try to think positively, practice meditation or relaxation techniques (if yes, what are they?)

   d. Do you worry or dwell on negative thoughts?

      Prompt: Do you think this is helpful? Do you think it is harmful? Do you feel you are able to detach from negative thoughts? Are you able to step back from negative thoughts and leave them alone? Do you tend to get caught up in worrying or dwelling on thoughts?

   e. Do you get reminders or flashbacks?

      Prompt: How do you respond when these things happen?

   f. Has this impacted on any other aspects such as sleep?

   g. Have you been coping with any anxiety/low mood/trauma by changing any behaviours?
      Prompt: check for avoidance behaviours- avoiding seeing people, public places (check for disfigurement concerns)

      Prompt: changes in eating, alcohol consumption, exercise etc

4. **Posttraumatic Growth/Adjustment**
   Sometimes after a traumatic event people experience what is called post-traumatic growth. The next few questions are about this.
   a. Do you think its easy to adjust after your (burn or plastic injury)

   b. What kind of worries do you have for the future?

   c. How well do you feel you bounce back after a difficult situation?
      Prompt: Do you feel like you can go back to normal after your injury?

   d. Do you see this as a possible opportunity for growth?

5. **Psychological Support**
   Finally, we want to hear what sort of psychological support you have received or would like to receive
   a. Have you ever been offered psychological support before?
      If no- move on to the next question

      If yes- could you tell me about what support you were offered?
      Prompt: What did you think of this?
      Prompt: How useful did you find it?
      Prompt: What did it involve? Was it mindfulness, CBT, counselling etc
      Number of sessions, format (individual or group therapy), how long did it last.

   b. What type of psychological support would you want if it was offered to you?
      Prompt: What would it involve? Individual? Group Therapy?
      Prompt: How would you want to access it? Online, face to face?
      Prompt: What would be a good way to hear about it?

   c. What would you want to address/want help with in therapy?
      Prompt: What are your priority issues that you would want to target?

   d. What do you hope to achieve with therapy
      Prompt: What are your treatment goals? Do you know what might help you achieve these?

Thank them for their time, ask them if they have any questions and end the interview.