Exploring the impact of interventions in Cognitive Analytic Therapy

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

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Abbreviations List

Paper 1

Cognitive Analytic Therapy (CAT)- Page 13 Randomised controlled trials (RCTs)- Page 14 Target problem procedures (TPP)- Page 15 Multiple self-states model (MSSM)- Page 15 Sequential Diagrammatic Reformulation (SDR)- Page 17 Narrative reformulation (NR)- Page 17 Agency for Healthcare Research and Quality (AHRQ)- Page 18 Effective Public Health Practice Project (EPPHP)- Page 18 Association for Cognitive Analytic Therapy (ACAT)- Page 19 Critical Appraisal Skills Programme (CASP)- Page 20 Self-Reflection and Insight Scale (SRIS)- Page 25 Clinical Outcome in Routine Evaluation 10 (CORE 10) Page 25 Reflective Practice Questionnaire (RPQ)- Page 25 Beck Depression Inventory II (BDI II)- Page 25 Inventory of Interpersonal Problems- 32 (IIP-32)- Page 25 Brief Symptom Inventory (BSI)- Page 25 Patient Health Questionnaire 9 (PHQ 9)- Page 26 Generalised Anxiety Disorder 7 (GAD 7)- Page 26 Work and Social Adjustment Scale (WSAS)- Page 26 Working Alliance Inventory- Short (WAI-S)- Page 26 Helpful Aspect of Therapy (HAT)- Page 26 Sexual Compulsivity Scale (SCS)- Page 26 Personality Structure Questionnaire (PSQ)- Page 27 Simplified Personal Questionnaire (SPQ)- Page 27 Young Schema Questionnaire- short version (YSQ-SV)- Page 27 Beck Depression Inventory (BDI)- Page 28 Dissociative Experiences Scale-II (DES-II)- Page 28 Core Conflicted Relationship Theme Method (CCRT)- Page 28 Structural Analysis of Social Behaviour- Cyclic Maladaptive Patterns (SASB- CMP)- Page 28

Paper 2

Non suicidal self-injury (NSSI)- Page 64 Cognitive Analytic Therapy (CAT)- Page 64 Cognitive Analytic Therapy for the containment of self-harm (CATCH)- Page 64 Randomised Controlled Trial- Page 64 Treatment as usual (TAU)- Page 64 Cognitive Behaviour Therapy (CBT)- 66 Dialectic Behaviour Therapy (DBTO- Page 66 Mentalisation based therapy (MBT)- Page 66 Psychodynamic Interpersonal Therapy (PIT)- Page 67 Target problem procedures (TPP)- Page 69 Sequential Diagrammatic Reformulation (SDR)- Page 69 Medical Research Council (MRC)- Page 70 British Psychological Society (BPS)- Page 72 Diagnostic and Statistical Manual of Mental Disorders V (DSM V)- Page 72 Adverse Effects in Psychotherapy (AEP)- Page 73 Self-injurious Thoughts and Behaviours Inventory-Short-Form (SITBI-SF)- Page 74 Patient Health Questionnaire 9 (PHQ 9)- Page 74 Personality Structure Questionnaire (PSQ)- Page 75 Self-Compassion Scale (SCS)- Page 75 Alexian Brothers Urges to Self-Injure Scale (ABUSI)- Page 76 Competence of Cognitive Analytic Therapy (CCAT)- Page 76 Reliable Change Index (RCI)- Page 80 Standardised Individual Difference (SID)- Page 80 Association for Cognitive Analytic Therapy (ACAT)- Page 81 Confidence intervals (CI)- Page 91

Paper 3 Abbreviations

Cognitive Analytic Therapy (CAT)- Page 113 Randomised Controlled Trials (RCTs)- Page 114 Medical Subject Headings (MeSH)- Page 115 Agency for Healthcare Research and Quality (AHRQ)- Page 117 Effective Public Health Practice Project (EPHPP)- Page 117 Critical Appraisal Skills Programme (CASP)- Page 117 Sequential Diagrammatic Reformulation (SDR)- Page 121 Medical Research Council (MRC)- Page 122 Public and patient involvement (PPI)- Page 123 Community Liaison Group (CLG)- Page 124 Cognitive Behaviour Therapy (CBT)- Page 124 Centre for Research in Public Health and Community Care (CRIPACC)- Page 125 National Institute for Health Research (NIHR)- Page 125 Research Ethics Committee (REC)- Page 131 British Psychological Society (BPS)- Page 133-134 There have been a number of changes made to Paper 2. The initial aim of the empirical paper was to establish the feasibility of CATCH and to investigate whether CATCH plus TAU was more effective than TAU alone with a large pilot trial with group comparisons. This study was designed to inform the development of a larger scale RCT. However, due to logistic challenges affecting recruitment and other implementation challenges necessitated further feasibility work which meant the study was re-purposed. The study was refocused around feasibility and safety. The first submission compared a brief Cognitive Analytic Informed Therapy (CAT) intervention CATCH (Cognitive Analytic Therapy for the Containment of Self-Harm) to treatment as usual (TAU). There were two follow up pointspost therapy assessment and follow up. After submission in April 2020, it was discovered that there were some errors in the analysis. These were discussed at the first viva and the outcome from that was for the trainee to re run the analysis to correct any errors. The trainee was not able to get access to the hard copy of the data to check for accuracy until August 2020 due to lockdown restrictions at the university. When they went through the data they found that some anonymised hard copies of data, largely from the post therapy assessment were missing. This necessitated a further change in the analysis where there was only a single follow-up point. An extension to the initial submission was requested to balance full time work with carrying out the new analysis and making the recommended revisions.

Thesis Abstract

This thesis forms part of the examination for the Doctor of Clinical Psychology (ClinPsyD) in the faculty of Biology, Medicine and Health (School of Health Sciences) at The University of Manchester.

The aim of this thesis was to understand more about the potential impact of interventions in Cognitive Analytic Therapy (CAT). The thesis is presented in three separate papers. Paper one is a systematic review of quantitative and qualitative literature exploring the impact of reformulation in CAT. Following a standardised approach, four databases were searched and a sample of 20 papers were identified. Results suggest there is a real lack of consistency between quantitative and qualitative studies. Across a series of small-scale non-controlled studies evidence of symptom change following reformulation was mixed. In the only controlled study identified in the area, the inclusion of narrative reformulation within CAT was not associated with any treatment benefit. Positive features of reformulation were reported in qualitative studies. These included how it helped guide perceived change, provided clarity and understanding for clients and supported the therapeutic relationship.

Paper Two is an empirical investigation examining the feasibility and acceptability of CATCH (Cognitive Analytic Therapy Containment of Self-Harm) as a brief intervention for people with non-suicidal self-injury (NSSI) and as a preliminary evaluation regarding the efficacy of the approach on depression, self-compassion and urges to self-injure. A two arm (CATCH plus Treatment as Usual (TAU) and TAU alone) open feasibility randomised controlled trial (RCT) with 14 participants was conducted. Results suggest CATCH is feasible and safe for use with people with NSSI. Clinical outcomes suggest evidence of improvements in depression for participants in CATCH plus TAU and deterioration for participants in TAU. There was evidence of improvement in urges to self-injure for both groups. This reduction was more marked for the CATCH group. There was a small and similar improvement in self-compassion for both group.

Finally, Paper Three is a critical reflection of the process involved in conducting the project. It includes reflections on methodological approaches used, strengths, limitations and implications of the findings for research and clinical practice. The paper concludes with personal reflections on the endeavour of completing this thesis.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Paper 1: A systematic review of the impact of reformulation in Cognitive Analytic Therapy (CAT)

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ABSTRACT

Objectives: Cognitive analytic therapy (CAT) is a relational, integrative, and time-limited psychotherapy informed by cognitive and psychodynamic approaches. Within CAT there are three distinct therapeutic phases: reformulation, recognition and revision. The aim of this review was to narratively synthesise the extant literature concerning the impact of reformulation (as defined within CAT). The impact of reformulation was investigated in two ways. Firstly, evidence was synthesised concerning whether reformulation was associated with improvements in therapy outcome. Secondly, data were synthesised regarding client's perceptions or experience of reformulation.

Method: A literature search of electronic databases PsycINFO, CINAHL, Medline and Web of Science from date of inception to January 2020 was undertaken. The online journal Reformulation was hand searched in addition to the electronic searches. All studies that met the inclusion criteria were appraised using two research study quality checklists. Data were analysed using a convergent synthesis design.

Results: Twenty studies met the inclusion criteria. Evidence of symptomatic change following reformulation was mixed across a series of small-scale non-controlled studies. There was no evidence of any pattern of symptomatic change whereby certain populations were more likely to see a change associated with reformulation. In the only controlled study identified, the inclusion of a narrative reformulation letter within CAT was not associated with any treatment benefit. The qualitative studies largely highlighted positive features of reformulation, including reports of how reformulation helped guide perceived change, helped to synthesise complex information, developed clients' understanding of their problems, and their connection to their therapists.

Conclusion: There appears a real lack of consistency between quantitative and qualitative studies regarding the efficacy of reformulation. This limits any common conclusions or synthesis that can be made. Further research is recommended.

Keywords: Reformulation, Cognitive Analytic Therapy, systematic review, qualitative, quantitative, mixed methods, narrative synthesis

1. INTRODUCTION

CAT is a relational, integrative, and time-limited psychotherapy informed by cognitive and psychodynamic approaches (Ryle & Kerr, 2002). CAT was specifically designed for the needs of pressured public health services (Ryle, 1995). CAT has evolved in use across a range of diverse areas and applications including personality disorder (Clarke et al., 2013); anxiety and depression (Marriott & Kellett, 2009); hoarding disorder (Spence et al., 2019); psychosis (Taylor et al., 2018), long-term physical health conditions (Fosbury et al., 1997) and bipolar disorder (Evans et al., 2017). A key component of CAT is the process of *reformulation*, whereby a shared understanding of an individual's difficulties is developed between therapist and client. The evidence based for CAT as a whole is summarised in two literature reviews (Calvert & Kellett, 2014; Ryle et al., 2014). However, the evidence base regarding the therapeutic impact of reformulation, in particular, is less clear.

Calvert and Kellett (2014) noted that the development of CAT outcome research remains incoherent with little evidence of considered progression along an established framework. The popularity of CAT in routine practice has meant that the evidence base for treatment features a greater proportion of practice-based studies. Nevertheless, there are a number of randomised controlled trials (RCTs), of various levels of quality that highlight the potential value of CAT. These RCT's focused on personality disorders (Clarke et al., 2013; Chanen et al., 2008), bipolar disorder (Evans et al., 2017), eating disorders, (Dare et al., 2001; Treasure et al., 1995), and long-term physical health conditions (Fosbury et al., 1997). Ryle et al. (2014) found a weighted mean effect size of d=0.83 across four RCTs and 22 studies of effectiveness conducted in routine clinical practice using a variety of outcome methodologies.

Whilst establishing the overall efficacy of a therapy is important, understanding the mechanisms and active ingredients of a particular intervention is also of value (Kazdin, 2007). Whilst most therapies are developed with a clear theoretical explanation of how the therapy is supposed to bring about change, the actual scientific knowledge about these mechanisms is limited (Cuijpers et al., 2019a). For complex, multi-component therapies, investigating the particular components of a therapy may be helpful in identifying which aspects of the therapy are most valued by clients, and which aspects constitute key mechanisms of change. This information in turn can help in further developing the approach to achieve better outcomes for clients. CAT is a complex multi-component therapy (Ryle & Kerr, 2002). Investigating the impact of the different components of CAT may therefore help to better understand what aspects of this approach are most essential in benefiting clients.

CAT practice rests on three theoretical foundations: reciprocal roles, target problem procedures (TPP) and the multiple self-states model (MSSM) (Ryle & Kerr, 2002). Reciprocal roles refer to patterns of relating to oneself and others. Early relational experiences are internalised (e.g. experiencing warmth, empathy, criticism or rejection) and these provide a template that guides how the individual experiences and responds to future relationships both with others and themselves. For example, as a baby you are responded to by a comforting soothing parent, you learn what it is to comforted but also what it is to be a comforter by enacting it with yourself (self-soothing) or other (e.g. cradling a doll). Equally when you experience a harsh critical parent you learn what it is to be crushed and demoralised, feeling not good enough. You also learn to be self-critical and to be critical of others (Kerr, 2005; Ryle, 2001; Ryle & Kerr, 2002).

A procedure is seen as a 'linked chain of mental processes and actions involved in the execution of aim directed acts' (Ryle, 1985, p. 2). Llewelyn (2003) describes how we all use chains of procedures all the time, and while most of them are effective, others may be unhelpful to us (e.g. One finds it difficult to look after oneself and keep oneself well. This may be underpinned by the procedure, feeling unwanted and inadequate. In order to feel 'in control', one may elicit care, take on too much, anxiously strive and eventually feel exhausted or overwhelmed. As a result they may develop an illness and gain reluctant care from others. The aim of being 'in control' may not be met. As a result one may feel compelled to strive again and so on). Distress is perpetuated through the use of these problem procedures that are ineffective and distressing.

Further theoretical cohesion in CAT came with the MSSM (Ryle, 1997). This elaboration attempted to explain more complex difficulties within a CAT framework (e.g. personality disorder; Ryle et al., 2014). This model outlines how overwhelming or intolerable life experiences lead to problems in switching between particular roles and states, resulting in instability in affect, behaviour, and self (Kerr, 2001). For example, during an experience of feeling 'enraged', an individual may not be aware of the other relevant aspects of the reciprocal roles but only their own, immediate and overwhelming response. The individual's capacity to self-reflect or self-observe is not available.

Within CAT there are three distinct therapeutic phases: reformulation, recognition and revision (Pollock et al., 2001). CAT uses the term "reformulation" rather than formulation because there is an assumption that a client already has their own understanding of their experiences and presenting problems (Ryle and Kerr, 2002). Reformulation essentially involves the application of CAT concepts and theory in forming a shared understanding of a

client's difficulties. Reformulation starts at the initial meeting and involves the creation of a Sequential Diagrammatic Reformulation (SDR) (Ryle & Kerr, 2002)). This is essentially, a visual map of the client's problems, procedures and underlying reciprocal roles (Ryle, 1995). Reformulation typically culminates with the reading of a narrative reformulation (NR) letter to the client in session four or five, which forms the basis of future therapy. Both written and diagrammatic tools draw on the work of Bruner's (1986) description of modes of conveying knowledge. It also draws on the work of Vygotsky (1978) who suggested that a pupil can learn more with the support of 'scaffolding' of a teacher than alone. It is suggested that the process and sharing of the reformulation letter allows the client's difficulties and offer the client a new understanding of themselves (Kerr, 2001; Ryle, 1990). Reformulation is therefore considered an essential part of CAT. A systematic review will help determine whether research evidence so far supports the hypothesised importance of this aspect of CAT.

The aim of this review was to narratively synthesise the literature concerning the impact of reformulation (as defined within CAT). The impact of reformulation was investigated in two ways. Firstly, evidence was synthesised concerning whether reformulation was associated with improvements in therapy outcome. Therapy outcomes included improvements in a client's mental health difficulties or wellbeing and change in therapeutic mechanisms or intermediate processes assumed to be relevant to the success of the therapy (e.g. working alliance). Secondly, data were synthesised regarding client's perceptions or experience of reformulation. These data will help determine the acceptability of reformulation as a process, whether it is perceived as useful, and if so, in what ways.

2.0 METHOD

2.1 Pre-registration of review protocol

The protocol for this review was pre-registered on PROSPERO (CRD42019153233) (Appendix A). A change of the tool used to assess the quality of quantitative studies reflects a departure from the original protocol. This was made to allow for a more appropriate assessment of the quality of included studies. The Agency for Healthcare Research and Quality tool (AHRQ) (Viswanathan et al., 2012) was replaced with the Quality Assessment Tool for Quantitative Studies (Thomas et al., 2004). This was considered more appropriate because it can be used to assess the methodological quality of a range of study types. The search process largely identified case series data indicating change pre-post reformulation. This tool is also used by the Effective Public Health Practice Project (EPPHP) (www.ephpp.ca) and is considered suitable to be used in reviews of effectiveness (Armijo-Olive et al., 2012).

2.2 Search strategy

The electronic databases PsycINFO, CINAHL, Medline and Web of Science were searched by a reviewer (SB) from the earliest date available until January 2020, using the following search term "Cognitive Analytic". The online CAT-specific journal *Reformulation* was handsearched in addition to the electronic searches because references for this journal were not included in the databases. Given that the scale of the CAT literature is limited, additional search terms to narrow down the number of articles identified was not considered necessary and could have increased the risk of potentially eligible articles being excluded. A similar broad search term has been adopted by other systematic reviews of the CAT literature (Calvert & Kellett, 2014; Ryle, et al., 2014).

Initially two reviewers (SB, CO) independently screened all titles and abstracts and any disagreements were arbitrated by a third reviewer (PT). In addition to the articles identified through the search method, a reviewer (SB) checked the reference lists and cited articles of all included studies. The authors of included studies, three experts in the area (two psychologists and a psychiatrist with multiple publications relating to CAT) and prominent members of the Association for Cognitive Analytic Therapy (ACAT) and Catalyse websites were contacted and asked about further potentially eligible published and unpublished research.

Citation chaining (Boland et al., 2017) was used to search for potentially eligible studies not detected by the electronic search using the reference list of eligible papers. This included seeing which papers have subsequently cited key references (forward searching) and looking at the reference list to find other relevant papers the search may have missed (backward searching). Reference management software (Endnote) was used to download, track and sort references, and remove duplicates. A Kappa coefficient of .83 (95% CI .54, 1.00) showed high agreement between reviewers on screening and eligibility of studies to be included in the review.

2.3 Study eligibility

The inclusion criteria for this review required studies to have; i) included participants who were aged 18 years or older; ii) participants to have had experience of CAT or CAT-informed reformulation or assessment; iii) included either measurement of participants' experiences of reformulation (either qualitative or quantitative) or b) include measurement of therapy outcomes before and after reformulation; or c) include measurement of therapy outcomes in groups who have and have not received reformulation, allowing comparison ; iv) be

written in or translated to English; and v) be published or be part of the grey literature. 'Therapy outcomes' included improvements in a client's mental health difficulties or wellbeing and change in therapeutic mechanisms or intermediate processes assumed to be relevant to the success of the therapy (e.g. working alliance). NR and SDR are considered key to reformulation (Ryle & Kerr, 2002) but use different mechanisms and focus. How they impact therapeutic outcomes and experience of reformulation is likely to be different. It was therefore considered useful to include studies where only one of these components was investigated. All quantitative, qualitative and mixed method studies that met the inclusion criteria were included in the synthesis. The inclusion criteria were intentionally broad to ensure that as large a number of studies as possible were included.

2.4 Methodological quality

The methodological quality of quantitative studies was assessed using the Quality Assessment tool for Quantitative studies from the EPHPP (Thomas et al., 2004; Appendix B). This tool assesses the quality of quantitative studies across eight domains. Each domain results in a rating of strong, moderate and weak, marked against pre-defined criteria as described by Thomas et al (2004). These quality labels reflect individual domains not overall scores. Two questions in the analysis section (unit of allocation and unit of analysis) were not used because it was the same for all studies included. Qualitative studies were assessed using the Critical Appraisal Skills Programme (CASP, 2018; Appendix C). This is a methodological checklist providing key criteria relevant to qualitative research. These criteria include what the results are, whether they are valid and whether they contribute to existing knowledge and understanding (CASP, 2018). To address subjectivity, all assessments (for both quantitative and qualitative data) were undertaken by two independent reviewers (SB and CO), with disagreements being resolved through team discussion. Where studies

employed a mixed-methods design with relevant quantitative and qualitative components, both tools were applied in evaluating the study. A rating of overall quality was not included as recommended by Higgins et al. (2011). Instead quality ratings were provided broken down by domain, allowing for common themes and areas of concern to be identified.

2.5 Data extraction & synthesis

Reviewers (SB and CO) independently extracted data relevant to the study question using a data extraction spreadsheet. Discrepancies and uncertainties were resolved through team discussion or via contact with the author themselves. Extracted information included i) author, year and country ii) participant characteristics; iii) key study characteristics, interventions and comparators; iv) analysis and v) study outcomes (qualitative themes, feedback ratings and results of statistical analyses).

Given the inclusion of qualitative research and the heterogeneity (in terms of study design, samples and outcome measures) in quantitative research, a narrative synthesis was considered most appropriate. The studies included in this review were analysed using a convergent synthesis design (Hong et al., 2017), where qualitative and quantitative evidence is analysed separately using different synthesis methods and results of both syntheses are integrated during a final synthesis. Both qualitative and quantitative data were therefore extracted and analysed separately with a focus on study outcomes and strength of evidence. These results were then integrated in the Discussion. The aim of the narrative synthesis was to identify themes arising from qualitative and quantitative studies and to identify areas of agreements and disagreements.

A critical realist epistemological stance was taken as this is most consistent with the goals of the review. This stance assumes that psychological phenomena do have some external basis

in reality outside of any single individual's interpretation, but these phenomena are fuzzy and bounded by culture and context that also requires consideration (Kempster & Parry, 2011). For the qualitative papers, the reviewer adapted Braun & Clarke's (2006) thematic analysis approach to finding patterns of meaning across the studies. This approach was chosen because thematic analysis is regarded as a useful method for identifying, analysing and reporting patterns (themes) within data.

3.0 RESULTS

3.1 Study Characteristics

The search flow diagram is presented in Figure 1. A total of 20 studies were included in the review; seven qualitative, six quantitative and seven mixed methods studies. Eight papers contributed with quantitative data, eight papers contributed with qualitative data and four contributed with both quantitative and qualitative data.

16 (seven quantitative, five qualitative and four mixed method) of the studies were published in peer reviewed journals, three qualitative studies were unpublished theses and the final quantitative paper was an unpublished report shared by the author. Studies included participants with mental health challenges treated in primary and secondary care. The majority of quantitative studies employed single case and small N designs (k = 8), with other studies employing RCTs (k=1), case series methodology (k=1), non-experimental design (k=1) and a retrospective data analysis (k = 1). All studies took place in the UK. Key study characteristics are summarised in Table 1 and Table 2.

Figure 1:

PRISMA flow diagram of search strategy

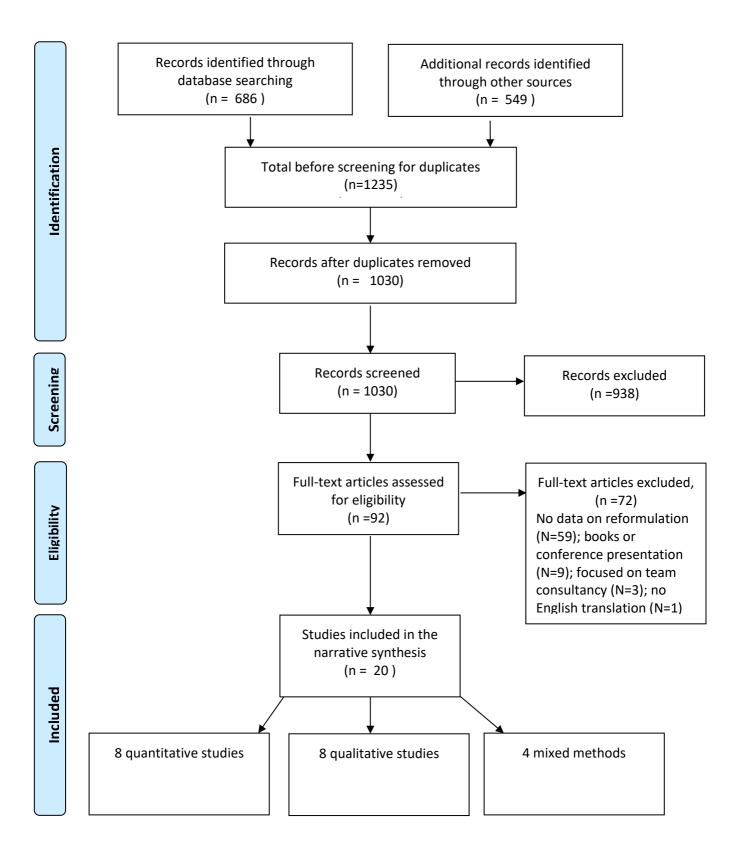


Table 1:

Characteristics of Quantitative studies

Study	Methodology	Measures	Intervention	Sample	Key findings
Tyrer & Masterson (2019); UK	Single case repeated measures design/Template analysis	Self-Reflection and Insight Scale (SRIS; Grant, Franklin & Langford, 2002); Clinical Outcome in Routine Evaluation 10 (CORE-10; Connell & Barkham, 2007)	16 session CAT	N=6 (1 male/5 females) psychiatric outpatients; age range 26-73 years (mean/SD 41.6/17.1 years)	Visual analysis showed increased insight for all Participant's over course of therapy, which continued at follow up. Only one participant showed clinically significant improvement following implementation of CAT tools. For all but one, there was no clinically significant symptom change following the implementation of reformulation
Hamilton (2019); UK	Longitudinal design (follow up at two weeks)	Reflective Practice Questionnaire (RPQ; Priddis & Rogers, 2017); CAT reformulation evaluation questionnaire (Cooper, 2018; unpublished)	2 session reformulation	N=31 (gender not specified) university students; ages not specified	No statistically significant change following reformulation in reflective capacity or associated psychological constructs was found. At an individual level, there was some individual level improvements on dimensions of reflective capacity and related attributes although a mixed picture was found.
Curling et al (2018b); UK	Hermeneutic single case efficacy design	Prestwich Jealously Questionnaire (Beckett, Tarrier, Intilli & Beech, 1992); Beck Depression Inventory (BDI-II; Beck, Steer & Brown, 1995); Inventory of Interpersonal Problems-32 (IIP-32; Hughes & Barkham, 2005); Brief Symptom Inventory (BSI; Derogatis, 1993)	16 session CAT	N=1 (1 female) psychiatric outpatients; age 38 years	Visual analysis showed a change of trajectory of jealously following introduction of NR. NR and active use of SDR was scored as very helpful by participant

Study	Methodology	Measures	Intervention	Sample	Key Findings
Curling et al (2018a); UK	A/B single case experimental designs with extended follow up	Same measures used as Curling et al (2018b)	16-24 session CAT	N=3 (1 male/2 females) psychiatric outpatient; age range 36-58 years (mean/SD- 49.3/9.6 years)	Visual analysis showed increasing trend in jealously during baseline reversed following NR for two clients. Change was attributed to therapy and several aspects of CAT were rated as extremely helpful in bringing about change
Kellett et al (2018); UK	Randomised controlled deconstruction trial	Patient Health Questionnaire 9 (PHQ9; Kroneke, Spitzer & Williams, 2001); Generalised Anxiety Disorder 7 (GAD7; Spitzer, Kroenke, Williams & Lowe, 2006); Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear & Greist, 2002); Working Alliance Inventory- short (WAI-S; Tracey & Kokotovi, 1989); Helpful Aspects of Therapy (HAT; Llewelyn, 1988)	8 session CAT with 8 week follow up	N=95 (52 full CAT/43 CAT-NR) psychiatric outpatients; age range 19-65 years (individual ages not specified)	In the two arm RCT, there was no significant difference in depression outcomes found between CAT arm and CAT minus NR arm of treatment. At follow up of secondary outcomes there was no significant difference in anxiety outcomes, functional impairment, therapeutic alliance or ratings of helpfulness of therapy between both arms.
Kellett et al (2017); UK	A/B single case experimental design	Sexual Compulsivity Scale (SCS; Kalichman & Rompa,1995); BDI-II; Beck, Steer & Brown, 1996); BSI (Derogatis,1993)	24 session CAT	N=1 (1 male); psychiatric outpatients; age 41 years	Visual analysis of the data, showed a change in outcome which coincided with the introduction of NR

Study	Methodology	Measures	Intervention	Sample	Key Findings
Kellett & Hardy (2014); UK	A/B single case experimental design with extended follow up	BSI (Derogatis, 1993);BDI-II (Beck, Steer & Brown, 1996); IIP-32 (Hughes & Barkham, 2005); Personality Structure Questionnaire (PSQ; Pollock, Broadbent, Clarke, Dorrian & Ryle, 2001)	24 session CAT	N=1 (1 male) psychiatric outpatient; age 36 years	Visual analysis of data showed changes in measures of suspiciousness and paranoia coincided with the introduction of NR
Shine & Westacott (2010); UK	Time series analysis and template analysis	Simplified Personal Questionnaire (SPQ; Shapiro, 1961); WAI-SR (Hatcher & Gillaspy, 2006)	8 session CAT	N=5 (1 male/4 females) psychiatric outpatient; age range 22-63 years (mean/SD- 42.4/14.9 years)	Visual analysis showed no change on SPQ and WAI-SR measures following reformulation. Incremental change across time series was observed for two clients on WAI-SR
Kellett (2007);UK	Single case A/B multiple baseline design	BSI (Derogatis, 1993); BDI-II (Beck, Steer & Brown, 1996); IIP-32 (Hughes & Barkham, 2005); PSQ (Pollock, Broadbent, Clarke, Dorrian & Ryle, 2001); Young Schema Questionnaire- short version (YSQ-SV; Young, 1998)	24 session CAT (with four additional follow up sessions)	N=1 (1 female) psychiatric outpatient; age 21 years	Visual analysis showed no change on measures following reformulation. Incremental change across time series was observed.

Study	Methodology	Measures	Intervention	Sample	Key Findings
Kellett (2005); UK	A/B single case experimental design	BSI (Derogatis, 1993); PSQ (Pollock, Broadbent, Clarke, Dorrian & Ryle, 2001); Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock & Erlbaugh, 1961); IIP-32 (Barkham, Hardy & Starup, 1996); Dissociative Experiences Scale (DES-II; Carlson and colleagues, 1993); State Scale of Dissociation (SSD; Kruger & Mace, 2002)	24 session CAT	N=1 (1 male) psychiatric outpatient; age not given	Visual analysis showed no change of depersonalisation and identify confusion following reformulation
Kerr (2001); (UK)	Single case experimental design	Staff and client report	Between 1 and 6 sessions of CAT	N=4 male inpatients; age range 23-50 years (Mean/SD- 32/10.7 years)	Staff reported improvement in 'disturbed and non-compliant behaviour' coincided with the introduction of reformulation for two of the four participants
Bennett & Parry (1998); UK	Retrospective data analysis	Matching and paired comparison using Core Conflictual Relationship Theme Method (CCRT; Luborsky & Crits-Christoph, 1989;1990) The Structural Analysis of Social Behaviour-Cyclic Maladaptive Patterns (SASB-CMP; Schacht & Henry, 1994; Johnson, Popp, Schacht, Mellon & Strupp, 1989)		N=1 (1 male) outpatient; age 30 years	Rater's perceived reformulation to be accurate and that it is possible to develop a reformulation which appears to capture a client's interpersonal problems after three sessions without the use of standardised and complex methodologies, on the basis CAT clinical skills

Table 2:

Characteristics of Qualitative Studies

Study	Methodology	Data collection	Sample characteristics	Key findings
Tyrer & Masterson (2019) (UK)	Single case repeated measures design; Template analysis	Client change interview	N=6 (1 male/5 females) psychiatric outpatients; age range 26-73 years (mean/SD 41.6/17.1 years)	Themes identified included: Recognising patterns; Breaking the links; Working in partnership
Rose, 2019 (UK)	Interpretative Phenomenological Analysis	Semi-structured interviews	N=6 (1 male/5 females) psychiatric outpatients; age 25-47 years (mean/SD 25/8.6 years)	Themes identified included: Changes due to CAT; Strong emotions; The process
Taylor et al (2018) (UK)	Mixed methods case series	Client interview	N=7 (4 males/3 females) psychiatric outpatients; age range 19-34 years (mean/SD- 26.7/10 years)	Themes identified included: Usefulness of CAT tools; Gaining insight into experience of psychosis; Building a therapeutic relationship; Making positive changes
Evans et al (2017) UK)	Randomised control trial/mixed methods	Thematic analysis of HAT forms (Llewelyn, Elliott, Shapiro, Firth & Hardy 1988)	N=18 (9 CAT/9 TAU) psychiatric outpatients; gender not specified; age not specified	Themes identified included: Building and using SDR; The experience of narrative feedback; Identifying exits
Taplin, 2015 (UK)	Interpretative Phenomenological Analysis	Semi-structured interviews	N=7 (4 males/3 females) psychiatric outpatients; age 37-56 years (mean/SD 46/6.6 years)	Themes identified included: Chaos to clarity; The change process; Relationship dynamics; Focus on treatment contexts/options
Kellett & Hardy (2014) (UK)	A/B single case experimental design with extended follow up	Client interview	N=1 (1 male) psychiatric outpatient; age 36 years	Key changes identified: Seeing people differently; Being able to manage paranoid thoughts; Stopping playing 'the game'. There was a therapeutic benefit of the exits on the SDR. Key variables included emergent trust, reflective use of the NR and mindfulness of paranoia

Study	Methodology	Data Collection	Sample Characteristics	Key Findings
Ruppert, 2013 (UK)	Template analysis	Focus groups and post session feedback forms	N=6 (2 males/4 females) psychiatric outpatients; age range- late 20s-50s years	Themes identified included: Reformulation and self- understanding; CAT tools.
Rayner et al, 2011 (UK)	Grounded theory	Semi-structured interviews	N=9 (1 male/8 female) psychiatric outpatients; age range 25-60 years (mean/SD 41.7/11.2 years	Themes identified included: Being with the therapist; Understanding the feeling; Keeping it real; CAT tools. A core conceptual framework of 'doing with' appeared in all interviews
Shine & Westacott, (2010) (UK)	Time series analysis and template analysis	Semi- structured interview	N=5 (1 male/4 females) psychiatric outpatients; age range 22-63 years (mean/SD- 42.4/14.9 years)	Themes identified included: Feeling heard; Understanding patterns; Space to talk; Feeling accepted; Having something tangible; Working together; Feeling exposed
Hamill et al, 2008 (UK)	Grounded thematic analysis	Semi-structured interviews	N=8 (3 males/5 females) psychiatric outpatients; age range 20-85 years	Categories identified included: Understanding and awareness of self over time; Patients perceptions of therapeutic relationship; Patients perceptions of the structure of therapy; Using letters to communicate self with others
Evans & Parry (1996) (UK)	Multiple baseline across subjects	Semi-structured interview	N=4 (4 females) psychiatric outpatients; age range 24- 42years (mean/SD 32/7 years)	Reformulation did not have a systematic short-term impact upon measures of the client's perceived helpfulness of the sessions, the therapeutic alliance or individual problems

3.2 Methodological quality

The methodological quality of quantitative studies is summarised in Table 3. The quality of the quantitative papers were generally rated moderate to strong across the domains of the EPHPP based on the criteria described by Thomas et al. (2004). There were common methodological problems affecting the quantitative data. The majority of the studies were single case experimental design or case series evaluations (k=9). These small N studies are likely to be limited by selection biases and may not be representative of wider clinical populations. A risk of self-selection bias (or selection biases inked to clinicians identifying cases) was present for 11 studies. Visual analysis was employed by the majority of the studies using quantitative methods (k=8) to determine changes in outcome variables linked to reformulation. While visual analysis is a long-established method for determining the effects of change of single subject data (Kazdin, 1982), the absence of any formal decision rules for guiding inferences associated with visual connections may lead to inconsistent interpretations of performance (Ottenbacher, 1990). This may make it challenging to separate out true changes in outcomes from 'noise' in the data. This is further compounded by few attempts or no attempts to account for confounding factors that may underlie observed effects. There was inadequate reporting of missing data in all of the studies, increasing a risk of bias related to how missing data was managed. It is not clear whether an 'intent to treat' protocol was followed in in the included studies.

A summary of the methodological quality of qualitative studies is summarised in Table 4. Across the domains of the CASP the overall quality of qualitative studies suggested there was adequate information provided to answer the research questions or the studies were considered 'high quality'. There are a number of potential risks to methodological quality to consider. Reflexivity was only considered in a small number of papers (k=4). How the

background of the researchers has impacted on the analysis, collection and interpretation of the data in the remaining studies is unclear. As a result, the transparency and rigor of analysis may have affected interpretation of the data.

A number of the studies explored experiences of therapy occurring as part of regular practice rather than a research trial which is a relative strength of these studies. This may have strengthened the real-world relevance of these studies. However, there was a lack of evaluation or control of the competence of therapists' use of CAT tools, or measure of therapeutic fidelity.

Table 3:

Summary of Quality Assessment of Quantitative Papers using EPHPP Tool

Paper	Selection Bias	Study Design	Confounders	Blinding	Data Collection Methods	Withdrawals and Dropouts
Tyrer, 2019	Weak	Moderate	Weak	Moderate	Strong	Strong
Hamilton, 2019	Moderate	Moderate	Weak	Weak	Moderate	Moderate
Taylor, 2018	Moderate	Moderate	Weak	Moderate	Strong	Moderate
Curling, 2018a	Weak	Moderate	Weak	Moderate	Strong	Weak
Curling, 2018b	Weak	Moderate	N/A	Weak	Weak	Strong
Kellett, 2018	Strong	Strong	Weak	Strong	Strong	Strong
Kellett, 2017	Moderate	Moderate	N/A	Moderate	Strong	Strong
Evans, 2017	Moderate	Strong	Weak	Moderate	Strong	Strong
Kellett, 2014	Moderate	Moderate	N/A	Weak	Strong	Strong
Shine, 2010	Moderate	Moderate	Weak	Weak	Strong	Strong
Kellett <i>,</i> 2007	Moderate	Moderate	N/A	Moderate	Strong	Strong
Kellett <i>,</i> 2005	Weak	Moderate	N/A	Moderate	Strong	Strong
Kerr, 2001	Moderate	Weak	Weak	Moderate	Weak	Moderate
Bennett <i>,</i> 1998	Weak	Weak	N/A	Weak	Strong	N/A
Evans, 1996	Weak	Weak	N/A	Weak	Weak	Strong

Table 4:Summary of Quality Assessment of Qualitative Papers using CASP

CASP Question	Tyrer,	Rose,	Curling	Taylor,	Evans,	Taplin,	Kellett,	Ruppert,	Rayner,	Shine,	Hamill,	Evans,
	2019	2019	2018b	2018	2017	2015	2014	2013	2011	2010	2008	1996
Clarity of research aims	++	++	++	++	++	++	++	++	++	++	++	++
Qualitative methodology appropriate?	++	++	++	++	++	++	++	++	++	++	++	++
Appropriate design for research aims?	++	++	++	++	+	++	+	++	++	++	++	+
Appropriate recruitment strategy?	++	++	-	++	++	++	+	++	++	+	++	_
Appropriate data collection?	++	++	++	++	+	++	+	+	++	++	++	_
Appropriate consideration of relationship between research and participant?	++	+	+	++	+	++	+	++	++	++	++	-
Consideration of ethical issues	++	++	+	+	+	++	+	++	++	+	++	+
Was the analysis sufficiently rigorous?	++	++	+	++	+	++	-	++	++	++	++	+
Is there a clear statement of findings?	++	++	++	++	-	++	-	++	++	++	++	_
How valuable was the research?	++	++	++	++	++	++	++	++	++	++	++	+

Note ++ yes/high quality/adequate information provided to fully answer the question

+ Can't tell/medium quality/information provided but addition detail would have more

adequately addressed the question

- No/low quality/information was not provided or suggested a negative response

3.3 Quantitative studies

3.3.1 Therapeutic change following reformulation. Evidence concerning symptomatic change following reformulation was mixed. A number of studies used visual analysis of outcome data to evaluate the effect of reformulation (k=8). How sensitive a visual analysis was in identifying shifts in outcome following reformulation was unclear. These studies scored either weak or moderate on assessment of selection bias, as they were less likely to be representative of the target population. Of these four studies (Kellett, 2005; Kellett & Hardy, 2014; Kellett et al., 2017; Curling et al., 2018a) showed evidence of sudden treatment gains following the introduction of reformulation. These improvements were across a range of measures and various presenting problems following reformulation. Another three studies (Kellett, 2007; Shine & Westacott, 2010; Tyrer & Masterson, 2019) did not show changes in step or slope following reformulation. One further study, Curling et al., (2018b) used idiographic measures to show that for 2/3 participants a deterioration in symptoms at baseline was reversed following the introduction of narrative reformulation. Kerr (2001) reported significant changes in mental state, overt 'disturbed' behaviour and treatment compliance as assessed clinically by staff for three of four participants with schizophrenia spectrum disorders. All these studies lacked a control group which meant that it is impossible to confidently attribute changes to reformulation as it is not possible to say whether changes would have happened anyway or whether it was caused by other factors. There are a number of limitations in quality of Kerr (2001), particularly in study design, data collection and consideration of confounders which may limit the validity and reliability of their findings.

In the only dismantling trial, Kellett et al. (2018) found no significant difference (Full CAT d=1.68, p= 0.001; CAT-NR d=1.63, p< 0.001) in therapy outcomes between CAT for

depression with NR included and CAT for depression without the NR component. This suggests that there is no evidence that NR does not specifically enhance therapeutic outcome. However, the extensive use of trial selection criteria in Kellett et al. (2018) may limit the generalisability of their findings. Tyrer & Masterson (2019) found no significant change in measures of self-reflection, insight and anxiety, depression, trauma, physical problems, functioning and risk to self, following reformulation for clients (n = 6) with a range of mental health difficulties including depression, low mood and anxiety. In contrast, the same participants, in a client change interview about what helped, reported that meaningful changes in therapy were directly linked to reformulation tools. Tyrer & Masterson (2019) note potential bias in recruitment which may have led to more positive therapeutic outcomes, specifically that therapists may have recruited clients thought to be most likely to engage in therapy. Any participant bias may have resulted in overly positive outcomes. Similar results were reported by Curling et al. (2018b) who found that the utility of NR and SDR and the active use of the SDR to recognise problematic patterns between sessions was rated as 'very helpful' based on scores on the HAT form (Llewelyn, et al., 1988) (Curling et al., 2018b). The very small N=1 sample in Curling et al. (2018b) is a cause of concern in terms of generalisability of the results. A specific criticism identified by Curling et al. (2018b) was whether they measured a therapist effect rather than therapeutic effectiveness.

Following visual analysis of outcome data, Kellett (2007) reported improvements in mental health and personality integration over the course of CAT, but no observable improvement immediately following reformulation. Similar results were found by Hamilton (2019), who reported no significant change in reflective capacity or associated constructs following reformulation. A lack of a comparison group and controlling for potential confounders

suggests these results should be interpreted with caution. Two studies (Shine & Westacott, 2010; Evans & Perry, 1996) failed to find any effect on symptom amelioration or impact on the therapeutic relationship following reformulation.

The overall state of the quantitative evidence of therapeutic change following reformulation is mixed. There is no consistent evidence that reformulation is associated with improvements in outcomes. Studies where improvements were found are limited by small N samples and a lack of a control group. In mixed method studies, there is some evidence to suggest that while therapeutic change is occurring following reformulation, this change is not reflected in quantitative measures used. There was an over reliance on self-report measures of outcomes in included quantitative studies which represents a methodological concern. There is a possibility of response bias resulting from 'experimental demand' (Hersen, 1978) which may not have been controlled for.

3.3.2 Accuracy of reformulation. Bennett & Parry (1998) found accurate reformulation can be achieved within the time limitations imposed by clinical practice and can be validated by detailed research measures. In this study the accuracy of reformulation was validated using the CCRT (Luborsky & Crits-Christoph, 1990) and SASB-CMP (Schacht & Henry, 1994). However, with a N of 1 the results need to be interpreted with caution.

3.4 Key themes and findings from qualitative studies

3.4.1 Tangible objects. A common theme across studies (k = 9) was how tools that form part of reformulation (SDRs and NR letters) were perceived by clients as tangible reminders and representations of the work undertaken within therapy. These studies largely scored highly on assessment of quality specifically in the context of clarity of research aims and rigorous analysis. Poorer quality ratings were generally in relation to recruitment strategy,

consideration of the relationship between the researcher and participant and consideration of ethical issues. While information was provided in relation to these topics, additional detail would have allowed for a more thorough analysis of individual study quality.

CAT tools appeared to operate as a secure collaborative base from which to explore therapy. This was described as a different experience of thinking about oneself helped by using concrete real-life examples. Such a process may allow for the externalising of thoughts, emotions, memories and experiences, allowing the participants take ownership of them in a meaningful way. It may also aid the process of making issues more tangible and aid in increasing a client's self-awareness (Tyrer & Masterson, 2019). This process appeared to occur within and across therapy sessions. Tyrer & Masterson (2019) scored highly on all quality assessment domains, however, there was some concern over homogeneity of sample which limits the conclusions that can be drawn on the impact of reformulation tools. Shine & Westacott (2010) and Evans & Parry (1996) suggest that the impact of reformulation is a more cumulative and gradual process which appears to support Tyrer & Masterson (2019).

Seeing things written down in black and white made participants' experiences appear more real and stark (Rayner et al., 2011). One caveat to note when drawing conclusions from Rayner et al. (2011) is the homogenous sample in the study. All participants were of white British or Irish origin and eight of the 15 participants were female. Ruppert (2013) describe a more ambivalent and contradictory relationship with CAT tools in a group therapy context. While there was an acknowledgement that it aided group processes and focus. There was a frustration, on the part of clients, that individual maps were not changing enough. More

justification for the data collection methods used to address the research question would have strengthened confidence in the findings of Ruppert (2013).

3.4.2 Connection to the therapist. A sense of reformulation being collaborative, interactive and a foundation for a trusting relationship with the therapist was evident across studies (k = 7). The map appeared to be an embodiment of common therapeutic factors (e.g. validation, empowerment, control and acknowledgement; Hamill et al., 2008). Hearing the reformulation letter being read aloud during reformulation seemed to instil a feeling of being heard and connected to the therapist (Rayner et al., 2011). Both Hamill et al. (2008) and Rayner et al. (2011) scored highly for methodological quality which strengthens the credibility and transferability of their findings. Participants appeared to value being heard without judgement, which offered an opportunity to let their guard down and overcome feelings of embarrassment. This sense of connection seemed to be helped by the explicit manner of describing how unhelpful procedures and roles might be enacted within therapy, which offered a mechanism through which ruptures in the therapeutic alliance could be repaired. CAT tools had the potential to cause some difficulty in the therapeutic relationship (Rayner et al., 2011; Tyrer & Masterson, 2019). This largely related to these tools sometimes bringing a sense of confusion or a lack of common understanding around reciprocal roles, where these aspects are not navigating successfully.

3.4.3 Self-awareness and understanding. Reformulation helped improve clients understanding and self-awareness (Rose, 2019). This may be through a process of facilitation and helping clients develop a more robust understanding of patterns in their behaviour (Tyrer & Masterson, 2019). A potential recruitment bias and homogeneity of the sample included limits the transferability of their findings. Having these patterns presented

in written or diagrammatic form helped clients foster an awareness of how these patterns developed, how they were enacted and the relationship between the two. Change, from a client's perspective seemed implicit in their burgeoning understanding and awareness (Taplin et al., 2015). This awareness appeared to be facilitated by working with the materials in the moment (e.g. hearing the NR or using the SDR to bring attention to enactments). CAT tools may be useful in a group context to aid in increased self-awareness and understanding (Ruppert, 2013). Reflecting on the SDR of other people can help clients make sense of their own. There is potential for this to be a cause of frustration if not managed appropriately.

3.4.4. *Emotional reactions.* Reformulation could evoke strong emotional reactions in many participants (sadness, pain, shock, fear, frustration, feeling overwhelmed or exposed) (Rose, 2019; Evans & Parry, 1996). A number of shortcomings, including problems with selection bias and limitations of the study design were identified in the assessment of quality of Evans & Parry (1996), and as a results, their findings need to be interpreted with caution. The recognition of these emotional reactions was often balanced with an awareness of how the process had helped the individual. The importance of the therapeutic relationship, being containing and trusting, was commented on as being crucial in managing some of these emotional responses. These positive and negative emotional experiences appeared to evidence people's emotional connection to the map and the mapping process and relates to the theme 'connecting with the therapist'.

3.4.5 Hope for the future. CAT reformulation tools may be viewed as a symbol of hope and a vehicle for positive change both during and between sessions (Rose 2019); Rayner et al. (2011); Taplin et al. (2015); Taylor et al. (2018); Hamill et al. (2008); Hamilton et al. (2019) and Evans et al. (2017). NR and SDR were a vehicle to encourage clients to change their

behaviour in order to 'exit' from established patterns of responding, to contemplate change and put that into action. NR and SDR may offer a clear pathway for therapy and a foundation for a planned, contained ending. Potentially reformulation tools help with the first stage of therapeutic change; understanding patterns. This may link to the theme of 'emotional reactions' as there may be an awareness of needing to go through the discomfort of acknowledging painful emotions in order to gain a better understanding of them. The collaborative nature of reformulation could help normalise the unpredictability of the future and the impact of external events. It may reinforce the view that change is continuous and not a discrete process, open to change and requires responsibility and commitment.

4.0 DISCUSSION

The aim of the review was to synthesise the extant literature on the impact of reformulation within CAT. This was the first narrative synthesis systematic review on reformulation literature in CAT. The results were at times clear and at other times inconsistent, particularly across quantitative studies and between quantitative and qualitative studies. Given the complexity and context of what is being investigated and the relatively small number of studies, the multifaceted nature of the evidence base may be understandable. Evidence of symptomatic change following reformulation was mixed across a series of small-scale non-controlled studies. There was no evidence of any pattern of symptomatic change whereby certain populations were more likely to see a change associated with reformulation. In the only controlled study identified, the inclusion of NR within CAT was not associated with any treatment benefit.

These mixed quantitative results are in contrast to the qualitative data, which shows a more consistent pattern of results. The qualitative studies largely highlighted positive features of reformulation, including reports of how reformulation helped guide perceived change, helped to synthesise complex information, developed clients' understanding of their problems, and their connection to their therapists. Qualitative research highlighted how reformulation helped participants build connections with the therapist and with the self. It also offered tangible evidence of therapeutic work. Collectively, the qualitative research highlights that reformulation is a valued part of therapy and that it appears to be acceptable to clients. However, it is difficult to discern what therapeutic effect reformulation is having or how participant's experiences may have differed in the absence of reformulation. One potential hypothesis is that CAT tools, such as reformulation, are the foundation of the

relationship, which then have the impact instead of the tools giving stepwise or concrete change.

Strong emotional reaction to reformulation was a common theme across studies. Negative experiences of reformulation were rare and often balanced against recognition of the positive experiences of reformulation and awareness of its potential value in therapeutic change. Ryle (1990) suggested that the impact of reformulation seemed to lead to self-reflection and the recognition of unhelpful interpersonal patterns which appears an important goal of therapy. This has important implications for clinical practice. It highlights the need to work within a client's Zone of Proximal Development (Vygotsky, 1978), scaffolding where necessary to support a client manage these emotions. Within CAT, this involves a therapist being aware of being 'in advance' of the client, stretching them, but not too far ahead. It requires the therapist to make judgements about what reflections the client is able to enter into.

In view of a number of limitations apparent across quantitative studies it is not surprising that current evidence for the impact of reformulation is inconclusive. The majority of quantitative studies involved small sample, single arm studies. As a result, it is difficult to attribute therapeutic change to the intervention. There was limited data on whether reformulation has a 'sleeper', longer term effect. It is unknown whether there is a cumulative or longitudinal impact of reformulation or how it influences later change in therapy.

Controlled trials and more sophisticated small N designs are a welcome addition to the literature on reformulation. Dismantling trials are suggested as one trial design suited to determining the active constituent components of therapies (Carrico & Antoni, 2008).

However, Bell et al., (2013) suggests that while dismantling trials can offer an elegant design to identify active components in psychotherapy, they are likely to find small or no differences between the standard treatment condition and the dismantled condition. Bell et al. (2013) argue that added component trials are more likely to improve therapy outcomes by incrementally advancing therapies. This may be a direction for the next wave of research on the key components of CAT. Any future studies investigating mechanisms of change could include a fine grained trial methodology analysing the exact shape of this change. These studies should involve multiple measures of potential (specific and non-specific) CAT process measures (e.g. PSQ; Pollock et al., 2001). Furthermore, within client variance could be monitored over time using the repertory grid technique (Kelly, 1955) and experience sampling methodology (Bolger & Laurenceau, 2013). Repertory grids provide an idiographic assessment tool and so might be a way to monitor changes in person-specific psychological processes associated with reformulation over time. Experience sampling methodology (Bolger & Laurenceau, 2013) provides a way to monitor more micro-longitudinal moments by moment processes and so may be a way to see things change in the moment following reformulation. While further studies are needed to improve confidence in the findings, it will be important that the generalisability of these studies is not limited by the extensive use of trial selection criteria and the exclusion of people with comorbid conditions.

An important consideration for the next wave of research is that currently CAT therapists are involved in co-authoring most of the evidence related to reformulation. This is understandable given the relatively small but burgeoning research base in CAT. However, allegiance effects could result in these authors having an interest in positive findings and may limit confidence in their conclusions. Having CAT clinicians working more with

independent university based research groups would strengthen evaluation of the approach.

Successful reformulation is contextualised within a supportive and collaborative relationship (Ryle & Kerr, 2002). Therefore, it may be difficult to empirically differentiate which are the key agents of change. Measures of working alliance may not capture the subtlety of that change. It also remains unclear whether the quantitative measures used could capture the sort of change highlighted by the qualitative studies on reformulation. Change is complex and often reflects subtle variations in symptoms related to different diagnostic categories. There is an ongoing debate about whether a focus on improving diagnosis specific symptoms can capture this holistic change (Kinderman, , 2013). More sophisticated and nuanced measurement tools will help overcome the challenge of measuring therapeutic change following reformulation and in CAT more broadly. This could include more idiographic and creative measurement techniques. Such refinements can make reformulation as efficient and relevant as possible while promoting hope and the potential for change for client.

This narrative synthesis had a number of relative strengths. It was pre-registered on PROSPERO prior to commencement and involved the searching of multiple databases. Including both quantitative and qualitative papers allowed for a richer exploration of a complex therapeutic phenomenon. Parallel screening and quality assessment ensured there was a check for bias and reliability. It also ensured that all appropriate studies were included.

While the review contributed novel and important information on the impact of reformulation in CAT, it should be considered in light of some limitations. There was wide

variation in the research methodologies of included papers, which prevented the use of techniques such as meta-analysis to better pool the results of studies. The review search only included studies published in English. In the final analysis all studies were carried out in the United Kingdom. While multiple databases were searched this did not include grey literature databases. However, to mitigate this limitation, members of the CAT community were contacted to ensure as many of these studies as possible were included. Finally, a list of excluded studies was not included in the review, which could be considered a limitation.

There was a lack of CAT specific mechanism measures in the included studies. Furthermore, therapist competence and adherence to theory was often assumed. The importance of examining trans-diagnostic change mechanisms will inform understanding of the processes leading to therapeutic change, help improve CAT outcomes and refine therapeutic procedures to identify which clients are likely to benefit from CAT and reformulation. It is worth noting that this is a challenge for psychotherapy in general and not specific to CAT (Kazdin, 2009).

In conclusion, reformulation involves idiosyncratically supporting individuals to reformulate their target problem procedures and reciprocal roles within a normalising and empowering framework. There appears a lack of consistency between quantitative and qualitative studies regarding its impact on participants. This limits any common conclusions or synthesis that can be made. More research, deconstructing the efficacy of case formulation is warranted. This could include separating general mechanisms of therapeutic change from therapy specifics mechanisms. Determining if these mechanisms of change are common to several disorders or trans-diagnostic would be useful. Having independent research teams involved in this research could reduce the potential for bias in recruitment and analysis.

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Paper 2: Cognitive Analytic Therapy for the Containment of Self-Harm (CATCH): A pilot

randomised controlled trial

Paper 2: Cognitive Analytic Therapy for the Containment of Self-Harm (CATCH): A pilot randomised controlled trial

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ABSTRACT

Objectives: Non suicidal self-injury (NSSI) is a complex phenomenon associated with a range of intra and interpersonal difficulties, psychological distress and comorbidity. It is an important predictor of future suicidal thoughts and behaviours and evidence of therapeutic efficacy is limited. Cognitive Analytic Therapy (CAT) is a brief, integrative and pragmatic therapy that has a unique process of reformulation focusing on clients' patterns of relating to themselves and others. The purpose of this study was to determine whether a brief two session CAT informed intervention Cognitive Analytic Therapy for the containment of self-harm (CATCH) was feasible to deliver and safe for people with NSSI, and to gather initial evidence regarding its effects on depression, urges to self-injure and self-compassion.

Method: The CATCH study was a two-armed, open feasibility randomised controlled trial (RCT) whereby 14 participants were randomly allocated to receive either CATCH plus treatment as usual (TAU) or TAU alone. Participants completed weekly online clinical outcome measures during their involvement in the study. Feasibility was based on the proportion of eligible participants consenting to the study, attrition, the proportion of participants completing intervention and the proportion of participants completing two sessions. Safety of the intervention, for people in the CATCH plus TAU arm was evaluated using a self-report measure of adverse experiences.

Results: Twenty nine people gave consent to be contacted by the research team during recruitment for the study. Sixty seven percent of people eligible to participate in the study consented to be involved. Seven participants were allocated to CATCH plus TAU and seven to TAU alone. Of those offered CATCH, six of the seven participants completed both intervention sessions, the remaining participant attended one session. All seven attended both research sessions. Six out of seven participants in TAU attended both research sessions. Clinical outcomes suggest evidence of improvements in depression for the CATCH group seen both at the individual and group trend level. There were reductions in urges to self-injure that appeared more pronounced for the CATCH group. No unanticipated or serious adverse experiences were reported during the study.

Discussion: This study suggests that CATCH is a feasible and safe intervention for people with NSSI. Clinical outcomes point to there being some clinical utility in CATCH, although results are interpreted with caution. Further clinical studies of the treatment are warranted.

Keywords: Non-suicidal self-injury, self-harm, Cognitive Analytic Therapy, brief therapy, relational, interpersonal.

1.0 INTRODUCTION

NSSI is defined as the intentional and deliberate damage to the body without suicidal intent (Klonsky & Muehelenkamp, 2007). This differs from the broader definition of deliberate selfharm which is used to describe any self-directed harmful behaviours (indirect or direct), regardless of their suicidal intent (Kapur et al., 2013). NSSI behaviours are associated with a range of interpersonal and family difficulties (Buckmaster et al., 2019), stigma and feelings of shame (Burke et al., 2019) and are often a marker of psychological distress (Klonsky & Olino, 2008) and comorbid psychopathology (Bentley et al., 2015). NSSI is an important predictor of future suicidal thoughts and behaviours (Hamza et al. 2012). Estimates suggest that prevalence of NSSI in the United Kingdom has increased from 2.4% in 2000 to 6.4% in 2014 (McManus et al., 2019). There is a lifetime prevalence of 13.4-17.2% in adolescents and young adults with the age of onset typically around 13 years (Klonsky et al., 2003; Nock, et al., 2006; Swannell et al., 2014). The estimated prevalence for adults is 5.5.% (Swannell et al., 2014). As a result, supporting people with NSSI is an important target for psychotherapy. Effective management provides an opportunity for treating underlying psychiatric distress and may make an important contribution to suicide prevention (Department of Health, 2002a).

Psychotherapeutic approaches such as Cognitive Behaviour Therapy (CBT) (Muehlenkamp, 2006); Dialectical Behaviour Therapy (DBT) (Linehan, 1993); psychodynamic psychotherapies (Briggs et al., 2019) and Mentalisation based therapy (MBT) Allen & Fonagy (2006) have been used to treat NSSI. Hawton et al. (2016) focusing on self-harm rather than NSSI specifically) concluded that aside from CBT there were few promising interventions, precluding firm conclusions as to their effectiveness. Turner et al. (2016) suggest cautious optimism regarding the possible efficacy of emotional regulation group therapy, manual-

assisted cognitive therapy and DBT for reducing NSSI. Additionally, Turner et al. (2016) found that although DBT is often associated with reduced rates and frequency of NSSI in uncontrolled trials and reduced rates of self-harm more generally, further research is necessary to substantiate its advantage over active control conditions for NSSI specifically. Additionally, these interventions often include lengthy treatment plans with heavy time commitments and sometimes lack organisational support and investment, thus limiting their accessibility (Carmel et al., 2014).

People who engage in NSSI experience barriers to treatment, with associated risks of disengagement and high likelihood of repetition and relapse (Lizardi & Stanley, 2010; Joubert et al., 2012; Kapur et al., 2010). In recognition of these challenges, there has been growing interest in brief interventions for this population that are focused on maintaining long term contact and/or offering reengagement with services when needed (Lizard & Stanley, 2010; Kapur et al., 2010). Examples of beneficial brief therapy include Guthrie et al. (2002) who reported reduced suicidal ideation and further episodes of self-harm and higher patient satisfaction for participants following four sessions of brief Psychodynamic Interpersonal Therapy (PIT) compared to patients receiving usual care.

Given findings that NSSI is often preceded by relational conflict and can cause significant relational consequences (Prinstein et al., 2009), it can be argued that relational approaches to the treatment of NSSI may be indicated. Zelkowitz & Cole (2019) reported in their recent meta-analysis that experiencing high levels of self-criticism was found to be highly associated with NSSI. This suggests that a person's relationship with themselves can also be an important factor associated with NSSI. There is evidence that a negative self-concept, shame and self-criticism are related to NSSI (Sheehy et al., 2019). For many people, NSSI

appears to reflect an enactment of these negative ways of seeing and feeling towards oneself. Glassman et al. (2019) suggest that NSSI may arise out of a belief of being deserving of punishment and this can then result in strong feelings of shame. Aversive relational experiences can also be internalised into maladaptive schemas (Beck, 1979; Dozois and Rnic, 2015). Experiences of rejection can be internalised and can then form a way of relating to oneself that is self-attacking (Forrester et al., 2017). Self-injury may therefore serve as a means of self-punishment (Taylor et al., 2019). Self-injury has also been described as an alternative way to communicate distress and need to others (Nock, 2008).

Given this NSSI can be considered a relational act, in other words it reflects the way a person feels about themselves (and others) and it is, arguably, an enactment of that relationship (e.g. self-attacking, self-punishing). This fits with a CAT model, where the focus would be to help individuals notice these unhelpful relational patterns and shift towards a kinder or more compassionate way of seeing themselves, where they do not need NSSI anymore (Ryle & Kerr, 2002). CAT combines a pragmatic problem-solving focus with a relatively simple model of describing problematic relationship patterns (Ryle, 1995a).

CAT was designed and developed as a brief, integrative and pragmatic form of psychotherapy, specifically to meet typical public sector psychotherapy service demands (Ryle, 1990, 1995; Ryle & Kerr, 2002). Outcome research demonstrates the effectiveness of CAT for a diverse range of presenting problems (Calvert & Kellett, 2014; Ryle et al., 2014). Brief CAT interventions have been used with individuals with NSSI or individuals diagnosed with personality disorder (Sheard et al., 2000; Carradice, 2013), although their efficacy is unclear. Cowmeadow (1994; 1995) has presented two potential models of brief CAT specifically with people who have self-harmed which were not empirically evaluated.

CAT has a unique process of reformulation focusing on clients' patterns of relating to others and themselves (Denman, 2001; Ryle & Kerr, 2002). In CAT, client's presenting difficulties (such as NSSI) are described as 'target problems' and related target problem procedures (TPPs) (Leiman, 1997; Ryle, 1997). Another key aspect of reformulation is the identification of a client's reciprocal roles (Ryle, 1985). Reciprocal roles are patterns of relating to one self ('self to self') or to others ('self to others' and 'others to self') (Ryle, 1985). These can be helpful (e.g. caring-cared for) or unhelpful (e.g. neglecting-neglected). Reformulation results in the development of a sequential diagrammatic reformulation (SDR). The SDR is a visual (typically hand-drawn) map, collaboratively developed to clarify and identify key reciprocal roles and target problem procedures that maintain a client's difficulties. The SDR allows the therapist to manage the enactment of roles and procedures that may emerge within the therapeutic relationship (Ryle, 1997).

CAT, as a therapeutic model works well with complexity (such as NSSI) and is able to be adapted to the individual needs of each client, drawing on principles, rather than being guided by diagnostic frameworks or protocols (Ryle & Kerr, 2020). As the focus in CAT is on the identification of underlying patterns of relating to oneself and others, the therapy can move beyond particular symptoms or experiences to broader underlying relational patterns and procedures.

In developing an evidence base for complex interventions, an important early step is to ensure the therapy is safe for clients, and that it can feasibly be evaluated within a trial context (Craig et al., 2013). While previous research (Sheard et al., 2000; Cowmeadow, 1994, 1995) suggests that brief CAT may be suited to helping people who engage in NSSI, there has been no systematic evaluation of feasibility. Intervention feasibility can provide

sufficient methodological evidence about the design, planning and justification of a trial (Blatch-Jones et al., 2018). The Medical Research Council (MRC) (2008) guidelines also state that pilot trials are essential prior to any major trial seeking to evaluate a complex intervention such as a psychotherapy (Lancaster, 2015).

The primary aim of this study was to determine the feasibility and safety of a brief two session CAT informed intervention- CATCH for people with NSSI. Feasibility was based on the proportion of eligible participants consenting to the study, attrition, the proportion of participants completing intervention and the proportion of participants completing two sessions. Safety of the intervention was determined by adverse experiences and effects of the intervention.

A secondary aim was to obtain an initial estimate from baseline to follow up of the potential size of the therapeutic effects on depression, urges to self-injure and self-compassion. This study was not designed to assess efficacy, but nonetheless could identify whether there is a 'signal' suggesting a therapeutic effect may be plausible.

2.0 METHOD

2.1 Pre-registration

The current trial was part of a wider study, a protocol for which was pre-registered on the Open Science Framework (https://osf.io/yk9sj/register/5c08457ed2833380029cf73bf) and on ClinicalTrials.gov (study identifier NCT03853382) in February 2019.

2.2 Study Design

The initial aim of the empirical paper was to establish the feasibility of CATCH and, secondarily, to provide an indication of the effectiveness of CATCH plus TAU compared to TAU alone with a robust pilot trial with group comparisons. However, due to logistical issues affecting recruitment and other implementation challenges meant the study was repurposed. This refocus involved a feasibility trial with a single follow-up point. This was in line with recommendations suggested by Eldridge et al. (2016) for feasibility studies. The CATCH study is therefore most appropriately described as two-armed, open feasibility randomised controlled trial (RCT) whereby participants were randomly allocated to receive either a brief CAT-informed therapy (CATCH) plus TAU, or TAU alone. Researchers were not blind to treatment allocation. However, the majority of data for the study was collected online. One of the functions of online, self-report data collection was to reduce potential bias. As the main focus of the study was feasibility not efficacy, blinding was also not considered necessary.

2.3 Sample size

Initially it was hoped to recruit 40 participants into the study to allow for a robust comparison between groups in line with the secondary research aim. Recruitment began late due to delays with obtaining ethics and having to amend aspects of the protocol. Recruitment into the study was slow to start and was lower than anticipated. The preregistered protocol contingency involved dropping the secondary aim of testing the efficacy of the intervention. There is variation in recommendations for sample size in a feasibility trial. Hertzog (2008) cautions that it is not a simple or straightforward issue because studies are influenced by many factors. Nevertheless, Issac & Michael (1995) suggest between 10 and 30 participants. A sample size of n=14 is similar to previous feasibility trials of therapies, including CAT e.g. Gleeson et al., 2012). This allowed for an initial estimate of key feasibility indicators including recruitment, attrition, retention and adverse experiences.

2.4 Participants

Participants were recruited from a range of mental health and third sector services. These included secondary care NHS mental health services, university health services, charity and voluntary groups supporting people who self-harm. People were eligible to participate if they were i) aged over 16 years (parental guidance was not needed; British Psychological Society (BPS) Generic Professional Practice Guidelines (2008); ii) comfortable with and have to access to email and the internet for completing study measures; iii) currently under and receiving support from clinical/health service including NHS, third sector or university health services; iv) have had five or more instances of NSSI in the past year (following Diagnostic and Statistical Manual of Mental Disorders V [DSM-V criteria for NSSI disorder], American Psychiatric Association, 2013); v) have an adequate English language ability to understand

study materials; vi) and be deemed capable of providing informed consent by their clinical team. NSSI methods were operationalised to include cutting, burning, biting, scratching oneself, as well as head-banging or self-poisoning.

People were unable to take part if they were currently receiving any other psychological therapy or had previously had CAT. People were also excluded if they had been diagnosed with a learning disability or autism spectrum condition as judged by their clinical team, since the intervention had not been developed for these populations. If a person was judged to be at high risk of suicidal behaviour (operationalised as the presence of high or immediate suicidal intent and planning) or had been hospitalised as a result of self-harm in the month prior to initial contact with the research study team they were excluded from participating at that time. Participants in both groups were reimbursed with a 20 pound voucher for expenses associated with participation in the study.

2.5 Primary Outcome

2.5.1 Feasibility. Feasibility was based upon the proportion of eligible participants consenting to the study, attrition, the proportion of participants completing the intervention and the proportion of participants completing two sessions. Efforts were made within the study design to minimise missing data, including regular 'checking in' messages or calls with participants as a prompt to complete the online questionnaires.

2.5.2 Safety. Safety of the intervention was assessed using the Adverse Effects in Psychotherapy self-report measure (AEP) (Hutton et al., 2017; unpublished). Each item on the AEP is endorsed between 'not at all' (score of 1) to 'very much' (score of 5). The AEP has a potential total score of 135, with larger scores indicating more adverse experiences. Endorsement of items greater than 'a little' (score of 3) on the measure were deemed to be a notable adverse experience. Adverse experiences occurring during the course of the study (identified through discussion with the participant and their clinical team) were also monitored and recorded. These included hospitalisation (related to mental health), medically serious self-injury (i.e. requiring medical intervention) and suicidal ideation where a plan and intent were present. This scale is designed to cover a range of different potential adverse experiences, but there is no assumption that these necessarily load onto a common factor or latent variable, hence Cronbach's alpha may not necessarily be informative for this scale. As a result scores are analysed at the individual item level. The AEP questionnaire was used in a case series of CAT (Taylor et al., 2018).

2.5.3 Secondary outcomes.

Self-Injurious Thoughts and Behaviours Inventory Short-Form structured interview (SITBI-SF; Nock et al., 2007). The NSSI behaviour section from the SITBI-SF was completed with participants. These included questions on history, frequency, severity and methods of NSSI. The SITBI-SF has good construct validity and strong interrater reliability (k=.9; Nock et al., 2007). Of note, we administered only the NSSI questions for information on participants' history, frequency, severity, and methods of NSSI (the interview was designed to be used in a modular way so validity was not affected).

Patient Health Questionnaire (PHQ9; Kroenke et al., 2001). The PHQ9 was used to assess depression. It includes 9 items and determines the extent to which participants have been bothered by difficulties over the previous two weeks by rating on a scale of 0 (not at all) to 3 (nearly every day). The PHQ 9 has a potential total score of 27, with larger scores indicating more severe depression. The factor structure and internal reliability of the PHQ9 has been supported and its convergent validity with other measures of depression demonstrated

(Cameron et al., 2008). Kroenke et al (2001) report the PHQ9 has a Cronbach's Alpha of 0.89. For the PHQ 9 (Kroenke et al., 2001), we judged clinically significant change as a pre-treatment score of \geq 10 and a post-treatment score of \leq 9 with an improvement of score of \geq 5 (McMillian et al., 2010).

The Personality Structure Questionnaire (PSQ; Pollock et al., 2001). The PSQ measures personality aspects in line with the 'Multiple Self States Model' in CAT. The PSQ includes 8 items rated on a five-point scale with opposite ends representing agreement with an unstable or stable sense of self. The factor structure, reliability and validity of this measure has been empirically supported (Bedford et al, 2009; Pollock et al., 2001). The PSQ has a total score of 40, with higher scores representing more severe personality disturbance. A cut of score of \geq 26 has been supported for the identification of psychological difficulties, based on an Italian translation of the measure (Berrios et al., 2016). Bedford et al. (2009) report a Cronbach's Alpha of .87 for the whole PSQ measure.

Self-Compassion Scale (SCS; Neff, 2003). The SCS includes 26 items rated on a scale of 1 (almost never) to 5 (almost always) as to how often participants engage in a range of thoughts or behaviours. The SCS includes six subscales including self-criticism, self-kindness, isolation, common humanity, over-identification and mindfulness. There is evidence for the factor structure, reliability and validity of the SCS (Neff, 2016). There are no designated cut-off scores for the SCS because it was not designed for clinical populations. The SCS was included as it captures a form of self-relating and thus was considered a relevant process measure for CAT. The SCS measure has been used in previous research to measure change related to specific interventions (Ferrari et al., 2019). Neff et al. (2007) report a Cronbach's Alpha for the SCS of .94.

Alexian Brothers Urges to Self-injure Scale (ABUSI; Washburn et al., 2010). The ABUSI assesses the frequency, intensity, and duration of the urge to self-injure, as well as the difficulty of resisting the urge and the overall urge or desire to engage in self-injury in the prior week. Responses are on a 7-point scale with a maximum total score of 30 and higher scores reflecting more intense urges to self-injure. There is preliminary support for the reliability and validity of the ABUSI as a measure of the urge to self-injure (Washburn et al., 2010). Washburn et al. (2010) report a Cronbach's Alpha of .93 for the ABUSI measure. There are no cut-off scores reported for this measure.

Competence of Cognitive Analytic Therapy (CCAT; Bennett & Parry, 2004)

CCAT is a valid and reliable measure of CAT competency across 10 domains and a global score above 20 provides a cut-off for therapist competence for that session (Bennett & Parry, 2004). The CCAT has a total score of 40, with higher scores indicating more competently delivered CAT. Two domains were not included in the competency assessment because they are specific to 16-24 sessions CAT. Audiotapes of sessions for CCAT analysis were selected at random by the chief investigator. Barlow & Brown (2020) report a Cronbach's alpha for the CCAT of .96.

Additional demographics measure- questionnaire assessing demographic and clinical information was completed with all participants. This included questions related to age, gender, education, ethnicity, employment and mental health support needs and was recorded at baseline.

2.6 Procedure

Ethical approval was obtained from the local Research Ethics Committee (19/NW/0176). A diagrammatic representation of the recruitment process and study procedure is displayed in Figure 2.

Potential participants were initially identified by clinicians in relevant services. Clinicians were asked to briefly describe the research before seeking consent for individuals to be contacted by the research team. People could also self-refer into the study by contacting the research team directly in response to study adverts placed in services and on social media.

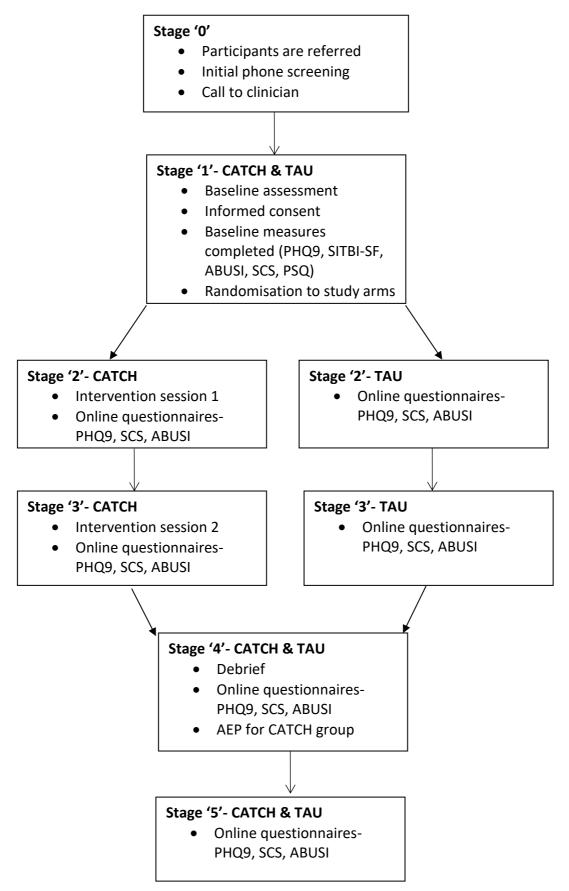
Referrals into the study were first screened for eligibility via telephone. During this contact risk to self was discussed, and should risk be identified it would be responded to using the risk management protocol (see Appendix D). Potential participants' clinicians or clinical teams were also contacted to confirm eligibility. Eligible individuals were invited to an initial face-to-face meeting where informed consent was taken.

Participants were invited to complete a series of measures in the face-to-face meeting with a researcher at baseline (SITBI-SF, ABUSI, PHQ9, PSQ). The PSQ was included at baseline to describe the sample in the context of personality integration. It was intended to complete the PSQ at the follow up session. However, due to a human error involving a miscommunication between therapists this was not the case. Following baseline, participants were randomly allocated to either CATCH plus TAU or TAU alone. Random allocation was undertaken by a member of the research team (PJT) who did not have direct contact with any participants and was not involved in screening or baseline. Randomisation used a random block design sequence with block sizes 2, 4, 6 generated via

sealedenvelope.com. Random allocation to both groups was 1:1. Participants were informed of their allocation by the researcher via phone. Following baseline, participants in both CATCH and TAU condition were asked to complete a series of measures (PHQ9, ABUSI, SCS). Participants in the CATCH group completed measures online after each session, at the face to face follow-up and one further online measure. Participants in the TAU group completed weekly measures online, at a face to face follow up and one further online measure. The initial plan was for this to occur over five weeks. This was not the case for participants in the CATCH group for reasons outlined above. The assessment time points used were baseline (week 0) and between week four and six for follow up. The rational for these follow up time points were that all participants had finished both intervention sessions at that point. A bespoke platform to host the online data collection was developed by the e-learning & IT development co-ordinator from the University of Manchester clinical psychology programme. Participants in the CATCH group were invited to a follow up assessment and interview when they had completed both intervention sessions. At this session, the AEP measure was completed. Participants in the TAU group attended the follow up after completing two weeks of online measures. The full study protocol can be found in Appendix E. All measures used are in Appendix F.

Figure 2:

Recruitment process and study procedure



2.7 CAT informed intervention

The therapy manual for CATCH (Appendix G) was adapted from a protocol developed by Sheard et al. (2000). The therapy manual was informed by models of longer-term CAT (Ryle & Kerr, 2002). Both sessions lasted approximately 90 minutes. The aim of the sessions was to develop a shared understanding of the client's experience of self-injury, capturing the antecedents, consequences and patterns related to this behaviour. This was explored through the development of a SDR. The aim of using CAT constructs of 'reciprocal roles' and 'procedures' was to help develop participants awareness and understanding of their experiences by reformulating or mapping these patterns by drawing them out showing how these patterns were maintained. Participants took a copy of the SDR and were encouraged to reflect on it between sessions. If appropriate an initial exploration took place of how a participant might start to pause or break free from some of these identified patterns and processes by developing basics 'exits' on the SDR.

2.8 Analysis

Analysis followed CONSORT 2010 Statement guidelines. Descriptive statistics related to feasibility and treatment safety were calculated. The mean change in secondary outcomes was estimated alongside 95% confidence intervals. Rates of reliable change were determined for two distinct approaches, the Reliable Change Index (RCI; Jacobsen & Traux, 1991) and also Standardised Individual Difference (SID; Payne & Jones, 1957). While the RCI is widely employed in research it is more liberal than the SID, which has been found to perform better than other approaches in terms of false positives (Ferrer & Pardo, 2014). Due to the variations in participant's length of time in the study, a consistent time point for group comparisons and change statistics was identified. This time point was between 28

and 35 days from joining the study for all participants. The data were analysed using IBM SPSS Statistics Version 26 (IMB Corp. 2019) predictive analytics software.

2.9 Treatment fidelity and competence

The intervention sessions were delivered by two researchers, both final year Trainee Clinical Psychologists, who had experience and training in delivering psychological interventions with people who engage in NSSI. Monthly supervision was delivered by an accredited CAT Psychotherapist, with additional biweekly supervision delivered by the Chief Investigator, a Senior Clinical Psychologist. Peer supervision was also engaged in on an ad hoc basis by the two researchers delivering the intervention. The competence of five of the fourteen CAT sessions was assessed using the CCAT (Bennett & Parry, 2004) by an accredited Association for Cognitive Analytic Therapy (ACAT) supervisor independent from the research.

3.0 RESULTS

3.1 Recruitment

Figure 3 shows the number of participants successfully recruited to the study for each month of the recruitment window. Recruitment was initially slow, but increased with each subsequent month. The final month of recruitment was the most successful. Potential explanations for this could include improved relationships between researchers and referring clinicians and familiarity with the research project and the research team. Both researchers were more available during the period of larger recruitment due a 'research block' at university, where their weeks were dedicated solely to research activities.

Figure 3:



Individuals recruited to CATCH per month

3.2 Feasibility

A consort flow diagram of recruitment is displayed in Figure 4. Data was not available on how many individuals were approached about participating in the research. One reason for this was that care coordinators did not have capacity to record this information systematically 29 people gave consent to be contacted by the research team during recruitment for the study. Following screening and baseline assessment eight of these were not eligible to participate because they were currently in therapy or had not engaged in NSSI on five or more occasions in the last year. A further three declined to participate when contacted to discuss participation. Two people ceased engaging with the research team either by not returning phone contact or email when assigned to the TAU group. A further two asked to postpone participation, which resulted in them not being able to take part in the study because recruitment had stopped when they wanted to participate. Sixty seven percent of people eligible to participate in the study consented to be involved. Therefore, the final sample consisted of seven participants in the intervention group (M age = 31.5 years; SD = 13.7 years; range 19-58; 6 females & 1 male) and seven participants in the TAU group (M age = 35.4 years; SD = 13.3 years; range 19-52; 2 males, 3 females & 2 gender not specified). Of the participants in the CATCH condition, 57% (n=4) had previously had CBT. In the TAU condition 86% of participants (n=6) have had CBT in the past. Group level participant characteristics are reported in Table 5. Individual level participant characteristics are displayed in Appendix H.

Figure 4:

Consort Flow Diagram

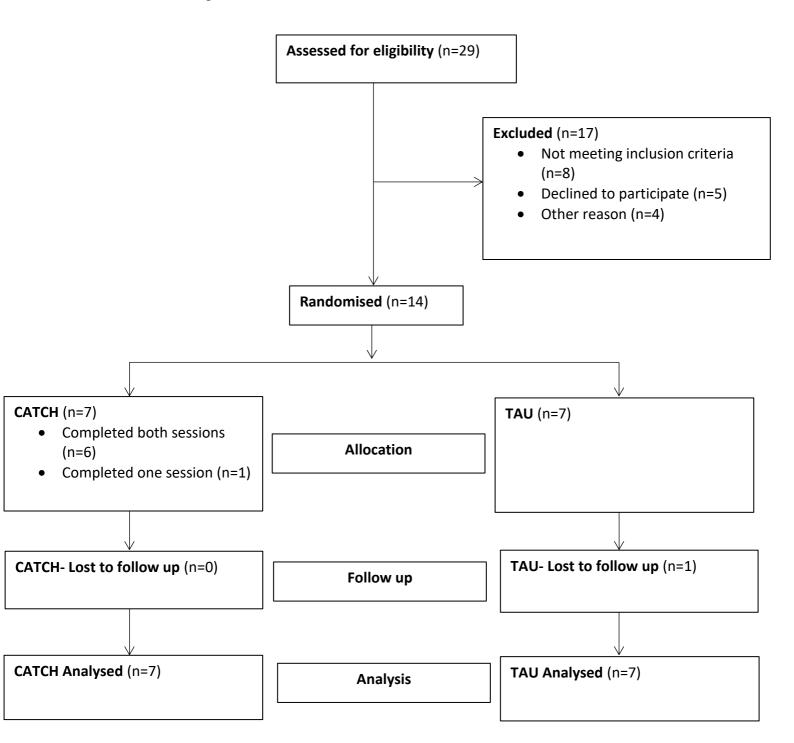


Table 5:

Group level participant characteristics

Variable	Intervention plus TAU Group	TAU Group n (% of group)	
	n (% of group)		
Gender			
Female	6 (86%)	3 (43%)	
Male	1 (14%)	2 (28%)	
Other	0	2 (28%)	
Ethnicity			
White	7 (100%)	6 (86%)	
Other	0	1 (14%)	
Employment			
Full time	2 (28%)	1 (14%)	
Part time	0	1 (14%)	
Out of work (not looking)	0	2 (28%)	
Unable to work	2 (28%)	1 (14%)	
Voluntary work	1 (14%)	1 (14%)	
Student	2 (28%)	1 (14%)	

Methods of NSSI used¹

Cutting	6 (86%)	6 (86%)
Picking skin (drawing blood)	7 (100%)	0
Scrapping skin (drawing blood)	7 (71%)	5 (71%)
Burning	4 (57%)	2 (28%)
Hitting self	4 (57%)	3 (43%)
Other	5 (71%)	3 (43%)
Attended previous therapy	4 (57%)	6 (86%)
Previously attempted suicide	3 (43%)	6 (86%)
Suicide attempt in last year	2 (28%)	2 (28%)
Sought medical treatment for NSSI	3 (43%)	2 (28%)
Location of sessions		
Home	2 (28%)	4 (57%)
University	3 (43%)	2 (28%)
Community Service	2 (28%)	1 (14%)
Personality Structure Questionnaire		
Mean (SD)	29.28 (6.54)	31.14 (5.4)

1 These methods were not mutually exclusive

3.3 Attendance rates and adherence

Across both CATCH and TAU groups, all participants (n=14) attended the research baseline assessment (week one). All participants (n=7) in the CATCH group attended the follow up session. Six participants (n=6) in the TAU group attended the follow up appointment. One participant (n=1) did not attend the follow up assessment because of a change in personal circumstances which meant that attending the session was not possible.

Six participants (n=6) completed both CATCH therapy sessions. One participant (n=1) chose not to complete the second CATCH therapy session because of an increase in stress due to a change in personal circumstances and they did not want the 'added pressure' of the CATCH session.

3.4 Intervention safety

No unanticipated or serious adverse experiences were reported during the study. This included hospitalisation or any planning of a suicide attempt or suicidal behaviour. Self-reported adverse experiences as recorded on the AEP questionnaire were minimally endorsed with participants' average item score ranging between 1.00 and 3.00. The mean total summed score for participants was M = 30.5 (SD = 2.92). An item endorsed at 3.00 corresponds to 'a little' for how prominent the adverse experience had been. An item endorsed at 1.00 suggests the adverse experience had 'not occurred at all'. Individual scores endorsed at 3.00 were recorded on three occasions by different participants ('taking part was making me want to self-harm'; 'I felt embarrassed talking about my problems with people I had not met before'; 'Taking part hasn't helped me with my problems'). There were no instances of items endorsed at higher than 3. In summary, no adverse experience was highly endorsed by any participant in the CATCH group at post therapy assessment. Mean scores for individual items on the AEP are shown in Appendix I.

3.5 Therapist Competency

The overall CCAT mean/SD for the sessions assessed was M=29.60/SD=7.23. The mean/SD for each domain is presented in Table 6. Each domain is scored between zero, completely incompetent practice, and four, highly competent practice. All sessions assessed were above the cut off score for competent CAT practice of twenty described by Bennett & Parry (2004).

Table 6:

Domain	Mean/SD
Early engagement, induction and remoralisation	3.2/0.74
Theory- Practice Links	3/0.89
CAT Tools & Techniques	3/0.63
Establishing and Maintaining external framework	3/0.89
Common Factors: Basic supportive good practice	3.2/0.74
Respect, Collaboration & Mutuality	3/0.89
Assimilation of problematic states and emotions	2.4/0.49
Making links and hypotheses	3.2/0.40
Identifying and managing 'threats' to the TA	2.6/0.80
Therapist management of own reactions	2.8/0.75

Mean and SD for each domain of the CCAT

3.6 Secondary clinical outcomes

Descriptive statistics concerning average scores on the secondary outcome measures at baseline and follow up (between weeks four and six) are presented in Table 7, along with mean change (and 95% confidence intervals). There was a trend toward improvement in depression (PHQ-9) for participants in the intervention group and deterioration in the TAU group from baseline to follow up. The deterioration in score for the TAU group was relatively small. There was a small and similar improvement in self-compassion scores for participants in both groups. There was a trend toward improvement in urges to self-injure in both groups. This trend was more pronounced in the intervention group at follow up.

Rates of reliable change are reported in Table 8. Rates calculated via the RCI and SID differed, with the SID being generally a more conservative indicator. Clinically significant reliable improvement in depression scores was observed for three participants in the intervention condition at follow up. A contrasting clinically significant deterioration was demonstrated for one participant in the TAU condition at follow up. Reliable improvement in self compassion was recorded on the RCI for two participants in the intervention condition at follow up, but not on the SID. A contrasting clinically significant deterioration was demonstrated for one participant in the intervention condition. Reliable improvement was recorded for one participant on the RCI in the TAU group, but not on the SID. Clinically significant reliable deterioration in urges to self-injure was recorded for one participant in the RCI in the TAU group, but not on the SID. There was a similar pattern of change for both the intervention and TAU groups on changes to urges to self-injure. Three participants in each group demonstrated reliable improvements on the RCI only. One participant in each group recorded reliable change on both the SID and the RCI.

Table 7:

	Baselir	ne	Follow-up (28-35 days after baseline)		Mean change	Group mean difference (95% Confidence intervals (CI)	
Variable	Μ	SD	Μ	SD	Baseline-Follow up		
Depression (CATCH)	19.00	7.76	13.28	4.42	-5.72 (-11.10- 0.31)	-6.44 (-11.22,2.06) ^{1a}	
Depression (TAU)	22.85	6.06	24.00	5.35	1.14 (-5.19-2.91)		
Self-compassion (CATCH)	88.14	5.81	79.71	9.46	4.42 (-7.95- 16.81)	0.28 (0.75 0.18) ² h	
Self-compassion (TAU)	84.57	2.14	80.00	6.53	4.57 (-1.96- 11.10)	-0.28 (-9.75,9.18) ^{2b}	
Urges to self-injure (CATCH)	21.28	6.65	16.71	4.23	-4.85 (-8.66-1.04)	10 77 (4 04 47 00)30	
Urges to self-injure (TAU)	24.28	5.94	19.71	4.82	-3.14 (-8.96-2.68)	10.77 (4.34,17.20) ^{3c}	

Descriptive statistics and mean change for secondary outcome measures at baseline and follow up

^a A positive score refers to a deterioration in scores of depression. A negative score refers to an improvement in scores of depression

^b A positive score refers to an improvement in scores of self-compassion. A negative score refers to deterioration in scores of self-compassion

^c A positive score refers to a deterioration in urges to self-injure. A negative scores refers to an improvement in urges to self-injure

Table 8.

	SID	RCI
Variable	Baseline- Post	Baseline- Post
Variable	therapy	therapy
	assessment	assessment
PHQ intervention		
Improvement	3	3
Deterioration	0	0
PHQ TAU		
Improvement	0	0
Deterioration	1	1
SCS intervention		
Improvement	0	2
Deterioration	1	1
SCS TAU		
Improvement	0	1
Deterioration	1	1
ABUSI		
intervention		
Improvement	1	3
Deterioration	0	0
ABUSI TAU		
Improvement	1	3
Deterioration	0	0

4.0 DISCUSSION

This was the first pilot RCT of a brief CAT informed intervention (CATCH) for people with NSSI. The primary aim of the study was to determine whether CATCH was feasible to undertake, safe for people with NSSI, and to gather preliminary data regarding the potential clinical impact of the intervention. This study makes a contribution by showing that CATCH is a safe and feasible form of brief psychological therapy suggesting that further evaluations would be suitable. It also adds to the emerging CAT evidence base (Calvert & Kellett, 2014). Six of the seven participants completed both intervention sessions, the remaining participant attended one session. This corresponds to an attendance at intervention of 92.85%. This suggests that it is possible to retain participants into a brief treatment study, including participants randomised to TAU. It is important to acknowledge the challenges in recruitment into the study. Difficulties in recruitment to health care interventions are well established (Bucci et al., 2014). However, ongoing difficulties with recruitment could impact the feasibility of a larger scale trial of CATCH. The number of participants recruited increased for each month of the recruitment window. This suggests that continued face to face communications with teams and the ongoing development of relationships with case managers and clinicians improved recruitment. As this research was conducted by trainee clinical psychologists, the capacity to build relationships with teams was limited. A larger recruitment window for any future trials of CATCH may reduce the challenges associated with recruitment experienced in the current study. Utilising capacity of assistant researchers could also improve recruitment. Further investigations of the barriers and facilitators of recruitment to CATCH may be warranted before a larger study is considered, perhaps using qualitative methodologies.

There was little evidence of adverse experiences during the trial as reported on the AEP measure. This supports the safety of the approach. Results build on the model proposed by Sheard et al. (2000) and suggest that a brief CAT informed intervention can be safely delivered. The data indicate that individuals with NSSI may be able to engage in a brief CAT informed therapy, such as CATCH.

Whilst the goal of this study was not to assess efficacy it is useful to see if there is any preliminary indication that CATCH could be helpful. Secondary outcomes need to be interpreted with caution given the small numbers of participants in both arms of the study. There was evidence of a reduction in scores of depression both at the individual and group trend level for the CATCH group. There was evidence of deterioration in depression scores at both the individual and group trend level for the CATCH group seems particularly encouraging given the association between NSSI, comorbidity with other psychopathology and suicide (Bentley et al., 2015; Hamza et al., 2012).

Mean change in scores of self-compassion were the same for both the CATCH and TAU group. Previous research has suggested that brief interventions have been shown to reduce negative emotions (Arimitsu & Hofmann, 2017) and raise mood and increase positivity towards others (Hutcherson et al., 2008). Despite the association between self-compassion and psychological wellbeing, the nature of the relationship between self-compassion and NSSI is unclear. While no psychotherapies to date have been developed using selfcompassion to target self-injury specifically, Van Vilet & Kalnins (2011) assert that because one of the functions of NSSI is to self-punish, self-compassion-based interventions may be particularly useful in counteracting self-directed hostility. The recognition, accurate

description and re-orchestration of these punishing self-states is one of the key activities of CAT (Ryle & Kerr, 2002). Self-compassion could therefore be a possible mechanism of change for CAT. However, how to measure this is crucial. The psychometric properties of the SCS have been extensively investigated. However, there is considerable debate regarding the validity of the SCS as a measure of self-compassion (Cleare et al. 2019). In particular, concerns have been expressed that by including 'negative' components of compassion, the SCS measures self-criticism, rumination and social isolation (MacBeth & Gumley, 2012; Muris, 2016). Future CATCH trials should consider how best to explore the mechanisms that underlie the relationship between self-compassion and NSSI to identify how these constructs could best be applied in a brief therapy.

There was evidence of an improvement in urges to self-injure for both the CATCH and TAU groups. This reduction was more marked for the CATCH group. These findings are in support of Guthrie et al. (2001) who found a reduction in self-reported attempts at self-harm following a brief therapeutic intervention. Including a measure of urges to self-injure is helpful because the relationship between urge to self-injure is associated with more severe psychopathology and self-injurious behaviour (Klonsky & Olino, 2008; Whitlock et al., 2008). However, the ABUSI is a self-report measure and as a result is vulnerable to both denial and misrepresentation of the urge to self-injure (Nock & Banaji, 2007). That the ABUSI measure was not sensitive enough to measure change with a small sample could also offer some explanation for the findings. Longer term follow-ups would be valuable in determining the trajectory of participants in the context of urges to self-injure and engaging in the behaviour.

There were methodological shortcomings to this study that require note. The number of participants randomised to both study arms was small particularly for a study that randomly allocated participants to treatment groups. While recruitment was initially slow, the number of participants recruited to the study increased month by month. Recruitment was delayed because gaining ethical approval was slower than expected and the need to get an amendment early on slowed the recruitment process further. Time constraints around the project (e.g. allowing time for write up) meant that recruitment could not be extended. The sample size was similar to other feasibility trials (e.g. Evans et al. 2017; Glesson et al., 2012) and was consistent with the primary aims of the study, which was to provide preliminary information regarding feasibility and safety and was not about statistical inference about efficacy. This study was part of a larger project that included an in-depth qualitative exploration of people's experiences of CATCH and the wider research process (Peel-Wainwright, 2020). However, the small sample size limits generalisability in absolute terms and means that estimates of feasibility indicators may be imprecise. This is particularly relevant for feasibility parameters such as attrition. It is likely that there were lower attrition rates in CATCH due to the smaller sample size. There is potential that with a larger sample, issues which were not picked up in the current study could arise, such as rare adverse experiences.

A lack of successful recruitment could impact the feasibility of the study. For CATCH the number of participants recruited increased for each month of the recruitment window. This suggests that continued face to face communications with teams and the ongoing development of relationships with case managers and clinicians improved recruitment. As this research was conducted by trainee clinical psychologists, the capacity to build relationships with teams was limited. A larger recruitment window into any future trials of

CATCH may reduce the challenges associated with recruitment experienced in the current study. Utilising capacity of assistant researchers could further improve recruitment. Having data on how many people were approached to participate in CATCH would help inform how large the recruitment window should be. This data was unavailable in the current study.

Arranging appointments with participants was logistically challenging. This challenge was exacerbated by the limited time the therapists had to complete sessions, the ongoing recruitment into the study and the availability of participants, particularly in the intervention group, where there was a necessary commitment to attend more sessions. This resulted in some participants being in the study longer than originally anticipated. This was further complicated by some participants being in the study over the Christmas period, which meant they were unavailable for periods of time. Despite this, it was still possible to get a relatively consistent pre-post comparison. These comparisons need to be interpreted with caution. In any case, feasibility trials such as CATCH are limited in terms of making claims about intervention effectiveness.

Given that the CATCH sessions were carried out by two therapists there is potential for a 'therapist effect' (Cella et al., 2011) which could have influenced the outcomes and could mean they would not be replicated in another trial. However, having a small number of therapists offering the intervention, who received the same training and supervision, may have enabled a higher level of consistency in offering the therapy.

The SCS assesses trait levels of self-compassion (Neff, 2015). The value of including a trait measure in a brief intervention could be questioned because of a mismatch between the speed of trait change and a brief intervention. However, other evaluations of therapies have used the SCS as an outcome measure and it appears sensitive to change e.g. Bluth et

al. (2016). Roberts et al. (2017) suggest that personality trait measures can be used to test the effectiveness of therapeutic interventions on clinical outcomes, such as anxiety and depression. Future research could include a state measure of self-compassion, which may better assess the present moment impact of adopting a more self-compassionate way of relating to oneself and whether there is an impact on wellbeing.

This study had a number of strengths. First, the trial protocol was registered before recruitment began on ClinicalTrials.gov. Secondly, the study closely followed Consort guidelines (Eldridge et al., 2016) for feasibility studies to ensure methodological rigor. A major strength of the current study was that there was an assessment of fidelity to the treatment model. Many practice-based outcome studies are based on the assumption that what therapists felt they delivered was actually delivered (Bond et al., 2000). The measure of CAT competency (CCAT) illustrated that the two therapists adhered to the treatment model during the sessions assessed. Including a measure of fidelity should allow any further CATCH trials to assess relationships between training, experience, competence and outcome. There was no longer term follow up in the study to determine whether any gains made on secondary outcome measures were maintained over time. While the main focus of this trial was feasibility, follow-up data is noted as particularly important when exploring psychological therapy; for therapy to be successful, arguably the impact needs to be maintained at follow-up (Spiegler, 2016).

The results of this study support the feasibility and safety of CATCH, and so suggest that further, larger-scale evaluations are warranted. Adequately powered RCTs with a focus on efficacy will be an important next step in evaluating CATCH. Larger studies such as these, would highlight any potential value of relational therapies to self-injury. These could include

using a CAT map to identify and track the repeated patterns to inform case management and as an attempt to reduce individual and team enactments of target problem procedures. Future research should include a measure of personality integration (e.g. PSQ) at baseline and follow up to inform whether any change occurs. This could be particularly relevant because changes in personality integration are a possible mechanism for change in CAT therapy (Ryle & Kerr, 2002). A future research trial will need to consider whether a measure of urges to self-injure is suitable on its own or if other measures of NSSI should be included. It may be useful to consider how urges are related to functions and frequency of NSSI. In conclusion, the study results support the feasibility and safety of CATCH in adults with a history of NSSI. Data provide a preliminary suggestion that the intervention may improve levels of depression and urges to self-injure in this population. There was no major change in scores of self-compassion. These secondary outcomes should be treated with caution. Collectively this study offers preliminary data that are required before embarking on a properly powered and controlled evaluation.

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Paper Three: Critical Reflection

Word Count

Main body: 5742

References: 1361

1.0 Introduction

The following paper provides a critical and reflective evaluation of the work undertaken as part of this research project. It will consider how the literature review and empirical paper fit within the wider context of research and underlying rationale and methodological considerations that informed the research. The strengths and limitations of the current project are acknowledged throughout, as is the authors' educational progress in the development and submission of this thesis.

2.0 Paper One: Literature Review

2.1 Topic Rationale.

This research project grew from ongoing empirical work within the wider research team investigating the feasibility of Cognitive Analytic Therapy (CAT) to severe and enduring mental health difficulties, such as psychosis (Taylor et al., 2018). The evidence base for CAT is relatively small compared to other psychotherapies and reviewed in two papers (Calvert & Kellett, 2014; Ryle et al., 2014). At the initial stages of development of this review, these papers were they only published systematic reviews on CAT. Preliminary discussions were had among the research team about carrying out an updated review of the CAT evidence base. Initial searches of PROSPERO revealed such a review was registered in January 2018 and was ongoing. As a result, the trainee consulted the literature to determine an appropriate topic area that would add to the burgeoning CAT research base.

A valid criticism of CAT has been that the theory and its various applications have sped ahead of the empirical validation of the model (Marriott & Kellett, 2009). The trainee reflected on this and it prompted discussions about the value of beginning to index the efficacy of some of the key interventions within CAT. No review existed that investigated the impact or efficacy of CAT tools or CAT specific interventions. Beginning to synthesise the literature of these interventions appeared appropriate and timely.

One of three main pillars of a CAT intervention is reformulation. Evidence from single-case experimental designs, discussed in paper 1, showed that narrative and diagrammatic reformulations are often key change points during therapy, demonstrating 'sudden gains' events. However, the evidence regarding the efficacy was inconclusive with a number of studies, also discussed in paper 1, suggesting that reformulation did not have significant symptomatic impact and questioned the clinical utility of it.

2.2 Literature search.

Despite the relative clarity in selecting a topic area, designing and running the literature search offered some challenges. Early discussions among the research team involved whether the review should focus on qualitative, quantitative papers or both. A focus on quantitative studies was not considered sufficient for the current review because of an insufficient number of Randomised Controlled Trials (RCTs). The trainee felt that a number of other important questions would not be answered such as 'why does it work?', 'how did it work?' or importantly 'what works in what context?'. It was agreed that including both qualitative and quantitative studies would gather a deeper understanding of the topic. The trainee hoped that by including both, they would complement each other by providing a better understanding of the impact of contextual factors and ensure a focus on outcomes that were important for clients.

This decision allowed for a critical realist approach to be taken towards the analysis. Critical realism posits that it is possible to gain a knowledge of an external reality, as in positivism,

yet this is mediated by one's perceptions and beliefs, as in constructivism (Fletcher, 2017). A critical realist approach favours mixed methods approach to research (Olsen, 2002). This allows for the identification of patterns, associations and how causal mechanisms operate as well as illuminating complex concepts and relationships.

An initial concern at the development stage of this research was whether there would be enough papers to include in the review. While the trainee felt it was important to set sufficiently sensitive yet specific parameters within the initial literature search to help with the subsequent screening process, they were mindful of using research terms that would be broad enough to capture the range of papers that investigate reformulation.

A brief scope (Google scholar and PsycInfo) using Medical Subject Headings (MeSH), recorded search totals of over 21,000 titles, the majority of which were not relevant. This highlighted how using MeSH was not suitable for this review as CAT is not typically included as a MeSH term and the terms available e.g. psychotherapy would be too broad. Constructive conversations regarding search terms and inclusion and exclusion criteria were aided by the use of a 'Who, What, How and Where' table described by Boland et al. (2014).

Further inclusion and exclusion decisions needed to be made throughout the initial search, piloting and early screening stages. A number of studies were omitted that discussed team formulation. This omission did not require any changes to be made to the review protocol. The decision to omit these studies was made by the trainee because the aim of this review was to synthesise data on the individuals' experience of reformulation and not the more global experience of team formulation. Although there is potential overlap between individual and team based experiences, the trainee felt that teams may focus on wider

systematic issues and dynamics which would arguably be a different focus than involving participants with direct experience of reformulation in clinical practice.

To synthesise the available literature on a relatively understudied area and to ensure a breath of relevant materials was included, it was decided to include papers from the grey literature and to hand search the journal Reformulation, which was not captured on any electronic searches. Additionally, the references of the retrieved papers were reviewed to eliminate further likelihood of omission. Advocates of the inclusion of 'grey' literature in systematic reviews point to its role in mitigating publication bias (Dwan et al.St, 2013). Studies that were not written in English were excluded. The research team acknowledge this may be a limitation, given that CAT is practiced in a number of countries worldwide. However, this arguably reflects where CAT is more widely practiced clinically. Exclusion based on language occurred for only one study, which was published in Greek. The authors and the journal were contacted and an English version of the paper was not available.

2.3 Quality Appraisal.

Articles included in systematic reviews should be assessed for methodological quality (Jadad et al., 2000) using validated tools to enable the critical appraisal of findings (Armijo-Olivo et al., 2012). In our review, a quality appraisal was undertaken by two researchers from the team (SB and CO) to evaluate the validity and reliability of each study. The outcome from the quality appraisal was not used as a decision making tool about inclusion or exclusion. There is contention about whether quality assessment should be used to exclude lower-quality studies or to offer a means of assessing the weight of different in included studies, given that lower-quality studies can still generate new insights (Shuster, 2011). As there is

no consensus regarding methods for excluding studies on the grounds of their interpreted quality (Thomas & Harden, 2008), all identified studies were included in this review.

There was a discussion within the research team about how best to assess the quality of quantitative studies. The Agency for Healthcare Research and Quality tool (AHRQ) (Viswanathan et al., 2012) was initially chosen by the trainee. On reflection and after further screening of papers from electronic searches it was felt that Effective Public Health Practice Project tool (EPHPP) (Thomas et al., 2004) offered the flexibility required to be adapted to better suit the needs of the current review (Sanderson, Tatt, & Higgins, 2007). Moreover, it offered clear instructions and was noted to possess good content and construct validity (Thomas et al., 2004) and inter-rater reliability (Armijo-Olivo et al., 2012). This was a learning opportunity for the trainee as it highlighted the importance of being knowledgeable about the types of papers being reviewed before choosing a quality appraisal tool.

Throughout the process the trainee was aware that there is little consensus in critical appraisal of qualitative studies on what makes a good study and what should be done with the findings of a quality appraisal if completed (Dixon-Woods et al., 2006; Porritt Gommersal & Lockwood, 2014; Thomas & Harden, 2008). The trainee held the view that the use of critical appraisal was necessary to investigate the extent to which the findings of the review represent participants' experiences. The Critical Appraisal Skills Programme (CASP) (CASP International Network, 2018) was chosen because the tool allowed for the appraisal of all types of qualitative data and did not provide an explicit scoring system. This allowed for the reader to interpret the findings of the evaluation.

On reflection the quality appraisal process was useful in the development of a more comprehensive understanding of the methodological quality of the included papers. It was perhaps more challenging than initially expected because it involved given an impartial rating of quality based on subjective judgements. It was useful to pilot the quality assessment on a small number of studies with the second member of the research team. This allowed for improved objective assessment by discussing those criteria that were more open to subjective interpretation.

2.4 Data synthesis.

Data synthesis of quantitative and qualitative studies was guided by narrative synthesis techniques (Popay et al., 2006). This approach 'relies primarily on the use of words and texts to summarise and explain the findings of the synthesis' (Popay et al., 2006; p. 5). Popay et al. (2006) propose four main elements within their guidance including considering the role of theories of change or effect relevant to the review; develop a preliminary synthesis through clustering and tabulating, describe and translate relevant data; explore relationships within and between data and assess the robustness of the synthesis product through critical reflections. This process was challenging in the context of the current review because of the different epistemologies of quantitative and qualitative methodologies across the studies. This difficulty was compounded by the variation in quality of some of the studies and the focus on reformulation across a broad range of applications and populations. The results of the data synthesis largely offered a range of descriptive data from single cases and qualitative studies which fitted with narrative synthesis.

Given the outcome of data extraction resulted in largely descriptive data, the trainee was mindful of maintaining clarity and robustness while exploring the relationships within the

data, particularly when building on the descriptive synthesis to generate themes in qualitative data. Going beyond the content of the primary studies to develop descriptive summaries was a challenging aspect of the qualitative synthesis. Thomas & Harden (2008) point out that this process largely relies on the judgement of the reviewer. To reduce the potential influence of the trainee, each theme was reviewed by three researchers (SB, PJT, SH) on drafts of the results. This led to a better synthesis of the findings as it was not just the interpretation of the trainee alone.

Using convergent synthesis design (Boland et al., 2017) with mixed methods is considered a strength of the review. It allow the trainee to synthesis the full range of diverse evidence that was available and establish a foundation from which other reviews can be undertaken. Regarding the impact of reformulation, in many respects the conclusion of the review was inconclusive. This may not be too surprising as there is mixed evidence regarding the efficacy of case formulation in psychotherapy (Bucci et al., 2016). Bieling & Kukyen (2003) suggest that there is a tendency to 'overvalue' case reformulation in therapy, which despite high clinical approval, is an activity that is not particularly well-grounded in scientific evidence.

2.5 Reflections on the state of the literature.

The strengths and limitations of our review paper have been discussed in Paper 1. Here, I will briefly discuss some of the challenges that I believe are apparent for the CAT research community to expand the CAT evidence base in a coherent way. This review highlighted the wide use of the single case experimental design within CAT research. This highlights efforts of clinicians working within the scientist-practitioner framework (Kazdin, 2010) adding to the evidence base. To strengthen this, more cohesion in developing a research community is

required if the generation of large scale service evaluation of the effectiveness of the model and its component interventions in front line clinical practice is to be achievable.

The work presented in Paper 1 makes an original contribution to the literature by investigating similarities and differences between both qualitative and quantitative studies, exploring relationships within the data and by broadly assessing the current strength of the evidence on the impact of reformulation. It also identified some areas and avenues for future research and what would enhance our understanding of the mechanisms of change in reformulation and highlighted how more sophisticated methods of measuring this change are needed, the outcome of which could enhance our understanding of 'what works in what context'.

3.0 Paper 2: Empirical Paper

3.1 Background and rationale.

I was drawn to CAT whilst on placement in an adult primary care setting, where my supervisor was a passionate advocate for the approach, particularly for people with more significant mental health difficulties. The aspect that particularly interested me was mapping, which I would later learn in CAT terminology is a sequential diagrammatic reformulation (SDR). Observing my supervisor with clients showed me the value of the joint activity of mapping and how it offered a mechanism of transferring some of the complexities of an explanatory hypothesis onto paper.

I had no experience of very brief therapy before embarking on this research. I did have initial reservations about the value of a brief CAT informed therapy when the standard length of CAT is 16 or 24 sessions. There appeared to be key aspects of a brief approach that feel like therapeutic opportunities namely the rapidity of contact and the necessity of active engagement which I was interesting in gaining experience in. I felt these would be very useful clinically, particularly when a rapid assessment is necessary (e.g. when assessing risk). At this time, the trainee reflected on the theme discussed in supervision, that 'brevity and depth can be companions, not antagonists' (Aveline, 2001; p. 378).

To consider this more, I reflected on what type of clinician I was. I felt that this would be an important benchmark about what I would find challenging and rewarding with a brief CAT informed therapy. In many ways I felt this therapy would fit with my own needs as a therapist, such as being active and on the importance of the therapeutic relationship. The focus and fluidity of brief work appealed despite frustrations around its limitations.

As discussed in Paper 2, there is a small but growing initiative to offer CAT in novel ways including in a brief format for with people with NSSI and self-harm. A very brief CAT intervention for self-harm by Sheard et al. (2000) offered a foundation for the current research. While Sheard et al. (2000) was specifically for people who over-dosed and were admitted to hospital, it offered a model that integrated an attempt to develop a shared understanding of a patient's experience of self-harm in a relational way. In addition some of techniques used in this approach were being investigated further. Potter (2010) described an application of active mapping to help people use their experience and develop their relational thinking. This brief intervention seemed particularly relevant for people with NSSI, in the context of increasing access despite limited resources and how more immediate psychological support may be needed to reduce the risk of deterioration and short-term repetition.

3.2 Methodology.

Guidelines on the development of complex interventions assert the importance of conducting small-scale feasibility and pilot studies prior to larger controlled trials (Craig et al., 2013; Medical Research Council [MRC], 2008). Blatch-Jones, et al., (2018) suggest that feasibility trials can provide important methodological evidence about the design and avoid any potential flaws and reduce the burden of 'research waste'. This seemed particularly relevant for populations with a high likelihood of repetition and relapse such as people with NSSI who may be less likely to participate in research (Lizard & Stanley, 2010).

Our study utilised a small-scale randomised control design as suggested by Arian et al., (2010). The goal was to develop a high quality feasibility trial in order to improve the validity of inferences that could be made from it. To support this endeavour we followed the

CONSORT 2010 statement: extension to randomised and feasibility trials (Eldridge et al., 2010). This offered a number of methodological recommendations and principles that guided the development of the trial. These included that the rationale for a pilot trial was to investigate areas of uncertainty about a future definitive trial; the number of participants in the study should be based on feasibility objectives; formal hypothesis testing for effectiveness was not indicated and that the aim of the pilot trial was not to assess efficacy as it would be underpowered to do this.

Other attempts were made beyond the CONSORT recommendations to ensure the development of a high quality trial. These included the development of a well-defined study protocol as suggested by Chan & Bhandari (2011); inclusion of frequent and repeated assessment time-points utilising weekly online measures and the inclusion of a follow up assessment.

Strength and limitations of the study are discussed in Paper 2. While the sample size is comparable to other published studies in CAT, it is small in absolute terms. Nonetheless, the sample size is consistent with the primary aim of the study which was to provide preliminary information about feasibility and safety.

3.3 Public and patient involvement (PPI).

An early consultation with the Community Liaison Group (CLG) offered valuable insights, particularly around language and study description which helped shape our information materials and how we described the research to service users as potential participants. The CLG wondered whether people would confuse CAT with Cognitive Behaviour Therapy (CBT) and suggested we needed to be clear on the distinction. Based on this feedback we developed a short information sheet to explain briefly about CAT to make it clear for people who may be interested but unclear on how CAT would differ from another therapy they may have previously engaged in.

The CLG underscored the importance of setting realistic expectations from the intervention, to be transparent about the aims and benefits and how it should be framed as 'tools of support not a cure'. The therapy manual used to guide the intervention gave explicit guidelines on how to manage this in the introduction phase of the first session. The trainee was conscious to offer participants time to consider their expectations given the constraints of a two session intervention.

On a broader point, the CLG discussed the importance of communicating with people about the mechanisms of research. Specifically they felt we should highlight the value of the Treatment as Usual (TAU) group and how participation in TAU was as valid as being in the intervention group because a control group was needed to see if there was a change following the intervention. The involvement of service-users from the CLG in the early stages of research design was really valued by the team and regarded as a relative strength of this study. Their involvement was also in line with recommendations and national strategic plans highlighting the importance of PPI in clinical research (e.g. Centre for

Research in Public Health and Community Care [CRIPACC] (2018); National Institute for Health Research [NIHR], (2014).

3.4 Recruitment.

The recruitment process was one of the most challenging aspects to the study. Evidence outlining barriers and facilitators to recruitment in mental health settings is described by Bucci et al., (2014). Recruitment difficulties were therefore anticipated due to the reported low resource and high workload of UK adult mental health teams. Recruitment difficulties/challenges were compounded by clinicians in services needing to manage risk of harm of people who agreed to participate in the study. Although anecdotal, there appeared to be a paternalistic approach among clinicians (Snowden & Young, 2017) which may have resulted in people not being told about the research. The trainee considered the ethical implications of the assumptions the clinicians were making and how, even if the potential participants did ultimately say no, it was still their right to make an informed decision. On a number of occasions clinicians raised concerns about whether participants would be at increased risk if they took part in the study and what would the value be if they were allocated to the TAU group. Navigation of this scenario required a tactful approach from the trainee and an overt appreciation that clinicians were likely attempting to avoid frustrating potential participants. Indeed, evidence suggests clinicians may perceive themselves as carers to their clients, feeling duty-bound to protect them from stress (Howard, de Salis et al., 2009).

We had proposed to recruit 40 participants in our ethics application. Our supervisors were confident we had established enough links in community services for recruitment of 40 people to feasible. We were initially encouraged that this target could be met. Clinicians and

teams were largely enthusiastic about the study and were optimistic about identifying potential participants among their caseload. This did not translate into people consenting to being contacted by the research team, potentially for the reasons discussed. This was surprising to the whole research team. These challenges are however reported in the literature. Fletcher et al. (2012) found that 50% of RCTs fail to recruit to their target number. Some useful mechanisms have been discussed among the research team that could help future recruitment. These include clinicians delegating the authority to trainees to identify potential participants on their caseload. Such mechanisms are currently in place for researchers and research assistant directly employed by various NHS trusts.

A positive reflection on the recruitment process was the feedback received from many participants. A number of participants expressed gratitude for being asked to participate, stating they found it empowering contributing to research and potentially help other individuals with similar experiences. Given the reticence of some clinicians to refer service users to the study, stemming from concerns that participation would destabilise them, the trainee was keen to feedback these comments to services. It is hoped that by acknowledging positive experiences of participating in research, clinicians would be more likely to refer to future studies. These positive experiences of participating in research are also reported in the literature (Taylor et al., 2010).

3.5 Measures and therapy.

The therapy was not undertaken as part of participants' usual care, which allowed for greater control over the timing and location of the therapy provided. There was flexibility in where the study sessions could take place. This was likely to have helped with recruitment and retaining participants in the study.

The decision to offer the option of completing the majority of the study measures online was considered a strength of this study. It was hoped that the anonymity of completing the measures online would encourage participants to be more honest about their feelings (Murdoch et al., 2014). An online platform was intended to reduce attrition and missing data from the study by making it easier for participants to complete the measures. Results discussed in Paper 2 on rates of missing data in the study would support the use of online data collection.

Strengths and limitations of the measures included in the study are discussed in Paper 2. That the majority of secondary outcomes were based on self-report and the follow up period being short are acknowledged as study weaknesses. The time and resource constraints of completing research as part of the doctorate were important considerations in not having a longer follow up. There were other relevant outcomes that were not measures, such as a measure symptom insight (Lincoln et al., 2007). Any addition of measures in future research needs to be considered in the context of burden on participants.

In preparation for this study, the trainee received additional training and supervision in how to deliver the intervention. This included role playing specific aspects of sessions (e.g. how to introduce the sessions to participants and how to actively map information from actual clinical cases). These experiences were valued by the trainee. They helped them ensure a focus on the relational aspects of NSSI, identifying procedures and reciprocal roles within sessions.

There was a discussion among the research team early in the development of the study about whether there would be a value in offering the client both a map of their

reformulation and a goodbye letter. While offering both would be common practice in standard CAT therapy, it was felt that it would be an unrealistic to complete both with limited resources within the short timeframe that people were engaged in the study. As discussed in paper 2, results imply that there was initial evidence of feasibility, helpfulness and safety for a brief CAT informed intervention for self-harm. Results suggest that future CAT studies with NSSI would also be able to recruit a sufficient number of participants. Future trials would need to properly powered and controlled, with a focus on understanding the mechanisms of change. As discussed CAT experiences an uptake versus credibility dilemma. As discussed in Paper 2, one potential mechanism to support clinicians to research the impact of CAT on NSSI would be the wide use of high quality single case experimental design methodologies. This is achievable by the single-handed clinician within the scientist-practitioner framework (Kazdin, 2010). In order to maximise benefit for participants, it will be important for have effective mechanisms in place to reduce dropout (Oldham et al., 2012) and also capture long-term follow-up outcomes.

Like in all therapies, the trainee was aware of the value and the challenge of positive endings for both the CATCH and TAU group. While the ending appeared to be positive for both groups, there was a sense of 'there being more to do'. This was discussed and reflected on in supervision, where we spoke about acknowledging this discomfort, while remembering that if a participant spoke about wanting more sessions or participating in more research, it is likely a positive reflection on the experience they had.

3.6 Researcher and therapist.

Engaging in a feasibility trial of a therapy meant that the trainee needed to integrate being both a researcher and a therapist, which felt uniquely challenging. The main worry the

trainee had was how to manage the dichotomous position of being a detached and impartial researcher while developing a genuine valued relationship with the participants. On reflection, the trainee felt that these may not be dichotomous positions and relationships. All therapists approach a session and a client with various different roles (a trainee, a supervisor, a brother etc.). It is not that these roles and relationships are not influential; it is how these influences are managed. The current trainee used their own personal reflective practice and supervision to help manage the dual therapist, researcher role.

The trainee found managing this relationship was easier with participants in the TAU group. Drawing upon some therapeutic skills was helpful with this group. For example, it was important to ensure that their experiences were validated and to listen to and empathise with their struggles and difficulties which may have come up at baseline or post therapy assessment. For both groups, explaining the rationale of the research as early as possible and being explicit and clear to participants and exploring their aims and expectations was helpful in avoiding ruptures in the relationship and showed how being a researcher and therapist can be complimentary.

3.7 Working in a team.

Initially there were three trainees working on the project. One of the trainees went on maternity leave a few months into the project which meant myself and one other trainee continued with the project. A personal reflection is that working with other trainees on the same project has been one of the most valuable aspects of the research process. The collaboration and support has made the process seem less daunting and allowed us to undertake an ambitious project given the constraints on time and resources on research

within the doctorate process. In order to ensure that tasks and activities of research were evenly distributed, an early plan of objectives was developed and who was responsible for their completion identified.

As a team we equally divided up which services we would contact and arrange to attend their respective team meetings to present the project, and emphasise the potential benefits to participants. It was hoped that by engaging with one trainee, it would facilitate the development of relationships and encourage teams to refer potential participants to the study and allow teams to 'put a face to a name'. This allowed for the research team to collaborate more closely with clinicians and teams that were more likely to refer to the study. The NHS Research Ethics Committee (REC) application was completed jointly by both trainees. The current trainee submitted two applications to Research and Development departments and acted as a point of contact for the corresponding Trusts. When someone contacted the research team, usually through the dedicated research email, both trainees alternated who contacted them to begin the process (e.g. telephone screening and baseline). It was hoped that this would divide the workload evenly. The random nature of allocation to CATCH or TAU meant that a more structured divide of the workload was not possible.

4.0 Personal reflections

Although I began the ClinPsyD with prior experience of conducting research within a clinical settings, this study was my first experience of doctoral level research and being involved with a project from beginning to end. My enthusiasm for the project was also accompanied by reservations regarding research competence at doctoral level, particularly in the early stages of study development.

My involvement in this research project will have a lasting and significant impact on my clinical practice. Practically, I have gained experience and skills in an additional model of therapy which will support my ongoing development as a clinician. I am grateful for the experiences of working within a brief model of therapy. I learned from this experience that brief work is not just an abbreviated version of a longer therapy and can see the value of it now more than ever in an environment of stretched clinical services.

Working in a brief CAT model has thought me skills to improve relational thinking. Being capable of thinking more relationally is important because self-self and other-self relationships can create powerful feelings and enactments, which is particularly relevant for working with people with complex mental health needs. In listening to audio recordings of sessions, I realised how subtle these relational patterns can be re-enacted in the therapy environment. This has helped me to improve my listening skills to be more aware of these in the moment. Ultimately this research project has raised my awareness of the utility of CAT as both as a stand-alone treatment and as an adjunct to other therapies.

There were times when I doubted my own competence in delivering a brief therapy. I felt there was an additional demand of actively mapping out often complex stories, recognising potential moments where change can occur. I was mindful that it was easy to get 'too busy' with the activity of mapping at the expense of being present with someone. This is a subtle skill for a therapist, yet of vital importance, particularly in a brief therapy. I hope to be able to refine this skill for many years to come. I realised quite early on that it is alright not to have all the pieces of the puzzle right away and to have trust in the process.

Completing a feasibility study has underlined the importance of working within a scientistpractitioner model. It reinforces the position advocated by Shapiro (1967;1985)

recommending the integration of these two components rather than a divided position between the two (Barker et al., 2002). It has highlighted for me the valued role of a clinical psychologist in evaluating interventions at the early stages of development. As I begin the transition to being a newly qualified clinical psychologist, I have seen the value of the multifaceted role of a clinical psychologist in service related research and evaluation as outlined in position papers such as New Ways of Working (British Psychological Society [BPS], 2007). I hope this experience of research will mean I will take a much more proactive approach to participating in ongoing research and service evaluation going forward.

The process of conducting this piece of research has been challenging and enjoyable. I feel a great sense of achievement from reaching this stage of the process. Research has shown me the value of taking ownership of my learning needs, whilst also being receptive to advice from more experience colleagues. Ultimately it has thought me that research is not a linear process, but one that requires you to embrace the uncertainty, trust in the process and be flexible and innovative to deal with obstacles and barriers as they arise, as they will do.

A number of challenges arose for the trainee after submitting their research initially. Following viva, the trainee needed to re-conduct the empirical analysis and be re-examined due to an oversight on their part during the initial study. During this re-analysis, the trainee became aware that some data was missing. This meant that any additional analysis would need to take account of this missing data. This period was a challenging one for the trainee.

One of the key things that this experience has taught the trainee is to try and maintain motivation in the face of disappointment. To do this, the trainee thought about how they could be more effective in 'looking for the silver lining' and to not look at challenging situations in purely black-and-white terms. Duckworth et al. (2007) describe 'grit' and

discuss this in the context of perseverance and passion for longer-term goals. Grit entails working towards challenges, maintaining effort and interest despite failure, adversity and plateaus in progress. The trainee experienced many challenges over the doctorate. They coped successfully with these situations and developed both personally and professionally because of them. The trainee hopes to spend the next period as a newly qualified psychologist to reflect on how they might apply skills learned to different situations and to further consider how overcoming adversity and challenge can lead to personal growth even if this may seem uncomfortable. The trainee hopes to further assimilate this awareness in their personal identify and also in their professional identity as both a researcher and clinician.

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APPENDICES

Appendix A: Prospero protocol

The impact of reformulation in cognitive analytic therapy (CAT): a systematic review

Stephen Bradley, Peter Taylor, Samantha Hartley

Citation

Stephen Bradley, Peter Taylor, Samantha Hartley. The impact of reformulation in cognitive analytic therapy (CAT): a systematic review. PROSPERO 2019 CRD42019153233 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019153233

Review question

This systematic review will endeavour to answer the following-

What is the impact of Reformulation in Cognitive Analytic Therapy (CAT)?

The impact of Reformulation will be investigated in two ways. Firstly, is Reformulation associated with improvements in therapy outcome? Therapy outcomes will include whether there is a change in a client's mental health difficulties or wellbeing following reformulation or whether there is a change in therapeutic mechanisms/intermediate processes assumed to be relevant (e.g. working alliance). Secondly, what are the client's perceptions or experience of Reformulation? This will include whether it is acceptable as a process, whether it is perceived as useful and if so, in what way. To our knowledge, there is no published or registered (e.g. on PROSPERO) systematic review investigating the impact of Reformulation.

Searches

Electronic databases including PsycINFO, Web of Science, MEDLINE and CINAHL will be searched. The following search term will be used ("Cognitive Analytic"). These will be searched from the first available date to October 2019. Given the scale of the CAT literature is limited, additional search terms to narrow down the number of articles identified are not needed and would increase the risk of potentially eligible articles being excluded.

Citation chaining will be used to search for potentially eligible studies not detected by the electronic search using the reference list of eligible papers. This will include seeing which papers have subsequently cited key references (forward searching). And, looking at the reference list to find other relevant research the search may have missed (backward searching).

Key authors in the area of CAT and the editors of the ACAT and Catalyse website will be contacted and asked about unpublished data. The Association of Cognitive Analytic Therapy (ACAT) website contains a list of published and forthcoming studies and this will be checked to ensure all relevant studies have been included. Reformulation (the newsletter for the Association for Cognitive Analytic Therapy) will be screened for relevant studies. Reference management software will be used to download and keep track of the search results, and to sort through duplicates and studies which do not meet the review criteria.

Types of study to be included

Inclusion criteria:

Studies will

• Include participants who have experienced reformulation (using a Cognitive Analytic Therapy framework).

• Include either a) measurement of participants' experiences of reformulation; or b) measurement of therapy outcomes before and after reformulation; or c) measurement of therapy outcomes in groups who have and have not received reformulation (allowing comparison).

• Be written in or translated to English

• Be published or be part of the grey literature

Exclusion criteria:

• Studies will be excluded if participants have not been treated with/exposed to Cognitive Analytic Therapy (CAT) or a CAT-informed assessment/intervention.

Condition or domain being studied

CAT or CAT-informed Reformulation or assessment. The review will not be limited to anyone disorder, condition or set of difficulties.

Participants/population

Inclusion criteria:

• Adults (>18 years); recorded common or complex mental health disorder; where participants have been exposed to CAT or CAT-informed Reformulation or assessment where there is either a) measurement of participants' experiences of reformulation; or b) measurement of therapy outcomes before and after reformulation; or c) measurement of therapy outcomes in groups who have and have not received reformulation (allowing comparison). Reformulation will be completed by an Association for Cognitive Analytic Therapy (ACAT) accredited CAT practitioner or psychotherapist, or a Health and Care Professions Council (HCPC) Registered Practitioner Psychologist, or a trainee psychologist supervised by a clinical psychologist. No restrictions will be placed on the inclusion of participant based on their diagnosis or presence of co morbidity.

Exclusion criteria:

• Participants who have not been exposed to a CAT or CAT-informed Reformulation or assessment where there is either a) measurement of participants' experiences of reformulation; or b) measurement of therapy outcomes before and after reformulation; or c) measurement of therapy outcomes in groups who have and have not received reformulation (allowing comparison).

Intervention(s), exposure(s)

Reformulation. This is defined as the joint creation between client and therapist of a new shared understanding of a client's difficulties, their causes and developmental origins, applying Cognitive Analytic Therapy (CAT) theory. Reformulations may be shared in written and diagrammatic form, or through dialogue.

CAT is an integrative model of treatment informed by principles from cognitive and psychodynamic psychotherapies (Ryle and Kerr, 2002). Therapy consists of three phases: Reformulation, recognition and revision.

Psychologists and Psychotherapists of all persuasions make case formulations of their clients, a process involving the selection and arranging of data according to their theoretical understanding of the issues to be addressed in therapy. In CAT, the account seeks to identify the personal meanings accorded to their experience by clients and to describe the problem procedures and evidence of poor integration of the procedural system which are responsible for maintaining their dysfunction and distress (Ryle and Kerr, 2002). The Reformulation process is designed to help deepen the client's understanding of themselves through this empathic joint therapeutic work.

Comparator(s)/control

Both single arm and controlled study designs will be included. Comparators may include usual treatment and active comparison treatments.

Context

Studies will not be excluded based on the setting within which Reformulation was completed. The setting itself will be extracted and reported.

Main outcome(s)

Participants' perceived helpfulness or acceptability of reformulation.

Therapy outcomes, defined as client's mental health difficulties or well-being following Reformulation and/or a change in therapeutic mechanisms/intermediate processes assumed to be relevant e.g. working alliance.

* Measures of effect

Dependent on the method of the study used we will look at baseline to treatment comparisons, and treatment to follow-up comparisons if possible.

Additional outcome(s)

Not applicable

* Measures of effect

Not applicable

Data extraction (selection and coding)

• Databases will be searched using the term outlined above

• Citations will be exported into a suitable reference management software programme and duplicates will be removed.

• Titles and abstracts of studies retrieved and those from additional sources will be screened to identify studies that potentially meet the inclusion criteria outlined above. Where it is uncertain if studies meet inclusion criteria through the abstract screen, they will be retained for the next stage of screening. Any studies not meeting criteria will be excluded at this stage.

• The full text of these potentially eligible studies will be retrieved and independently assessed for eligibility by a review team member and an independent researcher. Any disagreement between these individuals over the eligibility of particular studies will be resolved through discussion with other review team members

• Reference lists from articles included at this point will be searched for additional references not detected by the search using backward and forward searching.

• Conference abstracts and theses/dissertations arising from the search will also be screened for eligibility and, if needed, their authors will be contacted for more information or clarification.

• All authors of included studies will be emailed to ask if they have any other eligible research, either published or unpublished, to include. Further, we will check the references of all included papers for other potentially eligible studies

• Data from the included studies will be extracted using a data extraction form. Extracted information will include:

1. author, year, country

2. study setting

3. sample size/characteristics

4. key characteristics, intervention(s) and comparator(s), if appropriate

5. study design

6. analysis

7. study outcomes (qualitative themes; feedback ratings; results of statistical analyses)

• Accurate records (e.g. numbers of studies included/excluded) will be maintained at each of the above stages.

Risk of bias (quality) assessment

To assess the risk of bias across quantitative studies included, the methodological quality assessment tool for quantitative studies from the Effective Public Health Practice Project (EPHPP; Thomas et al, 2004) will be used.

For qualitative studies, the quality of the included studies will be assessed using the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies.

Studies will be assessed for risk of bias (or quality) by the lead author and also independently rated by an external researcher. Disagreements will be resolved through team discussion.

Strategy for data synthesis

The studies included in this review will be analysed using a convergent synthesis design. Both qualitative and quantitative data will be extracted and analysed separately with a focus on general implications or outcomes. The integration of these results will occur in the discussion by interpreting the results of these syntheses.

A narrative synthesis of the extracted research findings is planned. This will focus on common themes and gaps in the findings. Themes arising from qualitative and quantitative studies will be contrasted to analyse agreements and disagreements. Reasons for both similarities and differences in the findings will be explored systematically, with possible explanations for the pattern of results considered in a logical way for each of the included studies. Given the inclusion of qualitative research and the likely heterogeneity in study design for quantitative research, meta-analysis is unlikely to be suitable and so is not planned.

Analysis of subgroups or subsets

None planned

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Organisational affiliation of the review

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Review team members and their organisational affiliations

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Type and method of review

Narrative synthesis, Systematic review

Anticipated or actual start date

02 October 2019

Anticipated completion date

01 April 2020

Funding sources/sponsors

None

Conflicts of interest

None

Language

English

Country

England

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Cognition; Humans; Psychoanalytic Therapy

Date of registration in PROSPERO

16 October 2019

Date of publication of this version

21 January 2020

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	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

Revision note

A change to the quality assessment tool for quantitative studies was made. The Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies was included instead of the Agency for Healthcare Research and Quality (AHRQ) quality assessment tool.

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

16 October 2019 21 January 2020

Appendix B: EPHPP quality tool

Quality Assessment Tool for Quantitative Studies

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1. Very likely
- 2. Somewhat likely
- 3. Not likely
- 4. Can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1. 80-100%
- 2. 60 79%
- 3. Less than 60% agreement
- 4. Not applicable
- 5. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

DICTIONARY: SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

A: SELECTION BIAS SCORING

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) and there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); and there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); or there is less than 60% participation (Q2 is 3) or selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) STUDY DESIGN

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

• Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

• Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.

If NO is scored, then the study is a controlled clinical trial.

• Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)

An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)

An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study

A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest

Cohort (one group pre + post (before and after)

The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pre-test, act as their own control group.

Interrupted time series

A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

(Q1) Were important differences between groups taken into account (controlled for) in the analysis (or design)?

- 1. Yes
- 2. No
- 3. Can't tell
- 4. N/A (e.g. if N=1)

(Q2) If yes, indicate the percentage of relevant confounders that were controlled - either in the design (e.g. stratification, matching) or analysis?

1.

- 2. 80 100% (most)
- 3. 60 79% (some)
- 4. Less than 60% (few or none)
- 5. Can't Tell

6. Not applicable

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

DICTIONARY: CONFOUNDERS

By definition, a confounder is a variable that is associated with both the independent variable and the dependent variable. The authors should indicate if confounders were controlled in the design [by stratification or matching] or in the analysis. There should be no obvious dissimilarities between groups that may account for differences in outcomes.

- Examples of controlling for confounders in analysis include comparing groups (e.g. t-test) to check for differences if one group not included in analysis; partial correlation; controlling for variables in regression; covariates in ANCOVAs
- Examples of controlling for confounders in design include restriction (e.g. control for gender and age by including all males over 60 years) and matching (e.g. for age and gender also have to control for this in analysis as use different stats to unmatched studies) and randomisation (i.e. equal chance of being in each group, so likely similar distribution of confounding factors success can be examined via statistical comparison of baseline characteristics)

(Q1) If some attempt to control for confounders in either analysis or design rate as 'yes' (NB., where there are more than two analyses in one paper, if control for confounders in only one (e.g. regression but not t-tests) still rate yes – can rate the extent via percentage rating in Q2).

(Q2). Where there are two or more relevant analyses, the rating for percentage of confounders will be analysed across all relevant analyses (e.g. if there are two relevant analyses and a number of confounds are adjusted for but only in one out of the two analyses, then rate across both and reduce the final percentage rating – cannot score higher than '60-79%')

- Rating of 80-100% (most) = 2+ confounders controlled for in analysis or design (where applicable)
- Rating 60-79% (some) = 1+ confounders controlled for in analysis or design (where applicable)
- Rating less than 60% (few or none) = No attempt to control for confounders in analysis or design (where applicable)

*Where Q1 is no, Q2 is not applicable.

B: CONFOUNDERS SCORING

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); or (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 - 79% of relevant confounders (Q1 is 1) and (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) and (Q2 is 3) or control of confounders was not described (Q1 is 3) and (Q2 is 4).

D) BLINDING

(Q1) Was (were) the outcome assessors aware of the intervention or exposure status of participants?

- 1. Yes
- 2. No
- 3. Can't Tell

(Q2) Were the study participants aware of the research question?

- 1. Yes
- 2. No
- 3. Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); and the study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); or the study participants are not aware of the research question (Q2 is 2); or blinding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); and the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

(Q1) Were the data collection tools for outcome measure(s) shown to be valid?

- 1. Yes
- 2. No
- 3. Can't tell
- 4. Not applicable service use data*

(Q2) Were the data collection tools for outcome measure(s) shown to be reliable?

- 1. Yes
- 2. No
- 3. Can't tell
- 4. Not applicable service use data*

DICTIONARY: DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

<u>Self- reported data</u> includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

<u>Assessment/Screening</u> includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

<u>Medical Records/Vital Statistics</u> refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

C1: DATA COLLECTION METHODS SCORING – OUTCOME

Strong: The data collection tools have been shown to be valid (Q1 is 'yes'); **and** the data collection tools have been shown to be reliable (Q2 is 'yes').

Moderate: The data collection tools have been shown to be valid (Q1 is 'yes'); **and** the data collection tools have not been shown to be reliable (Q2 is 'no') **or** reliability is not described (Q2 is 'can't tell').

Weak: The data collection tools have not been shown to be valid (Q1 is no) **or** both reliability and validity are not described (Q1 and Q2 is 'can't tell').

D) WITHDRAWALS AND DROP-OUTS (if applicable)

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

- 1. Yes
- 2. No
- 3. Can't tell
- 4. Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

- 1. 80 -100%
- 2. 60 79%
- 3. less than 60%
- 4. Can't tell
- 5. Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

DICTIONARY: WITHDRAWALS AND DROP-OUTS

(Q1) Score **YES** if the authors describe BOTH the <u>numbers and reasons</u> for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

(Q2) The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period.

D: WITHDRAWALS AND DROP-OUTS SCORING

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) OR Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Not applicable = no follow up (not longitudinal)

INTERVENTION INTEGRITY

What percentage of participants received the allocated intervention or exposure of interest?

- 1. 80-100%
- 2. 60-79%
- 3. Less than 60%
- 4. Can't Tell

Was the consistency of the intervention measured? (e.g. audio recordings, ratings etc.)

- 1. Yes
- 2. No
- 3. Can't Tell

Is it likely that subjects received an unintended intervention (contamination or cointervention) that may influence the results?

- 1. Yes
- 2. No
- 3. Can't Tell

ANALYSES

Are the statistical methods appropriate for the study design?

- 1. Yes
- 2. No
- 3. Can't Tell

Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

- 1. Yes
- 2. No
- 3. Can't Tell

An intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated, whether they received it or not. Data of all participants will be included even if they drop out, don't complete questionnaires, interventions etc. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Appendix C: CASP quality tool

Critical Appraisal Skills Programme (CASP) Checklist: 10 questions to help you make sense of Qualitative research

Are the results valid?

Was there a clear statement of the aims of the research?
 (e.g. what was the goal of the research; why it was thought important; it's relevance)

Yes	
Can't tell	
No	

2. Is a qualitative methodology appropriate?

(e.g. if the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants; is qualitative research for the right methodology for addressing the research goal?)

Yes	
Can't tell	
No	

3. Was the research design appropriate to address the aims of the research?

(e.g. if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Yes	
Can't tell	
No	

4. Was the recruitment strategy appropriate to the aims of the research?

(e.g. has the researcher explained how they recruited participants? Consecutive sampling (from a waitlist etc.) is a good approach... snowball sampling (recruitment from acquaintances) is not)

Yes	
Can't tell	
No	

5. Was the data collected in a way that addressed the research issue?

(e.g. if the setting for the data collection was justified; if it is clear how data were collected e.g. focus group, semi-structured interview etc.; if the researcher has justified the methods chosen?; if the researcher has made the methods explicit (e.g. for an interview method, is there an indication of how interviews are conducted or did they use a topic guide); if methods were modified during the study. if so, has the researcher explained how and why; if the form of data is clear (e.g. tape recordings, video material, notes etc.); if the researcher has discussed saturation of data)

Yes	
Can't tell	
No	

6. Has the relationship between researcher and participant been adequately considered?

(e.g. has the researcher described their epistemological position? E.g. objectivism, social constructionism etc.)

Yes	
Can't tell	
No	

7. Have ethical issues been taken into consideration?

(e.g. if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained; if the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on participants during and after the study); if approval has been sought from the ethics committee)

Yes	
Can't tell	
No	

8. Was the data analysis sufficiently rigorous?

(e.g. are the findings explicit? Are the findings discussed in relation to the original research question? Is there adequate discussion of the evidence for and against the researcher's arguments?)

Yes	
Can't tell	
No	

9. Is there a clear statement of findings?

(e.g. if the findings are explicit; if there is adequate discussion of the evidence both for and against the researcher's arguments; if the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst); if the findings are discussed in relation to the original research question)

Yes	
Can't tell	
No	

10. How valuable is the research?

(e.g. if the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research based literature; if they identify new areas where research is necessary; if the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used)

Comments:

Appendix D: Risk Management Protocol

Cognitive Analytic Therapy-informed Containment for self-Harm (CATCH): A Feasibility

Trial

Overview

This protocol has been developed in collaboration between Alexandra Brown (Trainee Clinical Psychologist), Cameron Latham (Expert-by-Experience and Mental Health Consultant), Dr Peter Taylor (Clinical lecturer and Clinical psychologist) and Dr Adam Danquah (Clinical Lecturer and Clinical Psychologist).

General principles

A realistic and genuine discussion should be had with all participants during the first meeting (prior to consent being taken) about the possibility of distress/risk during the study, and what might be a helpful response if this were to happen for them.

This discussion should cover helpful contacts, any current risk management planning and other strategies they find helpful at times of distress, possibly also including other suggestions for helpful resource (e.g. Samaritans) if needed.

Another goal of this discussion is to explain the limits of confidentiality and discuss how to manage this should issues arise. Furthermore, during this discussion it should be agreed what actions will be taken by both participant and researcher if risk becomes apparent, with the emphasis (except in extremis) upon the researcher and participant building understanding and trust. Just as the researcher can be trusted to follow ethical and research standards, the participant should also be 'trusted' to know how to manage their emotions and feelings.

The researcher should also explain to the participant the study email account will not be checked consistently throughout each day, or overnight. The researcher will not be available outside of meetings and telephone contact, and it will also be sensitively explained to participants that the researcher cannot act as a crisis or clinical service. However, it is possible that participants may become distressed while in contact with the researcher during the initial baseline session, therapy sessions, the debrief session or the interview session. Therefore, the risk protocol covers these meetings and telephone calls.

Procedures to be followed throughout the study:-

To be enacted if a participant and the researcher is concerned about the participant's current and subsequent welfare, for example if a participant:

- Reports or displays notable distress
- Reports thoughts or feelings related to suicide
- Reports current urges to harm themselves

If participant reports or shows signs of low or moderate distress:

- Pause the session/phone call (with the participant's agreement) and allow time to talk about other topics including how the participant feels, and then carefully observe levels of distress.
- If distress seems to have lessened, discuss with participant whether or not they wish to continue with the study/the current phone call or session.
- If distress remains prominent or worsens, follow steps below.

If participants report more severe distress or thoughts/feelings related to current urge to self-harm or suicidal ideation:

- Halt or pause the session/phone call.
- Try to assess what the participant needs at this point in time active listening alone, validation, acknowledgement, normalisation.
- Allow the participant an appropriate amount of time to say more about how they are feeling and allow time to listen to them, be non-judgmental and empathic.
- Ask specifically about any thoughts of suicide, if not already mentioned.
- Where these are present, assess level of immediate risk (this should be done as part of a calm, collaborative conversation, avoiding appearing panicked). The researcher should ask about intent, planning/access to means, and how hard it feels to resist this for both suicide and NSSI. A Likert scale could be used to assist this discussion and quantify risk.
- Ask the participant: Do you feel that taking part in this interview is affecting how you feel? If so, in what way? / Is participation making you feel more like self-injuring or suicidal?
- If so, explain that the researcher has a duty of care and refer to current risk management (previously discussed) or previously agreed plan of action.
- Risk management should be a collaborative process, taking into account the wishes of the participant; however, the limits of confidentiality should be reiterated.
- In judging the level of risk associated with urges to self-harm/attempt suicide it is important to involve the participant themselves in discussing this. In doing this the researcher can check with the participant about the usual severity of their self-harm and aftercare (including any aftercare they provide themselves such as wound cleaning and also any health services they routinely attend), and also their degree of suicidal ideation.
- Be aware of the increased likelihood of subsequent contact, perhaps taking the form of a distressing email (see guidance below). The email account should have a standard automatic reply that reiterates signposting information.

Where taking part in the study is having an adverse effect on the participant the study should be immediately halted.

If the researcher considers the risk level to have returned to low to moderate, and the participant is euthymic, lucid and appears to have capacity, the participant will be asked if they wish to continue with the phone call, session or interview, and be reminded of their

right to withdraw at any point without adverse consequences for their psychological and health care.

If the participant does not feel able to continue the phone call, session or interview, but is eager to remain involved in the research, this could be discussed with them, once they have had a break from the study, and once the issue has been reviewed by the study supervisors. The participant would be judged as high risk of intentional or accidental suicide if

The participant would be judged as high risk of intentional or accidental suicide if

- Current suicidal ideation present, and suicidal intent rated moderate to high, but no plan or access to lethal means.
- Urges to self-harm that are hard to resist are present and could result in severe injury (e.g. planned overdose or hanging), long-term disability or death.

Clinical judgement should be employed in making this judgement and a cautious approach should generally be adopted where uncertain. The participant should be involved in this discussion where possible.

If high level of risk is identified, then the researcher should follow the procedure below:

- Encourage participant to immediately contact support(s) and clinician(s)/psychiatric emergency services to inform of risk
- □ If the participant does not feel able to do so, the researcher will seek permission from the participant to contact these people for them (clinician(s)/contact support(s)/psychiatric emergency services) to inform them of level of risk and enlist their assistance in getting participant to a clinician
- □ If participant does not agree to contacting supports/clinician(s)/psychiatric emergency services, then the researcher should inform the participant that they must break confidentiality and contact clinician(s)/contact support(s)/psychiatric emergency services to inform them of level of risk and enlist their assistance in getting participant to a clinician.*
- □ Call Project Supervisor(s)
- □ Record adverse event

* Where researcher is required to contact and inform others of risk this should be first discussed with the participant where possible. It can be emphasised this action is about keeping the participant safe. It can also be discussed if the participant has preferences regarding who you contact or how you share this information. Where possible (and not conflicting with duty of care or other requirements of the researcher) participants' preferences should be taken into account.

The participant would be judged as being at imminent risk of intentional or accidental suicide if:

- Current suicidal ideation present, and suicidal intent rated moderate to high, with plan and access to lethal means. moderate to high
- Plan to self-harm in a way that could result in severe injury, long-term disability or death (e.g. planned overdose or hanging), and access to means

If imminent level of risk is identified, then the researcher should follow the procedure below:

- □ Call Project Supervisor(s)
- □ If consent can be gained for the steps below then this is preferable, if not the researcher must break confidentiality
- Researcher tells/calls clinician (and people in support network, with the participant's consent) to inform them of level of risk and enlist their assistance in getting subject to a clinician
- □ If in with researcher: Participant should not be left alone. They can leave with family member/friend, researcher should accompany Participant to Hospital Emergency Department
- □ If on the phone: Participant should not remain at home alone. Researcher tells/calls clinician (and people in support network, with the participant's consent) to inform them of level of risk and enlist their assistance in getting the Participant to a clinician
- □ If an ambulance is being sent, stay on the phone with the Participant until the ambulance arrives.
- □ If Participant refuses to do the above: call 999 and inform of subject's location and risk level.
- □ Call participant 1-2 days following the above to follow up, repair rupture if appropriate
- □ Record serious adverse event

Risk expressed via email

It will be made clear that the address is to be used for the research project only and that emails will only be checked at regular intervals. This will be noted on advertising material and also within an automatic reply. Moreover, the automatic reply will reiterate signposting information. It will be made clear to participants that researchers will not necessarily be able to follow up emails by contacting participants where risk or distress is shared. This is important as there is a possibility that participants may understandably seek care from the research team, if they feel distressed or vulnerable. The team will set up clear boundaries related to email use, including the account only being checked during normal office hours (9am-5pm) and from a work location. Where researchers read an email from a participant that indicates high or immediate risk to themselves, they should act by informing the clinician (and people in the participant's support network, with the participant's consent) to inform them of level of risk. If the researcher has an appointment scheduled with the individual, they should first call the participant to check they still wish to see the researcher and checkin with the participant with regards to their level of risk and how they are feeling at that point.

Personal Safety and Boundaries

In responding to the above situations, it is important that the researcher balances these actions against their own personal safety and should avoid situations where their personal safety feels compromised. Lone working policies from The University of Manchester and partaking NHS trusts will be adhered to.

In addition, where any of the above incidents take place the researcher should inform their supervisor(s) and arrange a time to debrief with regards to the situation, including a focus on how they have personally been affected

Appendix 5: Study protocol

RESEARCH PROTOCOL

<u>Cognitive Analytic Therapy-informed Containment for self-Harm (CATCH): A</u> <u>Feasibility Trial</u>

1) RESEARCH TEAM & KEY CONTACTS

Chief Investigator:	Co-investigator(s):
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Email: peter.taylor-2@manchester.ac.uk Telephone: 01613060425	Email: <u>kelly-marie.peel-</u> wainwright@postgrad.manchester.ac.uk Telephone: 07377455237
Co-investigator(s):	Co-investigator(s):
Name: Stephen Bradley	Name: Dr Kate Williams
Address: Division of Psychology & Mental Health, Room 2.33, Zochonis Building, University of Manchester, Brunswick Street, M13 9PL	Address: Division of Psychology & Mental Health, Room 2.33, Zochonis Building, University of Manchester, Brunswick Street, M13 9PL
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Co-investigator(s):	Co-investigator(s):
Name: Dr Samantha Hartley	Name: Cameron Latham
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Clinical Supervisor:	Lead R&D Trust contact(s):
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Sponsor(s):	
Name: The University of Manchester	
Sponsor contact: Ms Lynne Macrae, Faculty Research Practice Governance Coordinator	
Address: Faculty of Biology, Medicine and Health 5.012 Carys Bannister Building University of Manchester M13 9PL	
Email: FBMHethics@manchester.ac.uk	
Telephone: 0161 275 5436	

2) ROLES

Dr Taylor will take overall responsibility for the running and management of the project and provide primary supervision to the researchers (SB, KW, KMPW). Dr Hartley will provide input into the qualitative analyses, secondary supervision of the researchers, and use her clinical knowledge of the CAT model to inform the project. SB, KW, and KMPW will support recruitment, data collection, data management and preliminary data analysis. SB, KW, and KMPW will also provide the therapy. Mr Turpin will provide clinical supervisions to therapists and has helped develop the therapy manual and approach. Mr Latham will provide his insight as an expert-by-experience (having previously self-injured for many years) and mental health consultant, guiding the development of materials and study procedures.

3) INTRODUCTION

Non-suicidal self-injury (NSSI) is when somebody engages in self-harm, such as cutting, without meaning to end his or her life. A large number of people engage in NSSI for lots of reasons, for example to cope with emotions. However, currently there are large waiting lists to access psychological therapy through the NHS. Therefore, it is important to research brief therapies so that individuals who engage in NSSI can receive treatment quicker. One potentially helpful therapy suggested is Cognitive Analytic Therapy (CAT), which focuses on patterns in

relationships. NSSI can be understood as a way in which people relate to themselves, which suggests that CAT would fit well in terms of understanding and working with these difficulties.

This study aims to evaluate a brief two-session CAT therapy for people who engage in NSSI. We aim to evaluate the feasibility and acceptability of the therapy, using interviews and questionnaires. This means looking at whether participants stick with the therapy, and how they find taking part in the therapy.

All participants will meet with a researcher for an initial session to complete baseline questionnaires about their current difficulties, thoughts and feelings. Participants will then be randomly allocated to a condition: either the therapy condition or the treatment-as-usual (TAU) condition. Participants in the therapy condition will receive two therapy sessions, whilst participants in the TAU condition will not receive any therapy sessions. All participants will attend a final session to complete more questionnaires. Participants will be asked to complete online surveys weekly. Some participants will be invited to take part in interviews about their experience of the therapy. All participants will receive a shopping voucher as compensation for their time. Using the data collected from this study, future work can be done to provide better treatment for people who engage in NSSI.

4) BACKGROUND

Non-suicidal self-injury (NSSI) is defined as the intentional and deliberate damage to the body without an intent to end one's life (Klonsky & Muehelenkamp, 2007). An estimated 4% of adults report having previously engaged in NSSI, with the age of onset typically around 13 years (Klonsky, Oltmanns, & Turkheimer, 2003; Nock et al., 2006). NSSI has been linked with a range of mental health difficulties such as depression and anxiety (Bentley, Cassiello-Robbins, Vittorio, Sauer-Zavala, & Barlow, 2015), emotion regulation (e.g., Borderline Personality Disorder; Snir, Rafaeli, Gadassi, Berenson, & Downey, 2015), and with an increased risk of suicide (Muehelenkamp & Gutierrez, 2007). Thus, NSSI is an important target for psychotherapy.

Brief psychotherapies have been developed for a range of mental health difficulties. Researchers have developed brief three and five-session Cognitive Analytic Therapy (CAT) interventions for use with NSSI or individuals diagnosed with a personality disorder respectively (Sheard et al., 2000; Carradice, 2013). CAT uses a relational therapeutic style whereby it recognises that people internalise relational patterns from childhood, which may reappear throughout life and inform relationships towards the self and others (Ryle, 2002). CAT may therefore be well-suited to helping people explore problematic relational patterns linked with NSSI.

Research by Dr Taylor highlights how NSSI is often functional for individuals, focussing on regulating intrapersonal and interpersonal states (Taylor et al., 2018a), and that NSSI is related to more negative forms of self-relating (Forrester et al., 2017), as well as challenging relational experiences like rejection (Cawley et al., 2018). As a result, CATinformed approaches may well be suited to helping those with NSSI, due to the emphasis on collaboratively making sense of intra and inter-personal patterns of relating that drive self-harm.

In developing an evidence base for complex interventions, an important early step is to ensure the therapy is safe and acceptable to clients, and that it can be feasibly

evaluated within in a trial context (Craig et al., 2008). Whilst it has been suggested by previous research that brief CAT approaches would be well-suited to helping people who engage in NSSI (Fien et al., 2018: unpublished service evaluation), research around the efficacy and acceptability of the therapy requires further investigation. Feasibility can be measured within a randomised trial context in terms of whether adequate numbers of participants can be successfully recruited and whether outcome data can be collected. This will inform whether it will be possible to conduct a further large scale project. Evaluating intervention acceptability is important because it will explore how appropriate, palatable and effective participants feel the intervention is (Kazdin, 1981). This is important to examine as engaging in an acceptable therapy is likely to increase cooperation, therapeutic change and overall clinical effectiveness (Kazdin, 2000). That is, even if a therapy is deemed clinically effective, if service users find the therapy unacceptable (for example they are unhappy with the length of treatment) it is significantly less likely to be engaged in. Therefore, an acceptability study would be important to conduct to evaluate whether further large scale efficacy research would be useful and meaningful to conduct. Within that context, it is important to look at the safety of the intervention. Evaluating safety involves looking at the number of adverse events and experiences reported by participants. A safe intervention is important in ensuring that participants do not experience deterioration in occupational, social, intrapersonal and interpersonal relating by participating.

The data will also be used to examine the association between important psychological variables (self-compassion, depression) and NSSI urges and behaviour. These secondary analyses would help inform theory regarding how NSSI develops and is maintained. For example, little research has explored the relationships between self-compassion (i.e., acting compassionately towards yourself) and NSSI, but self-compassion may reflect one important mechanism through which talking therapies can help those who self-injure (Gregory, Glazer, & Berenson, 2017). Thus, the planned secondary analyses will help extend our understanding of these associations.

5) STUDY OBJECTIVES

4.1 Primary Question/Objective:

To evaluate the acceptability of a brief, two-session Cognitive Analytic Therapy informed intervention for people who engage in non-suicidal self-injury.

To evaluate the feasibility of recruiting and retaining people who engage in nonsuicidal self-injury in a trial of a brief, two-session Cognitive Analytic Therapy informed intervention.

To evaluate the safety of a brief, two-session Cognitive Analytic Therapy informed intervention for people who engage in non-suicidal self-injury.

4.2 Secondary Question/Objective:

To evaluate the associations between self-compassion, depression and NSSI urges and behaviour. This question relates to additional secondary analyses of data that will help inform theory concerning the psychological factors related to self-injury.

6) STUDY DESIGN & PROTOCOL

Design

A feasibility Randomised Controlled Trial (RCT) design will be used. Participants will be randomly allocated to receive either the brief CAT-informed therapy plus Treatment as Usual (TAU), or just TAU alone. The trial will involve the collection of both quantitative (e.g. questionnaires) and qualitative (e.g. interviews) data.

Procedure

Once recruited, participants will engage in the following procedure:

Figure 1: Flow Chart of Study Procedure

Note. All sessions are face-to-face, except those with asterisks. Online surveys can be completed on paper if the participant prefers.

- Week 0: telephone screening (all participants)

- Week 1: baseline assessment (all participants) and randomisation

- Weeks 2 & 3: therapy (therapy condition participants only). Completion of online surveys (all participants)

Week 4: Debrief and questionnaires (all participants). Optional opportunity to take part in a qualitative interview (subset of 15 participants in the therapy condition)
Week 5: online surveys (all participants)

Telephone screening: The researcher will contact the individual to discuss the study in more detail, and determine eligibility. This would include determining current risk of suicide (as this is an exclusion criterion). This discussion would follow the risk management principles set out in the risk protocol, which has been co-developed by those with lived experience of NSSI and encourages a collaborative and open discussion. We will ask individuals for their consent to contact their clinician who we will discuss eligibility and potential risk with. We will also post/email the PIS to participants.

Baseline assessments: If the individual is eligible and wishes to take part in the study, baseline assessments will subsequently be carried out face-to-face. The researcher will explain the details of the study again and what is involved, and this information will also be available in the PIS. If the individual still wishes to take part they will then be asked to complete the consent form, followed by the baseline questionnaires (SITBI-SF, SCS, PHQ-9, PSQ, ABUSI). This meeting will last approximately 30 to 60 minutes. Following completion of this meeting, participants will be randomly assigned to either the therapy condition or the treatment-as-usual condition. Randomisation will be carried out by the project supervisor (Dr Peter Taylor). Participants will then be informed of which arm of the trial they have been randomly allocated to by phone or email. Notably, the possibility that participants could be allocated to either the therapy arm or the Treatment as Usual arm of the study will be made clear in the PIS and

explained verbally by the researcher during the telephone screening and at the start of the baseline assessment meeting before consent is taken.

Week 2 and 3: During weeks 2 all participants will be invited to complete a brief online survey, which will include questionnaires asking about their current difficulties and experiences. Completion of the survey will take approximately 10 to 20 minutes. Participants will be invited to take part in this survey by an email or text alert (depending on preference), which will include a link to the online survey. The survey will be hosted by the University of Manchester using a system developed within the Division of Psychology and Mental Health, which has been widely used in other research projects. Participants will be invited again to complete the survey in week 3. Participants allocated to the therapy group will also be invited to attend a therapy session in weeks 2 and 3.

The brief CAT-informed therapy will take place over two sessions. Session one will last around 90 minutes. In session one, we will discuss with the participant their experience of self-harm and begin to support them to make sense of patterns in their self-harming behaviour. This will be done by thinking about the events that come before or follow self-harm, as well as thoughts and emotions associated with selfharm; it will also be done by thinking about ways that the participant relates to him/herself and other people. By the end of the first session, the researcher and the participant will have collaboratively developed a written diagram which shows patterns in the participant's self-harm.

Session two will involve revisiting the mapping of patterns. The researcher and participant will the collaboratively develop 'exits' or ways to break patterns and cycles of thinking, feeling and behaviour. Both sessions will have structured endings.

Week 4: All participants will be invited to a further face-to-face meeting with a researcher where they asked to complete a final set of questionnaires (including the SCS, PHQ-9, ABUSI, and the Adverse Effects in Psychotherapy (AEP) self-report measure. This meeting would last approximately 20 minutes. A subset of 15 participants in the therapy condition will be invited to engage in qualitative interviews. All participants who have completed the therapy will be verbally asked to engage in the interviews during the week 4 meeting, until 15 participants have agreed to engage in the interviews. Participants will be informed that engaging in an interview would take place during week 5 and would last for approximately one hour. Participants will be informed that the interviews and perceptions of the therapy, and that they would receive an additional reimbursement for their time. Participants who consent to engage in interviews will be invited to a final session.

Participants who do not engage in the interviews (i.e. those in the control condition and those in the therapy condition that decline engaging in interviews or who complete therapy after 15 interviews have been engaged in) will be thanked, debriefed, and reimbursed during week 4.

Week 5: In week 5, all participants will be asked to complete online survey measures for a final time. Participants who engage in the qualitative interviews will have one

final session with a researcher which will last approximately one hour, and which will be recorded on an encrypted audio recorder. Following this interview, these participants will be thanked, debriefed and reimbursed.

7) MEASURES

- a. **Demographics** (age, gender, education, ethnicity, employment, diagnosis)
- b. Self-Injurious Thoughts and Behaviours Inventory Short-Form structured interview (SITBI-SF; Nock et al., 2007). We will administer the NSSI questions covering participants' history, frequency, severity, and methods of NSSI. Based on the supervisor's pilot data using this measure and to avoid extreme guesses, a subset of items regarding frequency of NSSI (e.g. "How many times in the past year have you purposefully hurt yourself without wanting to die?") will be adapted for Likert response formats. The SITBI-SF has good construct validity and strong interrater reliability (k = .90; Nock et al., 2007).
- c. Self-Compassion Scale (SCS; Neff, 2003).The SCS includes 26 items rated on a scale of 1 (almost never) to 5 (almost always) as to how often participants engage in a range of thoughts or behaviours. The SCS includes six subscales including self-criticism and self-kindness, isolation and common humanity, and over-identification and mindfulness. The factor structure and internal reliability of the SCS has been supported (neffet al., 2017).
- d. **Patient Health Questionnaire** (PHQ9; Kroenke et al., 2001).The PHQ9, used to assess depression, includes nine items and determines the extent to which participants have been bothered by difficulties over the last two weeks by rating on a scale of 0 (not at all) to 3 (nearly every day). The PHQ-9 has good construct validity and sensitivity to change (Beard et al., 2016).
- e. **The Personality Structure Questionnaire** (PSQ; Pollock et al., 2001) will be used to assess self-concept stability. The PSQ includes 8 items rated on a five-point scale with opposite ends representing agreement with an unstable or stable sense of self. The PSQ shows good construct validity (Pollock et al., 2001).
- f. Alexian Brothers Urges to Self-injure scale (ABUSI; Washburn et al., 2010). The ABUSI asks participants to rate their urges to self-injure over the last week on frequency, strength, time thinking of self-injuring, and ability to resist. The factor structure, validity and reliability of the ABUSI have been supported (Washburn et al., 2010).
- g. The Adverse Experiences in Psychotherapy Scale (AEP; Hutton, Byrne & Morrison, 2017; unpublished) is a self-report measure that asks about the presence of 28 potential adverse experiences that might occur as a result of therapy (e.g. "Taking part has made me feel more anxious"). This measure has been used in previous evaluations of CAT (Taylor et al., 2018b).

Completed at subsequent online sessions to monitor change:

- a. SCS
- b. PHQ-9
- c. ABUSI

Questionnaires to be completed at the debrief session:

- a. PSQ
- b. AEP

8) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

Participants will:

 Be aged over 16 years (parental guidance is not needed; BPS Generic Professional

Practice Guidelines, 2008)

2. Be comfortable with and have access to email and the internet for completing study

measures

3. Be currently under or receiving support form clinical/health service including NHS,

3rd sector, or University health services

4. Following Diagnostic and Statistical Manual of Mental Disorders (DSM-V; American Psychiatric Association, 2013) have had five or more instances of NSSI in the past year:

a. NSSI methods are operationalised to include cutting, burning, biting, or scratching oneself, as well as head-banging or self-poisoning.

- 2. Have an adequate English language ability to understand study materials
- 3. Be deemed capable of providing informed consent by their clinical team.

6.2 Exclusion Criteria:

Participants will not:

- Be currently receiving any other psychological therapy (e.g., including but not limited to Cognitive Behavioural Therapy and/or Dialectical Behaviour Therapy), and will not have received psychological therapies in the last one month.
- 2. Never had received Cognitive Analytic Therapy
- 1. Have been diagnosed with a Learning Disability or an Autism Spectrum Disorder as judged by clinical team since the therapy has not been developed for this population
- 2. Be currently judged at high risk of suicidal behaviour, operationalised as the presence of high or immediate suicidal intent and planning. If participants are keen to be involved, we could return to these people in a few months when their level of risk has reduced,
- 3. Have been hospitalised as a result of self-harm in the past month

6.3 Recruitment:

Participants will be recruited through NHS adult mental health teams within the North West, third sector organisations and University health services. Recruitment will occur through four routes:

1. Clinicians working within NHS services that are acting as recruitment sites for this study will be asked to tell potentially eligible clients that they come into contact with about the study, on behalf of the research team. The clinician will be asked to review their caseload (usually electronically) and utilise their clinical judgement to identify which clients may be eligible, given the inclusion and exclusion criteria which will be given to clinicians. If the clinician feels that a client would be appropriate for the study, they would share a Participant Information Sheet (PIS) with the client. If clients are interested, clinicians will ask participants to complete a consent-to-contact form which would be returned to the researcher. The

researcher would then follow this up by contacting the individual.

- Individuals could respond to posters within the community, including through universities, community centres, and online (e.g., social media, Gumtree) and refer themselves by emailing the research team through a dedicated email address.
- 3. The researchers would seek permission to attend support groups and meetings at relevant NHS or community centres. With permission from facilitators, members of the research team will give relevant information to individuals attending these groups and meetings, via a verbal presentation or disseminating posters. The research team would ask any individuals who were interested in participating in the study to approach a member of the research team, who would then ask them to complete a consent-to-contact form.

Members of the research team would also approach the facilitators of the support groups or meetings and ask them to give relevant information to individuals who they feel may be appropriate for the study, on behalf of the research team. The facilitator would then ask the potentially interested individual to complete a consent-to-contact form, on behalf of the researcher, which would then be returned to a member of the research team.

4. Rebecca Hughes (Consultant Clinical Psychologist and Clinical Manager of Gaskall House) has approved for NHS administrative staff at Gaskall House to review clinical waiting lists and contact potentially eligible participants, on behalf of the research team. The administrative staff would contact the individual

by phone or letter to tell them about the study and also send them the Participant Information Sheet (PIS). If the individual is interested in taking part they can either contact the research team directly via the dedicated study email address or complete a consent-to-contact form and hand it to the administrative staff at Gaskall House, who would then forward it to the research team.

6.4 Randomisation:

Participants will be allocated to groups at random. Randomisation will happen after the baseline visit and will be carried out independently by the primary project supervisor (Dr Peter Taylor) thus avoiding any potential unintentional bias from the three researchers who meet with study participants. Participants will be randomised according to a pre-specified randomisation schedule (online random sequence generator) which will be held by Peter Taylor.

6.5 Participants who withdraw consent [or lose capacity to 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.

If a participant choses to withdraw, any personally identifying information related to them will be destroyed. They will have the opportunity to request that their study data is withdrawn, as this will be linked to their participant ID. However, all data will be anonymised as soon as possible at the end of the study, and following anonymisation, it will not be possible to remove the participant's data from the project as there will be no way of identifying that participant's specific data.

All participants will be presumed to have capacity to consent unless there are grounds to question it. The researchers are not in a position to assess changes in capacity due to the short-term nature of the study and the lack of scope for a full capacity of assessment. The research team will have a health professional contact for each participant who will be asked to conduct a full capacity assessment if necessary.

9) OUTCOME MEASURES

The primary outcomes will be to determine the acceptability, feasibility, and safety of the brief CAT-informed therapy. Secondary outcomes will focus on psychological constructs hypothesised as potential mechanisms of change. These include self-injury urges, self-compassion, depression, and self-concept stability.

10) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Demographic details including the telephone numbers of participants will be collected in order to contact participants about attending appointments. Participant's personal details may be shared with their clinical team in order to monitor risk. An audio recording device will be utilised to record qualitative interviews, which will be stored on an encrypted pen drive and then on password protected servers, in accordance to the University of Manchester's Standard Operating Procedure (SOP) policy (http://documents.manchester.ac.uk/display.aspx?DocID=29971). All paper data will be stored in locked cabinets at the University of Manchester and all electronic data will be stored on password protected university servers. Only the study team will have access to personal, identifiable, and non-identifiable research data collected during this study. Data generated by the study will be stored for 10 years following the date of any publication. Participant contact details (e.g. phone number, email address) will be used for contacting participants during the course of the study, for example, for arranging meetings. This personally identifying information will be destroyed once participants have withdrawn or the study has been completed.

All information and data taken as part of the research study will be kept confidential. Confidentiality will only be breached if it is felt that the participants or others are at risk of harm. Where there is a requirement for confidentiality to be broken, this will be communicated to the participant unless it is felt that doing so will result in further risk (e.g. situations where the participant may harm self/others if they believe that they will be stopped). This information will be outlined in the Participant Information Sheet and will be discussed with the participants before consent is sought.

Brief direct quotations arising during the qualitative interviews may be published as part of the study. Participants will be made aware of this in advance and have the option of not taking part in these interviews, or withdrawing from the study altogether. Within direct quotations any personally identifiable information (e.g. names, locations) will be altered to avoid identification of the participant.

Only information that has been approved by the ethics committee will be recorded during the study as necessary. The location of any recording will be private and comfortable for the participant. Any potential risk will be considered in deciding the location of the appointment. Where possible the name of the interviewee will not be recorded unless verbal consent is required and this will be recorded separately from the interview. An encrypted University-provided device will be used for audio recording. The device used to make the recording will never be left unattended and will be locked away securely on university premises when it is not in use. Recordings will be transferred from the recording device to a University server as soon as possible to ensure that a master copy is backed up and the file is encrypted. Recording will be checked once transferred and before deleting from the recording device. A member of the research team or a University of Manchester staff member (who will have signed a transcription confidentiality agreement) will then transcribe the audio recording into electronically written format. This transcription will be anonymised and a pseudonym will be utilised to retain participant anonymisation. One this transcription has been completed and checked, the audio recording will be deleted from the University server.

Transcripts will be securely stored on University servers. Data will be encrypted to AES 256 standard when not in use. If a transcript is not held on University servers, it will be stored on an encrypted device for temporary storage only. These transcripts will be transferred to University servers and deleted from temporary storage as soon as possible.

This transcription of recordings will be done in a secure environment where the data subject cannot require the same level of security. Information will be kept in accordance with the University's Retention Schedule and Research Data Management Plan. Destruction of records will be performed in a secure manner, ensuring that records to be destroyed are transported securely and destroyed completely in a manner that renders the information completely and irreversibly destroyed. Should recordings or transcripts that have not been anonymised are lost, stolen, corrupted or disclosed to, or accessed by unauthorised persons, it will be reported to the Head of Information Governance as soon as possible in order that appropriate measures can be taken to contain any damage and minimise the harm which might arise.

Contact details entered into the Acuitas messaging system will only be accessed by the researcher, and wiped from this system once the study is finished or if the participant withdraws from the study. This system is secure and password-protected and is IT and research governance approved.

11) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

Patterns of change in the primary and secondary hypothesis will be graphed and corresponding effect size estimates and confidence intervals calculated. Clinically significant change on measures of self-injury or self-injury urges for each participant in the intervention arm of the study will be determined using Jacobsen & Traux's (1991) criteria. Jacobsen & Traux (1991) define clinically significant change as the extent to which therapy moves someone outside the range of the dysfunctional population or within the range of the functional population. Particular attention will be paid to the number of adverse events reported for each participant such as deterioration of their symptoms. In such cases this information will be linked with the participants' responses on the adverse experiences measure (see Measures section) in order to further confirm adverse experiences and explore whether they may be linked to the therapy itself.

To explore trends in the data with regards to treatment effects, we will use a randomintercept multi-level linear regression model. Data will be nested at two levels: time point within participant. This model accounts for the non-independence in the data. Within this analysis, both treatment group and time point will be included as covariates. An interaction between time and group will indicate whether there is a greater change in the outcome variable for the treatment groups compared to TAU.

Secondary analyses will focus on the relationships between NSSI, self-compassion, and depression. Linear regression will be conducted looking at predictors of NSSI at baseline and predictors of change in NSSI over time (covarying for treatment effect).

9.2 Qualitative Analysis

A Thematic Analysis (TA; Braun & Clarke, 2006) approach will be used to identify and explore key themes in participant's experience of the therapy. This will be used within a critical realist framework, which allows us to draw inferences about the therapy more broadly whilst recognising the particular social context of the participants. The following TA process will be used:

Stages	s of TA	Description
1.	Researcher	The researcher will listen to the interview several times
	familiarise self with	and transcribe a subset of the data.
	the data.	
1.	Generate initial	The researcher will start to identify features of the data
codes		that are interesting and could be important given the
		aims of the study.
1.	Search for themes.	The researcher will look for themes across the initial
		codes and categorise them as such.
1.	Review themes.	The researcher will review and refine themes to ensure
		that they 'fit' well with the data.
1.	Define and name	The themes are further operationalised and the
themes.		researcher will analyse how the themes relate to the
		research questions.
1.	Produce the report	The researcher will chose examples of data that support
		each theme to include in the final report.

An overarching critical realist epistemology will underpin the analyses, whereby inferences can be made about impact and experience of the therapy whilst recognising the constraints that emerge from the positioning and context of the study

9.2 Sample Size:

The study aims to recruit a total sample size of 60 participants. To account for a potential 20% drop out, we will recruit up to 72 participants. This target sample size is consistent with typical sample sizes for feasibility trials (Billingham et al., 2013). This number would also be adequate for estimating relevant study parameters, useful in informing future power calculations (Sim and Lewis, 2012).

12) DATA MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of the University of Manchester. The overall management of the programme will be overseen by the Chief Investigator, and NHS and University mentors. The research may be audited by the NHS or University of Manchester authorities. In order to review safety and efficacy, the research team will meet for fortnightly supervision for the duration of the study. As part of this meeting safety and data quality will be routinely reviewed, including the occurrence of any adverse or serious adverse events. The research team consists of qualified Clinical Psychologists who are highly experienced in conducting research around non-suicidal self-injury. Additionally, the therapists will meet with a Cognitive Analytic Psychotherapist monthly for clinical supervision to monitor therapeutic practice and quality.

13) SAFETY CONSIDERATIONS, ADVERSE EVENTS AND CLINICAL CONSIDERATIONS

Adverse Events (AEs) will be monitored throughout the trial by the core research team, consisting of three Trainee Clinical Psychologists and two qualified Clinical Psychologist. These will be reviewed during supervision fortnightly, or should an AE occur, the qualified Clinical Psychologists would be contacted without delay. In this case, the research team will judge whether the trial should be terminated. Where an

SAE, or a series of AE occur for a particular participant, the research team will halt the study for that individual and review a) where to withdraw the participant from the study, and b) whether to halt the entire project. This decision will be based on a consideration of the likelihood that the project itself (including the therapy) contributed to the SAE (thus making it an Adverse Reaction; AR). Information will be gathered including the participant's and researcher or therapist's perspective, and the timing of the AE or SAE (e.g. did it occur immediately after a therapy session?) to help inform this review. Where an AR is identified, it will be considered whether this could apply to other participants and therefore if the study as a whole should be halted prematurely. This review process will be documented.

The therapy will be delivered by three clinical psychology trainees with prior experience of delivering psychological therapies. Peer supervision will take place every two weeks. In addition, every four-weeks supervision from a CAT-qualified therapist with experience of delivering brief therapies aimed at self-harm (Dr Turpin) will be delivered. Ad hoc supervision will also be provided as and when needed by either Dr Taylor or Dr Hartley.

14) MINIMISING BIAS

For practical reasons it will not be possible to have different researchers provide the therapy and also collect the study data. This presents a risk of bias where those collecting outcome data also know whether or not a particular participant is receiving therapy. In order to minimise this bias data on outcome measures will be collected via an online self-report survey. As these measures are completed without any involvement of a researcher, risk of rater bias is therefore minimised. Randomisation will be undertaken by Dr Taylor, using an online random sequence generator. Dr Taylor will not be involved in screening potential participants or undertaking baseline assessments. This therefore minimises bias because treatment allocation will be concealed from those who have contact with participants prior to randomization.

15) ADHERENCE

In order to monitor adherence to the therapy a random subset of 10% of therapy sessions will be audio recorded using an encrypted device. These sessions would then be rated by an independent clinician using the CCAT (competence in CAT) tool (Bennett & Parry, 2004).

16) REMBURSEMENT

All participants will be reimbursed for their time and effort taking part in the main study, with a £15 shopping voucher. Those who take part in the qualitative interview will be reimbursed an additional £5.

17) PEER REVIEW

The research protocol has been thoroughly reviewed by the study team including both research supervisors. Additionally, the protocol has been assessed by our internal Research Subcommittee which includes academic clinical psychologists, service users, and trainee representatives, and has been approved.

18) PATIENT AND PUBLIC INVOLVEMENT

The researchers attended a Community Liaison Group (CLG) panel at the University of Manchester in August 2018 for consultation on the current study. The panel emphasised the importance of being explicit regarding all details of the study, particularly the fact that the research team cannot be utilised as a crisis service and that some participants will not receive the therapy. Helpfully, they advised on how to validate to participants in the TAU condition by explaining how valuable their input is to this research. The panel also advised on the use of language within the information sheet and interview schedule, such as finding an alternative to 'intervention' (i.e., therapy). In terms of accessibility, the panel suggested that participants are offered the opportunity to complete questionnaires in written form rather than electronically. It was also suggested that support for participants in the therapy arm following the study could be improved by liaising with their clinical team with regards to the therapy. The CLG felt that this might help participants continue to use some of the techniques learnt during the therapy. The CLG suggested participants be given copies of the diagrammatic formulations developed for this reason. Mr Latham will be involved for the life of the project as an expert-by-experience consultant and will advise on study design, implementation and results.

19) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee 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

Potential Risk of Distress

Past research (Biddle et al., 2013; Taylor et al., 2010) indicates that participation in research around self-harm (including NSSI) is often a largely positive experience and negative reactions are rare. Nonetheless, there is a low risk of some participants finding questions focused on difficult experiences or emotions uncomfortable or result in distress. A number of steps have been taken to minimize this risk: All participants will be informed of the possible risk of distress in the Participant Information Sheet, and this will be discussed with them verbally by the researcher before they are asked to consent to take part. Moreover, it will be made clear to participants that if they feel that the topic areas will add to significant emotional distress or could increase feelings related to NSSI then they are advised not to take part. Following the advice of individuals with personal experience of NSSI this information will be presented to potential participants as part of a collaborative discussion about what the study will involve and the possible risks.

All participants will be informed they do not need to answer any questions they do not wish to, and will be free to withdraw from the study at any time without detriment to

themselves. Participants will be advised to stop the study at any point should they become distressed (possibly stopping altogether, or taking a break depending on how the participant wants to proceed). During the face-to-face aspects and telephone of the study, the researcher, who are trainee clinical psychologists with extensive clinical experience of managing risk and responding to distress, will also be vigilant to signs of distress from the participant and respond accordingly, for example, by suggesting taking a break or halting the session or exploring where this distress is coming from. All participants will be provided with signposting information relating to local sources of help and support. Participants will be encouraged to make use of this list if they experience distress or emotional discomfort during or after the completion of the study. The study design and materials have been reviewed by Mr Cameron Latham, who is a mental health consultant with personal experience of NSSI, as well as many years of working alongside others struggling with NSSI. Mr Latham has checked the study to ensure the risk of distress is minimised throughout. A safety protocol will also be available to the researcher.

Management of Risk of Self-Harm During the Study

It is possible that participants will engage in self-harm during the study. We use the term self-harm here to refer to both NSSI and other self-injurious behaviour, including rarer events such as suicide attempts. As noted previously, those who are judged (in conversation between themselves and the researcher) to be at risk of attempting suicide will be advised not to take part in the study. Moreover, to participate in the study all individuals currently under the care of services will be required to provide contact details of a clinician involved in their care. This could be a therapist, member of a psychiatric team, or a General Practitioner. The clinicians would be informed of their involvement in the study (verbal consent to make this contact with clinicians would be sought during initial telephone meeting with the participant, prior to taking consent to participate).

In the case of lower-level self-injury, not requiring medical attention, participants who are not already actively seeking or in receipt of support for these difficulties will be encouraged to seek support. As noted they will be provided with up to date and relevant signposting information relating to local sources of support and help. As their clinician (e.g. GP or psychiatric team member) would be informed of their involvement in the study (with participants' consent) this means it would not be possible for a participant to take part in the study without their clinician being aware of their NSSI. Potential participants who do not wish their GP or other clinicians to be informed of their their their NSSI will have the option of not taking part in the study.

In the case that participants signal to the researcher that they plan to seriously harm themselves, a risk and safety plan protocol will be followed (see documents). This includes a series of steps to determine level of risk (low-immediate) and appropriate action plans. Action plans include following a safety plan with the participant, providing emergency contact numbers (e.g. Samaritans) and contacting clinical supervisors and/or emergency services if immediate risk is expressed. These steps may include the need to break confidentiality, by, for example, informing a clinician or the emergency services. In such cases this breaking of confidentiality would be discussed

with participants, unless there is judged a likelihood that this discussion itself could increase risk.

All instances of participants signalling either intent/planning of a serious act of selfharm (i.e. a suicide attempt or NSSI liable to require medical intervention) or reporting actual engagement in these behaviours will be treated as a serious adverse event and standard HRA and University of Manchester recording practices would be followed (these can be accessed at: https://www.hra.nhs.uk/approvals-amendments/managingyour-approval/safety-reporting/; and

https://www.manchester.ac.uk/research/environment/governance/policiesguidelines/).

Potential risk to researchers

When meeting participants in mental health settings, local policies to protect staff safety to protect mental health workers will be followed at all times. If a participant is being visited in their home there is potential risk of harm to the researcher. During the telephone screening call, the researcher will seek consent to contact the participants clinician or GP for the purposes of sharing any potential risk factors. This will involve consideration of risk of harm to participants, the researcher, others and the environment. Where a potential risk is identified two researchers will meet the participant. Where there is a possible risk or where risk is unknown the researchers will follow policy around staying safe on these visits e.g. having a safety checker. When meeting participants in their home and/or in the community e.g. GP surgery, the NHS lone working policies within each partaking trust and the University of Manchester will be adhered too. Meetings will always take place between 9am and 4pm to ensure other individuals will be around the facility or there is somebody that can be contacted e.g. the chief investigator or secondary supervisor .

Another potential risk to the researcher may be their emotional reaction (feeling uncomfortable/upset) to seeing participants distressed. The researchers are trainee clinical psychologists with prior and ongoing experience of working clinically with individuals who have been through highly distressing and difficult experiences, and so it is anticipated that the researcher will have the skills to be able to manage their feelings encountering distress. They will also be provided with fortnightly supervision from either the field supervisor (who is an accredited CAT therapist), by the chief investigator (who is a qualified Clinical Psychologist) or the secondary supervisor (also a qualified Clinical Psychologist) throughout the entirety of the research. During supervision sessions they will have the opportunity to discuss such issues.

20) 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.

21) FUNDING and RESOURCES

This project is part of research training award, namely the Doctorate of Clinical Psychology (DClinPsy) for three researchers. As such, a total of £1200 has been secured as funding from the University of Manchester. The University of Manchester will also provide equipment loan of an audio recorder for qualitative interviews. Additionally, the Association of Cognitive Analytic Therapists (ACAT) have agreed funding for this project of £2515.

22) PUBLICATION POLICY

Once the data have been analysed and written up for publication in the thesis, the resultant papers will be submitted to relevant journals. Brief reports may be submitted to the Association of Cognitive Analytic Therapy for dissemination amongst professionals interested and working with CAT.

Prior to publication, abstracts will be submitted to either domestic or international conferences for early dissemination of the results. Results will also be presented at an internal research conference. Results could be presented at any relevant mental health awareness events happening in the north-west to help ensure wider dissemination outside of a purely academic remit.

A press release will also be issued from the University of Manchester media department following acceptance of the published report relating to this study. Dr Taylor and Mr Latham have prior experience of press releases and engaging successfully with the media. For example, his research on self-harm risk in alternative subcultures (Hughes et al., 2018) has been covered in the Independent (https://www.independent.co.uk/news/health/goth-emo-metal-fans-self-harmsuicide-risk-a8289031.html), the Telegraph and the Mail online, amongst others, and also led to radio interviews on Key103 and Heart Manchester.

Participants interested in finding out the outcome of the study will be asked to initial a box on the consent form which states that they wish to be contacted by the researcher with the findings of the current research. These individuals will have their personal contact details secured safely until the end of the study, where they will be sent a summary of the findings. These details will be stored in an electronic, encrypted database and will not be linked to other study data. The summary will not refer to any individual results but will be an overall synthesis of the study findings. It will be written in lay terms (i.e. free from jargon or overly technical language).

The project findings will be used as a basis to inform a larger scale evaluation of the therapy, which will focus on clinical efficacy and cost effectiveness. Funding for this larger trial will be sought from the National Institute of Health Research (NIHR) Efficacy and Mechanisms Evaluation funding stream. The proposed project is an essential step in supporting the application for the larger trial and will provide valuable information relating not just to acceptability, feasibility and safety, but also to help inform power calculations and identify suitable outcomes for the larger trial.

23) TIME FRAME

The project will aim to start recruitment in March 2019 and run till April 2021. This time frame accounts for maternity leave being taken by one of the research team (KW). Please see Gantt chart on next page for detailed timeline.

Table 1: PROJECT GANTT CHART

	2018				2019											
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	De
Gaining approvals (ACAT,																
clinical psychology programme)																
Ethics and trust approvals																
Trial registration																
Procedure piloting and																
finalisation																
Participant recruitment																
Quantitative data collection																
phase 1																
Qualitative data collection																
Qualitative transcription & data																
analysis																
Quantitative data collection																
phase 2																
Quantitative analysis																
Paper write-up & dissemination																
	2020)											2021			
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Ар
Participant recruitment																

Qualitative transcription & data analysis			
Quantitative data collection			
phase 2			
Quantitative analysis			
Paper write-up & dissemination			



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Appendix F: Measures PHQ-9

Nine symptom checklist

Patient Name:		Date:	
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Dear Patient,

In an effort to provide the highest standard of care and meet the requirements of your insurance company, we ask that you fill out the form below. This form is used as both a screening tool and a diagnostic tool for depression. Your provider will discuss the form with you during your visit. Thank you for your cooperation and the opportunity to care for you.

1. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Severa days every	al	More half th		Nearly	,
	0	1		days 2		day 3	
a. Little interest or pleasure in doing things		Î	Î		Ì		Î
b. Feeling down, depressed, or hopeless.		Î	Ì		Ì		Î
c. Trouble falling/staying asleep, sleeping to ${\stackrel{\uparrow}{}}$	o much	1.	Î	Î		Î	
d. Feeling tired or having little energy.		Î	Î		Î		Î
e. Poor appetite or overeating.		Ŷ	Ŷ		Ŷ		Î
 f. Feeling bad about yourself – or that you a a failure or have let yourself or your family down. 		Î	ļ		Î		Î
g. Trouble concentrating on things, such as reading the newspaper or watching televis	sion.	Î	Ŷ		Î		Î
 h. Moving or speaking so slowly that other p could have noticed. Or the opposite – be fidgety or restless that you have been mo around a lot more than usual. 	ing so	Ĵ	Î		Ĵ		Î
i. Thoughts that you would be better off dea	ad or of	Î	Î		Î		Î



The University of Manchester hurting yourself in some way.

2. If you checked off any problem on this questionnaire so far, 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 difficu	ult Very difficult	Extremely difficult
Ŷ	Î	Î	Î

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost				Almost
Never				Always
1	2	3	4	5

_____1. I'm disapproving and judgmental about my own flaws and inadequacies.

_____ 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____ 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.

_____ 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.

_____ 5. I try to be loving towards myself when I'm feeling emotional pain.

_____ 6. When I fail at something important to me I become consumed by feelings of inadequacy.

_____7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.

_____8. When times are really difficult, I tend to be tough on myself.

9. When something upsets me I try to keep my emotions in balance.

_____ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____ 11. I'm intolerant and impatient towards those aspects of my personality I don't like.

_____ 12. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____ 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____ 14. When something painful happens I try to take a balanced view of the situation.

_____15. I try to see my failings as part of the human condition.

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_____ 16. When I see aspects of myself that I don't like, I get down on myself.

_____ 17. When I fail at something important to me I try to keep things in perspective.

_____ 18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.

_____ 19. I'm kind to myself when I'm experiencing suffering.

_____ 20. When something upsets me I get carried away with my feelings.

_____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.

_____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.

_____ 23. I'm tolerant of my own flaws and inadequacies.

_____ 24. When something painful happens I tend to blow the incident out of proportion.

_____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.

_____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Alexian Brothers Urge to Self-Injure Scale (ABUSI)

The questions below apply to the **last week**. Place **an "X" in the box** next to the most appropriate statement



1. How often have you thought about injuring yourself or about how you want to injure yourself?

Never, 0 times in the last week
Rarely, 1-2 times in the last week
Occasionally, 3-4 times in the last week
Sometimes, 5-10 times in the last week, or 1-2 times a day
Often, 11-20 times in the last week, or 3-6 times a day
Most of the time, 20-40 times in the last week, or 3-6 times a week

Nearly all of the time, more than 40 times in the last week, or more than 6 times a day

2. At time most severe point, how strong was your urge to self-injure in the last week?

None, at all
Slight, that is, a very mild urge
Mild urge
Moderate urge
Strong urge, but easily controlled
Strong urge, but difficult to control
Strong urge and would have self-injured if able to
Strong urge and would have sen-injured if able to

3. How much have you spent thinking about injuring or about how you want to injure yourself?

None	Less than 20 mins	21m-45m	46m-90m	90m to 3hrs	3-6hrs	>than 6 hrs



At all

4. How difficult was it to resist injuring yourself in the last week?

difficult

Not difficult	Very mildly	Mildly	Moderately	Very	Extremely	Was

difficult difficult

difficult difficult

not able to resist

5. Keeping in mind your responses to the previous questions, please rate your overall average urge or desire to injure yourself in the last week.

Never thought about it and never had the urge to self-injure
Rarely thought about it and rarely had to urge to self-injure
Occasionally thought about it and occasionally had the urge to self-injure
Sometimes thought about it and sometimes had the urge to self-injure
Often thought about it and often had the urge to self-injure
Thought about self-injure most of the time and had the urge to do it most of the
time

Thought about self-injure **nearly all** the time and had the urge to do it **nearly all** the time

Personality Structure Questionnaire

1	2	3	4	5	
Very	True	May	True	Very	
True		or		True	
		may			
		not			



	be true	
My sense of myself is always the same		How I act or feel is constantly changing
The various people in my life see me in much the same way		The various people in my life have different views of me as if I were not the same person
I have a stable and unchanging sense of myself		I am so different at different times that I wonder who I really am
I have no sense of opposed sides to my nature		I feel I am split between two (or more) ways of being, sharply differentiated from each other
My mood and sense of self seldom change suddenly		My mood can change abruptly in ways which make me feel unreal or out of control
My mood changes are always understandable		I am often confused by my mood changes which seem either unprovoked or quite out of scale with what provoked them
l never lose control		I get into states in which I lose control and do harm to myself and/or others
I never regret what I have said or done		I get into states in which I do and say things which I later deeply regret



Thoughts of Nonsuicidal Self-Injury

People sometimes have thoughts about hurting themselves without wanting to die. Other times they actually do things to hurt themselves. Right now I'm going to ask you some questions about what some people think, and then I'll ask you about what some people do in a bit.

71. Have you ever had thoughts of purposely hurting yourself without wanting to die? (for example, cutting or burning)

0 [] no

1 [] yes

72. How old were you the first time you thought of purposely hurting yourself without wanting to die?

73. How old were you the last time?

74. How many days in your life have you had thoughts of purposely hurting yourself without wanting to die? (Please give your best estimate)

75. How many days in the past year? ______

76. How many days in the past month? ______

77. How many days in the past week? ______

78. On the scale of 0 to 4, at the worst point, how intense were your thoughts of purposely hurting yourself without wanting to die?



79. On the scale of 0 to 4, on average, how intense were these thoughts?

80. What method did you think of using?

1 [] cut or carved skin

2 [] burned your skin (i.e., with a cigarette, match, or other hot object)

3 [] inserted sharp objects into your

4 [] picked areas of your body to the point of drawing blood

10 [] hit yourself on purpose

11 [] gave yourself a tattoo

12 [] scraped your skin to the point skin or nails of drawing blood

13 [] other (specify):_____

81. When you had these thoughts, how long did they usually last?

0 [] 0 seconds

1 [] 1–60 seconds

2 [] 2–15 minutes

3 [] 16–60 minutes

4 [] less than one day

5 [] 1–2 days

6 [] more than 2 days

7 [] wide range (spans > 2 responses)

82. On the scale of 0 to 4, what do you think the likelihood is that you will think about purposely hurting yourself without wanting to die in the future?

Nonsuicidal Self-Injury



83. Have you ever actually purposely hurt yourself without wanting to die? _____

0 [] no

1 [] yes

84. How old were you the first time you purposely hurt yourself without wanting to die? _____

85. How old were you the last time?

86. Now I'm going to go through a list of things that people sometimes purposely do to harm themselves without wanting to die. Please let me know which of these you've done:

1 [] cut or carved skin

2 [] burned your skin (i.e., with a cigarette, match or other hot object)

3 [] inserted sharp objects into your skin or nails

4 [] picked areas of your body to the point of drawing blood

5 [] hit yourself on purpose

6 [] gave yourself a tattoo

7 [] scraped your skin to the point of drawing blood

8 [] other (specify):_____

87. How many times in your life have you purposely hurt yourself without wanting to die? (Please give your best estimate)

88. How many times in the past year? _____

89. How many times in the past month? _____

90. How many times in the past week? _____

91. On average, how long have you thought of purposely hurting yourself without wanting to die before actually doing it?



The University of Manchester 0 [] 0 seconds

- 1 [] 1-60 seconds
- 2 [] 2–15 minutes
- 3 [] 16–60 minutes
- 4 [] less than one day
- 5 [] 1–2 days
- 6 [] more than 2 days
- 7 [] wide range (spans > 2 responses)

92. Have you ever received medical treatment for harm caused by purposely hurting yourself without wanting to die?

0 [] no

1 [] yes

93. On a scale of 0 to 4, what do you think the likelihood is that you will purposely hurt yourself without wanting to die in the future?

0–4 SCALE

0	1	2	3	4
Not at all	A little bit	Somewhat	Very Much	Extremely



Demographic Questionnaire

Cognitive Analytic Therapy-informed Containment for self-Harm (CATCH): A Feasibility Trial

Demographic Questionnaire

Please tick each box as appropriate:

Participant ID: _____

ABOUT YOU

- 1. What is your gender?
 - Male
 - Female
 - Other

2. What is your age? (please write below)

3. What is your ethnic group?

- White
- Mixed
- Asian
- Black
- Chinese
- Other (Please Specify) ______

4. What is your current employment status?

- Paid full-time employment
- Paid part-time employment
- Self-employed
- Out of work and looking for work
- Out of work but not currently looking for work
- Voluntary work
- A student
- Military
- Retired
- Unable to work



ABOUT YOUR HEALTH

- 5. Do you have a psychiatric/ mental health diagnosis?
 - Yes
 - No
- 6. Do you currently access mental health services?
 - Yes
 - No
- 7. Are you currently on any medication related to a mental health difficulty?
 - Yes
 Please state _____
 - No

Thank-you for completing this questionnaire



Adverse Experiences of Psychotherapy Questionnaire

Learning from you: Understanding your experience of CAT

Thank you for taking part in the study. We hope the results of our research will help us better understand the helpful and less helpful aspects of CAT. We would like to know a little bit more about your experience of the therapy, and in particular whether taking part has caused you any distress. This will help us improve the way we do things in the future. Please note you do <u>not</u> have to tell us this. You do not have to complete this form if you do not want to.

If you could take the time to complete this questionnaire we'd be very grateful:

Please indicate the extent to which you		VERY	Α	Q UITE A	VERY
agree with following statements:	AT ALL	LITTLE	LITTLE	Lot	Мисн
Taking part hasn't helped me with my					
problems.					
Taking part made my problems worse.					
Taking part made me feel more anxious.					
Taking part took up too much time.					
Taking part led to my mood becoming very low.					
Taking part made me feel more angry and irritable.					
I didn't feel ready to talk about my problems.					
Taking part made me think too much about					
bad things that have happened in the past.					
Taking part meant I stopped looking after					
myself properly.					
Taking part made me feel more suspicious.					
Taking part required too much energy or					
motivation.					
Taking part increased my thoughts of killing myself.					
I didn't feel listened to or believed by care staff.					
Taking part made my voices or visions worse.					
Taking part was making me fall out with my					
family or friends.					
Taking part was having a bad effect on my					
self-esteem.					
Taking part was making me want to harm					

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myself.	
I didn't like or feel I could trust my care	
team.	
I felt embarrassed talking about my problems	
with people I had not met before.	
Taking part made me have thoughts of	
harming other people.	
Taking part was making me feel hopeless	
about the future.	
Taking part meant I had to increase my	
medication in order to cope.	
Taking part involved too much hard work.	
Taking part made me worry that people	
would think badly of me because of my	
diagnosis.	
Taking part made me fall out with my doctor	
or care team.	
Taking part made me worry about losing	
control of my mind.	
My problems have improved to the point	
whereby I no longer feel I need help.	

If you would like to describe your experience of therapy in your own words, please use the following space:



Appendix G: Therapy manual

Therapy Manual Study Title: Cognitive Analytic Therapy-informed Containment for self-Harm (CATCH): A Feasibility Trial

TWO-SESSION COGNITIVE ANALYTIC THERAPY REFORMAULTION FOR SELF-HARM MANUAL

Peter Taylor Clive Turpin

This intervention is largely based upon: Sheard, T., Evans, J., Cash, D., Hicks, J., King, A., Morgan, N., Nereli, B., Porter, I., Rees, H., Sandford, J., Slinn, R., Sunder, K. and Ryle, A. (2000), A CAT-derived one to three session intervention for repeated deliberate self-harm: A description of the model and initial experience of trainee psychiatrists in using it. British Journal of Medical Psychology, 73: 179-196. doi:<u>10.1348/000711200160417</u>



The approach has been adapted to 1) shift the focus from overdoses to self-harm more broadly, 2) move away from an hospital based contest for the intervention, 3) reduce the session number to two sessions.



OVERVIEW

This manual gives a brief overview of a two-session Analytic Therapy (CAT) intervention aimed at those with experiences of self-harm. This manual assumes an existing knowledge of CAT and does not provide a details definition of CAT concepts and ideas. The intervention is based around two face-to-face sessions. Sessions should ideally be a week apart or less. The intervention centres on developing a shared, collaborative understanding of a client's self-harming behaviour, drawing upon the Cognitive Analytic Therapy (CAT) framework for making sense of these experiences. Broadly the goals of the intervention are to:

- Develop a shared understanding of the client's experience of self-harm, capturing the antecedents, consequences and patterns related to this behaviour
- Using CAT constructs of 'Reciprocal Roles' and 'Procedures' (see below) to help develop clients' awareness, and understanding of these experiences. These concepts do not necessarily need to be named in the therapy but should be used were appropriate by the therapist to help explore, develop and elaborate on the client's understanding of their experiences.
- Provide an initial exploration of how a client might start to pause or break free of some of the patterns of processes that are identified that they feel trapped in. This may include developing basic 'Exits' with the client, based on the reformulation that is developed.

Introducing the Intervention

As this is a short intervention it is important to be mindful of clients' expectations about the intervention and transparent about the aims and potential benefits. It is important to be clear about the length of the sessions and the intervention from the start, and may be helpful to remind clients of this as work progresses (e.g. at the end of the first session note that you have a single session left).

Clients will be made aware at the baseline assessment that the intervention is part of a research trial. However, related to this it is important to be clear, if asked, that you do not know if the intervention will be helpful for them. It can be stated that you are hoping to find out whether this sort of brief intervention can be helpful for people who self-harm, and that you know anecdotally that many people appear to value and benefit from this sort of intervention, but that you cannot say if it will be helpful for them.

When introducing the therapy it could be suggested that the goal of the intervention is on better understanding self-harm, rather than necessarily coming with solutions or new ways to cope. The intervention could be introduced as an opportunity to reflect on these experiences and has kept them going, or as a chance to try and think about one's experiences of self-harm from a different perspective.

Therapist Style

In line with a standard CAT approach the therapist should aspire to adopt the following therapeutic manner:



- Working collaboratively, getting alongside the client to try and understand their world and their experiences.
- Being curious and open minded.
- Showing appropriate empathy and concern (avoiding alarmist or judging comments).
- Within CAT therapists can be proactive, making suggestions or suggesting hypotheses, sharing their thoughts. However, this should be carefully paced in light of the client, to avoid running ahead of them or leaving them feeling overwhelmed or pressured to respond a certain way.

Session one

The initial session should last around 90 minutes. The session should be started by:

- Providing a brief introduction to what the therapy involves (see above), including the likely length and focus of the conversation, checking how this sounds to the client and how this fits with their expectations. (5 minutes)
- Reiterate requirements around risk and confidentiality (this will have been covered in their previous meeting with the researcher) including briefly referring back to the plan discussed in their first meeting about what might be done if there is a concern about risk of harm to themselves or others. (2 minutes)
- Asking the client to complete the Self-Harm Self-Help file (Appendix I). (5-10 minutes)

Self-Harm Self-Help file

The Self-Harm Self-Help file (see Appendix I) should be completed in an interactive manner, asking the client the questions verbally, with the file visible to both therapist and client. The goal of this activity is not to collect data or get to a "correct" answer, but to open a discussion about the client's experiences of self-harm. It should be explained to the client that the file is not an exhaustive list and won't fit for everyone.

The therapist should explore with the client if any of the feelings or patterns covered in the File seem particularly relevant to their self-harm. Where this is the case, this can provide a potential starting point in mapping out the client's experiences of self-harm. For example the therapist can start this process by writing out the states/feelings on a separate sheet of paper.

Where feelings or patterns list in the File have some relevance, but do not seem to capture the client's experience fully, this is an opportunity to try to further elaborate on the client's own experience (e.g., "So the feeling is not quite like X, how would you say it is different? Is it more like ..."). This would be another starting point for formulation.

If clients struggle to engage with the File or identify any feelings or patterns that fit for them, it is important to reflect that this is fine, the ideas in the File will not fit for many people. This is then a starting to point to suggest working together to try and better understand the client's own experiences around self-harm.

Mapping



The remainder of the session should then focus on the process of formulating or 'mapping' the client's experiences around self-harm. This should involve an active, collaborative discussion between the therapist and client, with the therapist drawing out a visual representation of the client's experiences as the discussion developed (e.g. Figure 1).

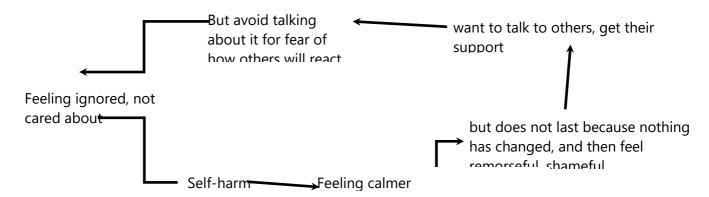


Figure 1. A simple map outlining hypothetical pattern of events around self-harm. See other examples in Sheard et al (2000).

A typical starting point would be begin with self-harm itself on the diagram, and then to either track backwards or forwards in time, asking about the events that precede or follow self-harm. Clients can be given the choice about the direction they would like to focus on. An exception might be where a client already strongly identifies with a file in the Self-Help File and this may become the natural starting point for mapping. In tracking a client's experiences it is likely that gaps will occur (e.g. going straight from an

event or feeling into self-harm). The therapist should work with the client to identify and try and fill these gaps. Symbols such as question marks can be used on the diagram to indicate areas or places where the client is not sure what goes there. Where clients describe a sudden shift in feeling, leading up to self-harm, it may help to draw out this shift (see Figure 2) as a means of exploring intervening states. A client might be asked at which point along this arrow would they be likely to self-harm, and what the feelings might be called that precede or follow this point.

? Feeling Calm Feeling worthless

Figure 2. Mapping sudden shifts in state



Alexithymia is commonly associated with self-harm, and as such it is possible that clients may struggle with the labelling and naming of emotional states or feelings. Suggestions can be provided by the therapist in a curious and open manner ("I wonder if the feeling is a bit like ... or more like ..."). Where possible it is good to use the client's own language and wording in drawing out the visual map.

Where clients do not explicitly refer to others in their lives it might be helpful to explicitly inquire about what others are doing or not doing at a particular point.

Where clients struggle to identify states preceding or following their self-harm, another approach may be to ask about what the place or state or feeling they are trying to get away from when the self-harm is, and likewise, what the state they are trying to get to is like.

The process of mapping should focus on typical experiences relating to self-harm. For some clients it may be helpful to begin by focussing on a specific incident of self-harm, but where this is done the therapist would then check whether this is pattern that typically occurs for other instances of self-harm. It is possible that for some clients there is no single pattern that fits every case and the focus may be on mapping out one or two commonly occurring patterns.

Appendix II provides a series of example diagrams that capture particular, general patterns (adapted from Sheard et al., 2000). These should typically not be used in the first instance, but may be helpful in some situations. For example, these diagrams can be considered where a client describes experiences that appear to match one of these diagrams. This may be helpful where a client is struggling to elaborate on their experiences. However, caution should be taken to try to avoid the situation where a client agrees a diagram fits their experience out of acquiescence. This might be avoided by being clear it is unlikely the standard diagram will fully match the client's experiences, and using it as an opportunity to then explore what might be different for the client.

The pacing of the mapping process should be largely led by the client. Based on CAT theory different clients will have different Zones of Proximal Development (ZPD; the area between what they might achieve alone, and what they are able to do, accommodate or tolerate with the therapist's help). As such some clients will be less able to develop and elaborate an understanding of their experiences than others. The goal of the therapist is to the get the client to the place that their ZPD allows, rather than to bring all clients to the same point (e.g. a fully completed and worked out map).

Some different ways clients might respond to the intervention are outlined below:

- Clients wishes to move too fast, sharing their experiences and insights but with little elaboration or connection with these experiences. For these individuals the job of the therapist is to slow the pace of the work and focus on deepening the shared understanding of the feelings and experiences linked to their self-harm. The above stance may also apply to clients who appear very avoidant of emotional content.
- Client is demanding rescue and expresses overwhelming, difficult feelings that flood the session. Therapist would try to adopt a more cognitive stance, identifying and labelling relevant emotions/feelings without exploring these and focus on how this link together within the map/diagram.



 Client wants to push on to solutions to their problems before an understanding of their self-harm has been developed. Therapist may respond by slowing the pace, reiterating the focus on understanding their self-harm, and the value of this. In some cases a client's need for quick solutions may even form part of the map (e.g. look for quick solutions but ultimately feel disappointed when these do not emerge or do not help) but this would need to be done carefully to avoid client feeling judged.

Identification of Reciprocal Role Procedures

During the process of mapping the therapist can begin to work with the client to identify particular Reciprocal Roles (RRs) that are linked to a client's experiences of self-harm. RRs are discussed in detail elsewhere. Briefly, the present internalised patterns of relating, that emerge through earlier experiences, and guide the way the individuals relate to themselves and others. RRs are bipolar (e.g. see Figure 3) and may capture three forms of relating: self-to-self; self-to-other; other-to-self. Thus an individual may feel rejected or shamed in response to a rejecting other (other-self), but they may also become rejecting and shaming to themselves, for example as part of negative inner dialogue (self-self).

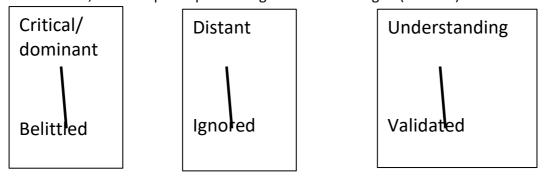


Figure 3. Example Reciprocal Roles

One method to help identify RRs is to focus on the following questions:

- How did you feel towards yourself at this time?
- How did you feel towards others at this time?
- How did others make you feel at this time?

It may also help to begin by identifying how the client felt in a given situation, before then moving on to ask about what the other person was doing or not doing (or what they were doing to themselves) that led to them feeling this way. By doing this the two poles of the RRs can be elucidated. When identifying RRs it is important that the pole labels are meaningful to clients and ideally deepen their awareness of the feelings present during that time. It is tempting for therapists to assume the opposite pole (rejected to rejecting, abused to abusive) but these poles do not necessarily co-occur and client's experiences may differ



(rejected to ignoring/uninterested). Hence RRs should match client's experiences as closely as possible.

Problem Procedures

Within CAT a number of commonly occurring, problematic procedures have been noted. Whilst these procedures do not describe every pattern a client might struggle with, they apply to some clients. Where present it may be helpful for the therapist to comment on these emerging patterns.

- Traps: Where negative expectations lead to behaviour which ends up confirming these expectations (I know she won't care so I avoid her and end up feeling like she does not care)
- Snags: Where a particular aim is abandoned because of expected negative consequences (I do not ask for help because I know they will react negatively)
- Dilemmas: Where a client feelings caught between two black or white or alternatives (Either I am a push-over and do what others tell me, or I kick back and get angry)

Identifying Patterns in the Room

Whilst CAT often focuses on identifying problematic patterns and RRs within the therapy relationship, this may not be possible within the short duration of this intervention, and is not expected. Nonetheless, there may be times where it is helpful to make links between the client's experiences and their relationship with yourself.

- Where patterns are apparent that seem likely to affect a client's likelihood of attending the next session (e.g. a pattern of feelings other cannot help and cutting off contact from them).
- Where client's way of relating is creating a barrier to progressing with the intervention (e.g. unwilling to engage in the intervention for fear that it might not help) it may help to reflect on how this process seems very difficult for them and ask about whether this feels like a barrier in other contexts.
- Where clients' reflects positively on the experience of the intervention it may helpful to explore of their interaction with yourself differs to others they have captured in the mapping.

Ending Session One

Ending are an important focus of CAT. Whilst this intervention is brief, it may be helpful to reiterate towards the end of session one that there is a single session left after this one, and to inquire about the client's feelings about this. It might be helpful to discuss what the client would like to get from this remaining session, or to consider how it might be best put to use. It can also be appropriate to acknowledge that the brevity of this intervention may be challenging or difficult (see below "Negative reactions to short intervention"). For some clients, where endings or related experiences (e.g. perceived rejection) have emerged as relevant feelings, it may be useful to link the ending of the session to this observation. In these instances it may help to explore how the client typically responds to endings and also how this (the next intervention session) could be an opportunity to do something



differently. This may include thinking aloud about why it might be difficult to attend the next session.

Clients should be encouraged to engage in some work between the two sessions. The nature of this is likely to depend on what was done in session one. For clients where a map has started to be developed they could be asked to reflect upon the map being drawn out and consider what needs adding or changing. For clients with a more complete map, they may be asked to see if they can spot any of the patterns described in the map during the following week.

The final 20 minutes should be kept aside to help ease the transition from the session back to everyday life. This is particularly important for clients who experience distress during the session, allowing space for these clients to return to a less distressed state before the session is closed. This might be achieved through validation and normalisation that this psychological work can be difficult, and non-problem talk on non-arousing subjects.

Session Two

Session two should be 60 to 90 minutes long. Once again the last 20 minutes can be set aside as time to wind-down and help the transition from the intervention to everyday life. Session two should begin with a review and recap of the ground covered in session one, using the diagram(s) or map(s) developed in the first session as a prompt. Also of any homework tasks set in the last session are reviewed. Where homework is not undertaken the reasons why, including whether this work was difficult or challenging, should be discussed. The diagram or map may help facilitate and exploration of the reasons behind not completing tasks. Using the map in this way may help these discussions feel nonjudgemental or less emotionally charged.

The focus of the second session will then depend on the progress made in session one, and may involve further development of the mapping process started in session one (see above) or a move in focus onto exits (see below).

Exits

Once a map has been collaboratively developed the next task is to consider how the client might be able to halt or break free of some of the patterns they are caught in. It is important not to move on to exits too soon, before a shared and valid understanding of a client's self-harm has been developed (though there may be an implicit or explicit pressure from some clients to do this).

Given the short duration of this intervention, exits are likely to be simple. Within the context of this intervention exits can also be presented as a starting point for longer-term change, for example, engaging with further psychotherapy as a means of changing the way they respond in a particular situation or providing them with additional coping resources. Helping develop a client's motivation and hope in relation to further therapy for a valid outcome to the intervention.

In developing exits a starting point would be to go through the map and ascertain where the client feels they are most likely to be able to notice what is going on, and stop, or pause, the pattern. This includes recognising there will be places where difficult states or feelings are too strong for the client to step out of the pattern, but there may be points where this is more possible. Symbols such as a pause sign can be added to the diagram to help indicate these points in the cycle. The therapist can then explore with the client what they might be able to do differently at this point. Potential ideas for exits are listed below:

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- Options for experimenting with different ways of seeking help or support that might break old patterns (e.g. patterns of avoidance).
- Client works on better identifying and reflecting on the pattern they are caught in, possibly cycling forward to where they know they are likely to end up, and using this knowledge as motivation for trying to halt the process.
- Use of flash cards or other visual aids or reminders to help halt or pause the process
- Exits drawing on existing support network and coping skills.

Exits can be added visually to the diagram. The map should be framed as a tool the client can take home after the therapy to help them in the future.

Ending

Time should be given to discussing the ending of the intervention, including any positive or negative feelings this generates. For clients with high or idealised expectations of change disappointment is likely, and time should be given to explore these feelings. Where appropriate links might be made back to the map that has been developed (e.g., "I wonder if you're feeling a little let down even? If we look at the map I notice there has been a common pattern of felling this way"). Clients could be encouraged to think about what the usually do with these feelings and what they could possibly do differently.

Negative Reactions to Short Intervention

From qualitative research we have seen that some individuals view their difficulties as very entrenched and can be sceptical of the idea that a short therapy will be of any use. If such concerns arise it can be noted to emphasise that such concerns are understandable, and whilst this two session intervention may not be enough to resolve or work through all of the difficult experiences they might have faced, it may nonetheless be a useful stepping stone, perhaps starting some helpful processes or changes in how they think about their experiences, that could lead to bigger changes in the future.

For some clients the brevity of the therapy may activate or bring to the surface negative feelings about treatment (e.g. that this intervention can't help or that nothing will help) or the possibility of change more generally (e.g. that nothing will help). Where such feelings are apparent it may be possible to comment on these and being them into the therapy room. Such feelings may be a useful indicator in thinking about patterns with others that are linked to their self-harm (e.g. they feel let down by others who cannot help and this feeling leads into self-harm). In these cases links could be made between the feeling in the therapy room and these wider patterns. However, care should be taken that this does not feel blaming or judging, and is done in a curious and open-minded way.

Negative feelings may also be apparent towards the end of a session, and it may be helpful to explore where these typical lead and how this situation could be different (e.g. feeling it won't help so maybe they will miss the next session altogether, but what might it be like if they attend the next session despite this feeling).



The University of Manchester Appendix I: Self-harm self-help file

The Self Harm Self Help File

This pamphlet is yours to take home with you. It is intended as a first step in helping you understand patterns of thinking, feeling and behaviour which have led to you harming yourself.

We try to sort out our problems in life and relationships but sometimes we end up even more stressed or things keep going wrong. Most of us have particular ways of trying to cope with problems which we have used all of our lives. These ways of coping are usually habits we learnt before we can remember; they are so familiar that we don't really know what they are. This is fine if they work well but can lead to a lot of stress and suffering if they don't.

Through using this pamphlet and talking with the doctor we hope to help you to stand back and take a look at yourself in order to try and see:

- if your ways of coping are not working very well or even adding to your stress
- and if so how you might begin to change them for the better



Part One: Confusion caused by changes in how we feel towards ourselves and other people

Some of us change a lot in the way we feel towards ourselves and other people from day to day, or moment to moment. When in these different states of mind we may have very strong feelings or feel completely unemotional.

Here are some examples of different states of mind which can happen sometimes or often in our lives, can you mark in the boxes which of these you experience and how strongly?

++ means you feel it definitely and strongly applies to you

- + means it applies to you but not strongly
- 0 means it does not apply to you

		++ + 0
1.	Feeling or expecting to be let down, rejected, hurt	
2.	Feeling or hoping to feel very safe, cared for, and perfectly close	
3.	Feeling angry with myself and wanting to harm myself	
4.	Feeling emotionally very calm or cut off and wanting to harm myself	
5.	Feeling or expecting to feel punished, victimised	
6.	Feeling guilty, bad, unworthy of love and care	
7.	Feeling I've always got to do things for others, that it's too much, tired out	
8.	Feeling very angry with others, and maybe wanting them to suffer	
9.	Feeling no one cares, feeling rejected, abandoned, very alone	
10	Wanting to give perfect love and care to another person	
11	Being very busy, on a high, cut off from emotions	
12	Feeling let down, cheated, and that other people owe me something	
13	Feeling numb, emotionally blanked off or cut off from myself and others	



These changes in how we feel towards ourselves and other people can confuse us and affect our sense of identity, which of the following descriptions best suits how you feel about yourself?

- 1. I have a stable and unchanging sense of myself
- 2. I am changeable but this does not much affect my sense of who I am
- 3. I am so changeable that I wonder who I really am



Part Two: Vicious circles

Sometimes we seem to go round in circles, we try and help ourselves but end up in just the same position or in an even worse one. It is as if we are trapped in a vicious circle. We can call this pattern a trap; here are some examples.

Can you mark in the boxes which, if any apply to you in your daily life?

Avoidance trap

Feeling unable to cope with certain situations, feelings, people and responsibilities we try to avoid them e.g. by not thinking about them, pretending they are not happening, or distracting ourselves through activity or drink etc.. Avoiding them makes us feel *temporarily better* but the problem or feelings are still there, building up and getting worse. With the problems or feelings getting worse we feel even less able to cope with them directly and so carry on trying to avoid them.

Applies to me:

Strongly Some of the time Rarely if ever



I must please others trap

Feeling unsure of ourselves we want to be liked so we try to be nice, avoid disagreements or risking upsetting people. We hope and *expect* them to be nice and agreeable in return. We therefore seem to be a bit of a pushover and we end up getting used and taken advantage of. Other people seem to demand love and care from us but we never seem to get it back ourselves. As a result we feel let down and then **either:**

become openly angry, demanding and resentful

or:

feel hopeless, give up, withdraw or run away and let people down (passive aggression)

Either way we end up upsetting people and they get angry with us and/or reject us. This makes us feel guilty and worthless and so we feel unsure of ourselves again.

Applies to me:

Strongly Some of the time Rarely if ever





"I'll only do things badly" trap

Feeling depressed and worthless things often seem hopeless. We expect to handle things badly and because of this we are not very effective in doing things, in social situations or in our relationships. We tend to either feel hopeless and give up too easily or feel very anxious and very aware of any shortcomings in what we do. Either way we feel a failure and this confirms our feeling of worthlessness and makes us feel more depressed and hopeless.

Applies to me:

Strongly Some of the time Rarely if ever



The Self Harm Self Help File is in the process of development by Drs. Tim Sheard and Jonathan Evans, Division of Psychiatry, 41 St. Michaels Hill, Bristol BS2 8DZ. You are free to make copies and use of it but acknowledging us as originators in any publications involving its use or distribution. We would particularly value any feedback on its use and modifications which you found of benefit



The University of Manchester Appendix II: Frequent patterns in self-harm diagrams



Frequent Patterns in Self Harm File

These diagrams outline patterns of caring for ourselves and relating to others which seem often to be part of, and which maybe underly our harming ourselves.

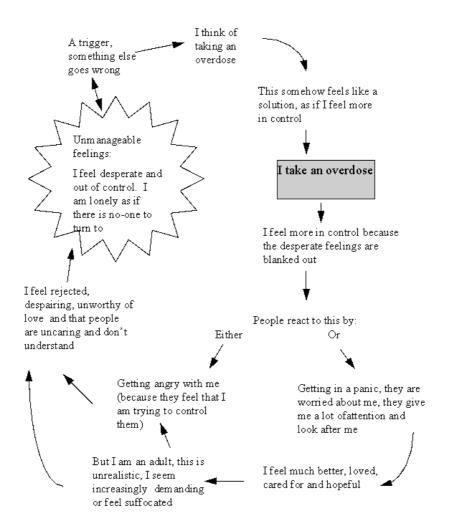
It starts with a general diagram looking at the consequences of taking an overdose, then there are seven particular diagrams of different patterns of trying to look after ourselves which go wrong and lead us back to square one.

At the end is a half blank diagram which you can fill in to suit you personally based on the understandings you have gained looking at the diagram set.

These diagrams are in the process of development by Drs. Tim Sheard and Jonathan Evans, Division of Psychiatry, 41 St. Michaels Hill, Bristol BS2 & DZ. You are free to make copies and use the them but acknowledging us as originators in any publications involving their use or distribution. We would particularly value any feedback on their use and modifications which you found of benefit

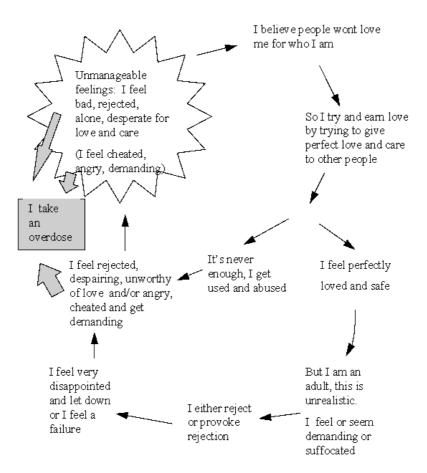


Possible effects of taking an overdose



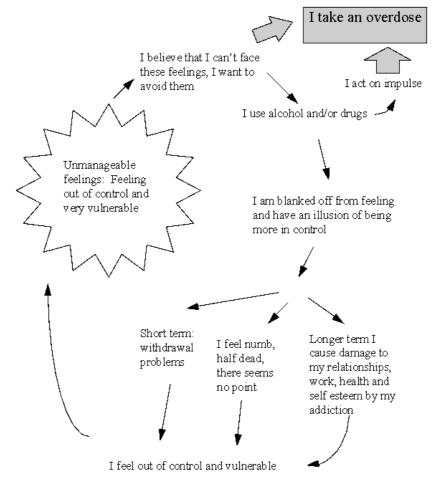


1. I am desperate for perfect love and care: but I feel unworthy of it



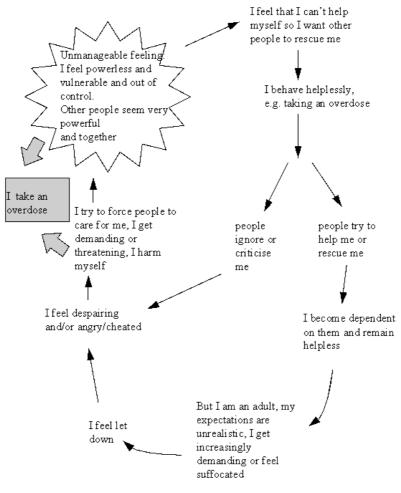


2. Using drugs and alcohol to cope



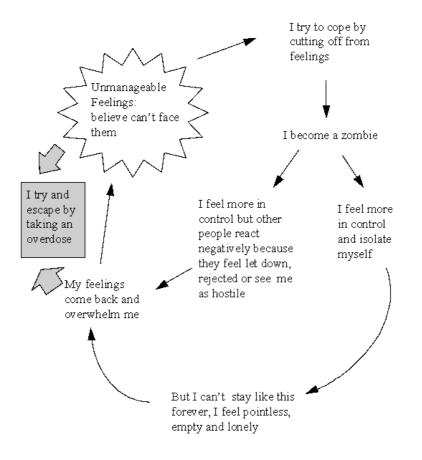


3. I feel powerless and want to be rescued



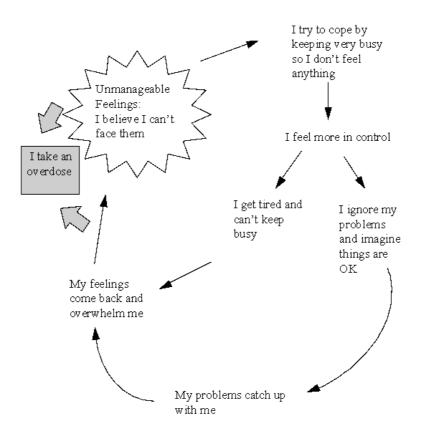


4. Trying to cope by cutting off from feelings



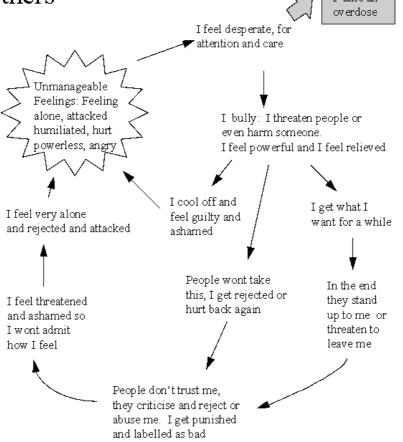


5. Trying to cope by keeping very busy all the time



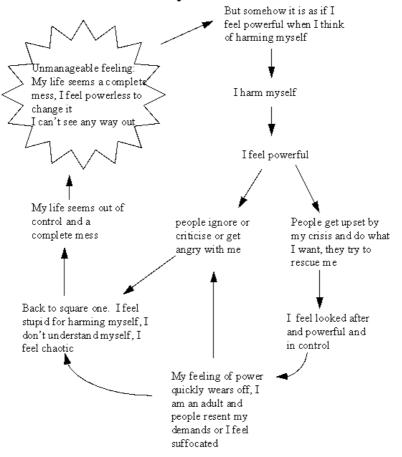


6. Trying to cope by being threatening, abusive or violent to others



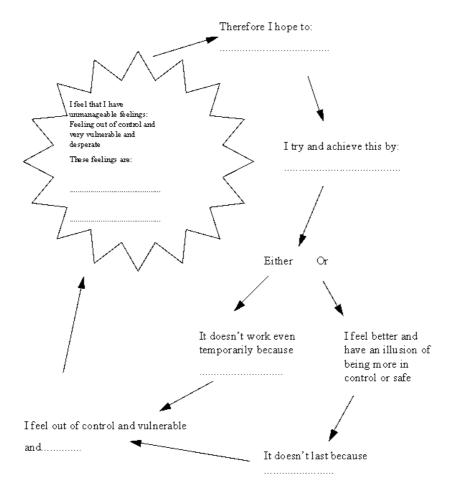


7. As if I only feel powerful when I harm myself





Personal diagram



Appendix H: Individual level participant characteristics

Parti cipa nt	A g e	Gen der	Ethn icity	Employ ment status	Diag nosis	Clinical service	Me dic ati on	Previ ous thera py	Typ e of the rap y	Pre vio us suic ide att	Sui cid e att em pt	Location of sessions	Com plet ed both sessi on
									,	em pt	in last yea r		
Int 1	34	Femal e	White	Full time	EDD	Psychotherap y service	Yes	Yes	CBT	No	No	Home	Y
Int 2	19	Femal e	White	Unable to work	EUPD	СМНТ	Yes	Yes	CBT	Yes	Yes	Home	Ν
Int 3	18	Male	White	Student	Anx; Dep	University Health service	No	No	-	No	No	University	Y
Int 4	44	Femal e	White	Unable to work	None	СМНТ	Yes	No	-	Yes	No	Communit y service	Y
Int 5	58	Femal e	White	Unable to work	EUPD; PTSD	None	Yes	No	-	No	No	Communit y service	Y
Int 6	24	Femal e	White	Full time	Anx; Dep	None	Yes	Yes	CBT	No	No	University	Y

Int 7	24	Femal e	White	Student	Dep; ED	Eating Disorder Service	Yes	Yes	CBT	Yes	Yes	University	Υ
TAU 1	45	Femal e	White	Out of work- not looking	EUPD; Anx	СМНТ	Yes	Yes	CBT	Yes	No	Home	N/A
TAU 2	37	Other	Mixed	Full time	Anx; Dep	Primary Care	No	Yes	СВТ	Yes	Yes	University	N/A
TAU 3	51	Male	White	Out of work- not looking	Anx; Dep	СМНТ	Yes	Yes	CFT	Yes	No	Home	N/A
TAU 4	24	Male	White	Unable to work	Anx; Dep	CMHT	Yes	Yes	СВТ	Yes	No	Home	N/A
TAU 5	52	Femal e	White	Voluntary	Anx; Dep	CMHT	Yes	Yes	CBT	No	No	Communit y service	N/A
TAU 6	20	Other	White	Student	EDD; MD	CMHT	Yes	Yes	CBT	Yes	Yes	Home	N/A
TAU 7	19	Femal e	White	Part time	Dep; ED	University health service	No	Yes	CBT	Yes	No	University	N/A

Notes Anxiety (Anx); Depression (Dep); Emotional Dysregulation Disorder (EDD); Emotionally Unstable Personality Disorder (EUPD); Post Traumatic Stress Disorder (PTSD); Eating Disorder service (ED)

Appendix I

Item by item descriptive statistics for the Adverse Experiences of Therapy questionnaire

ltem	Follow up M/SD
1. Taking part hasn't helped me with my problems.	(1.57/0.73)
2. Taking part made my problems worse.	(1/0)
3. Taking part made me feel more anxious.	(1.14/.35)
4. Taking part took up too much time.	(1.28/0.70)
5. Taking part led to my mood becoming very low.	(1/0)
6. Taking part made me feel more angry and irritable.	(1.14/0.86)
7. I didn't feel ready to talk about my problems.	(1.57/0.73)
8. Taking part made me think too much about bad things that have happened in the past.	(1.57/0.73)
9. Taking part meant I stopped looking after myself properly.	(1/0)
10. Taking part made me feel more suspicious.	(1/0)
11. Taking part required too much energy or motivation.	(1/0)
12. Taking part increased my thoughts of killing myself.	(1.28/0.70)

13. I didn't feel listened to or believed by care staff.	(1/0)
14. Taking part made my voices or visions worse.	(1.14/0.35)
15. Taking part was making me fall out with my family or friends.	(1/0)
16. Taking part was having a bad effect on my self-esteem.	(1/0)
17. Taking part was making me want to harm myself.	(1.57/0.73)
18. I didn't like or feel I could trust my care team.	(1.14/0.35)
19. I felt embarrassed talking about my problems with people I had not met before.	(1.57/0.73)
20. Taking part made me have thoughts of harming other people.	(1/0)
21. Taking part was making me feel hopeless about the future.	(1.28/0.45)
22. Taking part meant I had to increase my medication in order to cope.	(1/0)
23. Taking part involved too much hard work.	(1/0)
24. Taking part made me worry that people would think badly of me because of my diagnosis.	(1.28/0.45)
25. Taking part made me fall out with my doctor or care team.	(1/0)
26. Taking part made me worry about losing control of my mind.	(1/0)

27. My problems have improved to the point whereby I no longer feel I need help.	(1.57/1.04)
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