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Compassion Focused Therapy: Exploring Mechanisms of Change and Investigating the Feasibility of a Transdiagnostic Group for Older Adults

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Submitted in partial fulfilment of the requirements for the degree of

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Institute of Health and Wellbeing

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In loving memory I.M., M.M., & B.M.

Foreword

This foreword aims to give context to the changes to my original project. The project was interrupted in 2020 due to the COVID-19 pandemic. My original project intended to run two or three CFT groups across the data collection period depending on uptake from the first two groups. Following the second group in November 2019 it was decided that another group would run in June 2020. The pandemic led to this third group being cancelled resulting in lower participant recruitment than originally planned. Given data was collected from seven participants and data exploring recruitment and retention of participants was collected prior to the pandemic, this data is used in the present project.

Chapter 1: Systematic Review

A Systematic Review of Mechanisms of Change in Compassion-Focused Therapy Interventions

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Prepared in accordance with the author requirements for *Mindfulness* (Appendix 1.1)

Abstract

Objectives: Compassion focused therapy (CFT) is increasingly popular as an intervention. Despite not yet being recommended as a mental health treatment it does show promise in reducing mental health symptoms and improving wellbeing. It is a transdiagnostic approach, which targets underlying shame and self-criticism. To date, there is no systematic review that investigates the mechanisms of change by which CFT works.

Methods: A systematic search was undertaken of five databases: CINAHL (via EBSCOhost), EMBASE (via Ovid), Medline (Via EBSCOhost), Psychological & Behavioural Sciences Collection (via EBSCOhost) and PsycINFO (via EBSCOhost). The references of included articles were screened. Additionally, the 'British Journal of Clinical Psychology' was handsearched for relevant studies. Included studies were quality appraised using the Crow Critical Appraisal Tool (CCAT) and relevant data was extracted and analysed.

Results: Twenty studies were included in the review. The studies were heterogenous in nature and included both clinical and non-clinical populations. Only three studies specifically measured mechanisms of change. Data from the studies were synthesised focusing on mechanisms of change analysis, the components of CFT used in studies and the outcome measures used in studies to measure mechanisms of change.

Conclusions: The present review found that the heterogenous nature of the studies and the lack of coherence in research design, treatment protocols and potential outcomes mean there is not enough data to draw conclusions about replicable effects. There is an emerging literature base in CFT, and certain mechanism show potential for being key in the process of change.

Keywords: Compassion-focused therapy, CFT, Mechanisms of Change, self-compassion, self-criticism, shame

Introduction

Compassion focused therapy (CFT) is a relatively new mental health intervention. Initially developed by Paul Gilbert, the therapy evolved from Cognitive Behavioural Therapy (CBT) to address transdiagnostic mechanisms that underpin multiple mental health conditions (Gilbert, 2009). Recent evidence suggests CFT is beneficial in the treatment of mental health conditions marked by shame and self-criticism (Craig et al., 2020). However, compassion-based interventions are not yet specifically recommended in the NICE or SIGN guidelines as a treatment for any disorder.

It is important to evaluate the effectiveness of CFT in clinical settings before recommendations can be for use in routine care. Two systematic reviews have evaluated compassion interventions (Leaviss & Uttley, 2015; Craig et al., 2020). CFT was found to be a promising intervention in the treatment of eating disorders, depression, and psychosis and when compared to active treatments of mindfulness and behavioural self-help. The authors report that the findings indicate CFT is a promising intervention in complex clinical populations (Craig et al., 2020). However, the review found that treatment protocols varied and there was a lack of agreement on the specific core components of CFT.

Potential mechanisms of change

Self-compassion has also been shown to be related to mental wellbeing (Neff, 2003). Several mechanisms have been purported to be involved in change process in CFT and mental health including self-compassion (MacBeth & Gumley, 2012); fears of compassion (Kirby et al., 2019); self-criticism and shame (Braehler et al, 2013). CFT itself is based on the 'three systems' model of emotion regulation: the threat/self-protection system, the drive/reward system and the affiliative/soothing system (Gilbert, 2009). The overarching CFT theory of psychopathology suggests these systems become imbalanced and that behavioural control becomes excessively governed by the threat and the drive systems, which translates to an increase in self-criticism and shame and subsequently, suffering. The soothing system

becomes underdeveloped or insufficiently active, so an aim of CFT is to activate this system to facilitate increases in self-compassion and improved mental health (Kirby, 2017). Despite these well-reasoned theoretical arguments, research into CFT so far has struggled to empirically demonstrate the action of the specific mechanisms by which CFT is argued to work.

Mechanisms of Change Measures

A number of measures have been developed to assess potential CFT mechanisms or outcomes. In this study CFT measures are defined as those that evaluate a construct that is hypothesised to be a specific CFT mechanism of change, for example self-compassion, selfcriticism and shame.

Mechanisms of Change Analysis

Kazdin (2007) detailed research study analyses and designs that are appropriate in mechanism of change analysis. In terms of research design, RCTs give the most robust evidence in research design, however in mechanism of change analysis, change in a mechanism should precede change in outcomes such as mental health. Studies often lack this causal sequence which is necessary for mechanism of change analysis. Component analysis gives more evidence relevant to understanding the impact of treatment components on individual mechanisms. Kazdin also suggests that mechanisms of change research is often a process that involves many studies investigating different areas and gradually a picture of the mechanisms emerges from the collection of research. In terms of mediation analysis, structural equation modelling and bootstrap methods as the most suitable options for analysing change processes. Stockton et al (2019) utilised mediation analysis to investigate mediators of change in Acceptance and Commitment Therapy (ACT) and evaluated 12 studies using these techniques. Kazdin notes that often 'percentage of variance' is utilised as a mean of understanding the amount of variance attributed to a mechanism of change, however the

author argues that this is less accurate as there could be others factors contributing to shared variance.

In summary, research has demonstrated that CFT can improve mental health. It can also improve self-compassion and it can reduce shame and self-criticism. However, the assumption that change in outcomes such as shame, self-criticism, and self-compassion lead to change in mental health has not yet been demonstrated in the literature. It is important to understand not only whether treatments "work" but *how* interventions bring about change (Moore et al., 2015). Mechanisms are described as the process responsible for a therapeutic outcome (Kazdin, 2007). This can inform the refinement and optimisation of treatment and helps interventions to be replicated in trials. So, this systematic review aims to describe and critically evaluate the evidence for mechanism of change in compassion-based interventions.

Review Aims

- To identify and describe the mechanisms of change reported in CFT intervention studies.
- 2. To identify the common components of CFT interventions delivered.
- To describe the outcome measures used to evaluate change in people receiving CFT interventions.

Method

This systematic review was conducted in accordance with the PRISMA guidelines (Liberati et al, 2009). A systematic search strategy was carried out on 26th April 2021 using the following databases: CINAHL (via EBSCOhost), EMBASE (via Ovid), Medline (Via EBSCOhost), Psychological & Behavioural Sciences Collection (via EBSCOhost) and PsycINFO (via EBSCOhost). The references of included articles were reviewed. Additionally, the 'British Journal of Clinical Psychology' was hand-searched for relevant studies.

Search terms

Discussion with the university librarian on sensitivity and specificity led to the decision to keep search terms broad as compassion interventions are not mapped to Medical Subject Headings (MeSH). Search terms used:

("compassion" OR "compassionate") AND ("therapy" OR "treatment" OR "intervention" OR "training")

Inclusion Criteria

- 1. A CFT-based intervention (e.g., compassion focused therapy, compassionate mind training) delivered in a group or individual setting.
- 2. A validated CFT outcome measure is used to evaluate a mechanism of change over time (i.e., data acquired more than once, at least at pre- and post-treatment).
- 3. Participants aged 18 years or over.
- 4. Published in English language.

Exclusion Criteria

- Studies where compassion is combined with another type of therapy (e.g., Mindful Self-Compassion, cognitively based compassion training, compassion meditation, Mindfulness based compassionate living, or loving kindness meditation).
- 2. Studies that involved only one component of a compassion-based intervention package (e.g., compassionate imagery or compassionate letter writing).
- 3. Studies that only measured symptom reduction as the outcome measures (e.g., only measures of depression or anxiety symptoms are reported).
- 4. Studies that solely use an online or workbook self-help programme for the delivery method
- 5. Case series and N=1 designs
- 6. Grey literature (including unpublished dissertations, pre-prints)
- 7. Reviews or studies that use only qualitative methods.

Data Extraction and Synthesis

Data were extracted and analysed using a narrative synthesis approach to account for the heterogenous nature of the studies. Popay et al. (2006) described three stages in narrative synthesis:

(1) Preliminary Synthesis

Tabulation was used to extract data from the studies. The data extracted included type of CFT intervention, participant information, methodology, outcome measures, treatment target and mechanism of change target. A CFT mechanism was judged to be included if it is related to the CFT model, such as self-compassion, self-criticism, or shame.

(2) Exploring relationships between articles

Mechanisms of change were evaluated between studies that completed a specific mechanism of change analysis. Outcome measures and reported CFT components used across the studies were evaluated in relation to the targeted mechanisms of change. Studies reporting a specific aim to evaluate mechanisms of change were reported on.

Quality Assessment

The Crowe Critical Appraisal tool (CCAT) (Crowe and Sheppard, 2011) was used to assess the quality of included studies (Appendix 1.2). It was expected that included studies would be heterogenous, this tool was chosen as it can be used across a variety of research designs. The CCAT evaluates eight domains: preliminaries, introduction, design, sampling, data collection, ethical matters, results, and discussion. Each domain is scored out of 5 and a total score out of 40 is given. Prior to rating, the quality ratings for scores were determined. A score of >30 is high quality, 20-30 is moderate quality and <20 is low quality. Two raters assessed the quality of thirteen of the twenty papers to ensure scoring was accurate (Appendix 1.3). The agreement between assessors was 89.4% and disagreements were resolved through discussion. CCAT ratings are included in the Data Extraction table (Table 1). Authors were contacted for studies that did not report the specific intervention components used in their research. The quality assessment and strength of evidence available was evaluated to as part of assessing the trustworthiness of the synthesis (Popay et al., 2006).

Results

Screening and Selection

Articles were stored and evaluated using EndNote software. The initial searches generated 11,008 results. Once duplicates were removed there were 9,630 articles screened via titles and abstracts. 51 full text articles were retrieved and reviewed for eligibility using the inclusion and exclusion criteria. Independent arbitration on eligibility for inclusion was sought for 7 articles (completed by the project supervisor). Twenty papers were included in the review. Reference lists of included papers and the British Journal of Clinical Psychology were hand searched as a sensitivity check to ensure that eligible papers were not excluded (see Figure 1).

(1) Preliminary Synthesis

A total of 20 eligible articles were included in this review. The details extracted from included studies can be found in Table 1. Main findings from the studies are summarised in Appendix 1.4.

Study Characteristics

The details of the studies, including design, methods and sample size are found in Table 1. Thirteen used an observational design, four were non-randomised controlled trials and three were randomised controlled trials (RCTs). Twelve of the studies were published in the last three years and the earliest study was published in 2006. There was a wide variety of sample populations; fourteen studies recruited from a clinical population, three recruited students with or without mental health problems, two studies used a public sample, and one was conducted with healthcare professionals. The number of participants ranged from 5 to 177.

Fifteen studies were delivered as a CFT group, although methods differed across studies. Four

studies were a CMT group, and one was a CFT continuing professional development (CPD)

workshop. Intervention lengths varied from a 3-day workshop to 18 weekly sessions.

Seventeen of the studies delivered at least 8 sessions.

Figure 1

PRISMA Flowchart for Systematic Reviews



Table 1

Characteristics and Quality Ratings of Reviewed Studies

Study	Design	Population (Gender)	Ν	Treatment description	Control group	Frequency and type of sessions	Outcome measures	Treatment target	Mechanism of change measured	Quality Rating (Max score 40)
Ashworth et al (2015)	Observational	Acquired brain injury patients attending a rehabilitation outpatient programme (7 M: 5 F)	N=12	CFT group & individual CFT sessions	None	18-week programme - included 4- day CFT group and up to 18 individual CFT sessions.	HADS, FSCRS	Depression and anxiety	Self-criticism self- reassurance	26 (moderate)
Beaumont et al (2016)	Observational	Healthcare professional's CPD (Gender not reported)	N=28	CPD workshop on CFT	None	3-day workshop	SCS-SF, FSCS	Self- criticism, self- compassion	Self- criticism, self- compassion	25 (moderate)
Carlyle et al (2019)	Non- randomised controlled trial	Opioid use patients attending (24 M: 14 F)	N=38 15 CFT: 12 relax: 11WLC	CFT group	Relaxation (active control) and WLC	3x 2hour CFT sessions	OCDUS, DASS, FSCRS	Drug use, anxiety, depression	Self-criticism self- reassurance	33 (good)
Carter et al, (2020)	Observational	Students with BMI >30 (1 M: 4 F)	N=5	CFT group	None	Twice weekly 2- hour group for 6 weeks	BISS, CEAS, OAS, SoCS, EAT-26, IPAQ, PSQ	Body weight shame	Self- compassion, shame, social comparison	31 (good)

Study	Design	Population (Gender)	Ν	Treatment description	Control group	Frequency and type of sessions	Outcome measures	Treatment target	Mechanism of change measured	Quality Rating (Max score 40)
Chou et al (2020)	Non- Randomised Controlled Trial	Patients with hoarding disorder (DSM- 5 diagnosis) (7 M: 13 F)	N=20 (13 CFT: 7 CBT)	CFT group	CBT group	16 weekly two-hour sessions	SIHD, MINI, SI-R, BDI, BAI, FIS, SCI, Brief COPE, DTS, SAM, ESS, FSCRS	Hoarding disorder	Distress tolerance self- ambivalence, shame, self- compassion, self-criticism	35 (good)
Cuppage et al (2018)	Non- Randomised Controlled Trial	Patients with problematic shame and self- criticism (60 F: 27 M)	N=87 (58 CFT:29 TAU)	CFT group	TAU	14 x 3-hour sessions. Then 4 additional monthly sessions.	BSI, FSCS, FCS, OAS, SSPS	Psychopath ology	Fears of self- compassion, social safeness, shame, self- criticism	33 (good)
Fox et al (2021)	Observational	Students with primary presenting problem relating to shame or self- criticism (55 F: 20 M)	N=75	CFT group	None	12 weekly 2- hour sessions	FCS, CEAS, FSCRS, DEQ, TOSCA, OQ-45	Self- reassurance , self- criticism, shame	Self- reassurance, self- criticism, shame	32 (good)
Frostadottir and Dorjee (2019)	Non- Randomised Controlled Trial	Patients with mild to moderate anxiety, depression, or stress (51 F: 7M)	N=58 (20 MBCT: 18 CFT: 20 control)	CFT group	MBCT group and waitlist control group	8 two hour bi-weekly sessions over 4 weeks	FFMQ, SCS, RRQ, DASS- 21	Anxiety, depression, stress	Mindfulness, self- compassion, rumination	37 (good)

Study	Design	Population (Gender)	Ν	Treatment description	Control group	Frequency and type of sessions	Outcome measures	Treatment target	Mechanism of change measured	Quality Rating (Max score 40)
Gilbert and Proctor (2006)	Observational	Patients with severe and complex mental health difficulties with high levels of shame and self- criticism (4 F: 2M)	N=6	CMT group	None	12 x 2-hour weekly sessions	HADS, FSCS, FSCRS, SRV, OAS, SoCS, SBS	Depression, anxiety	Self- criticism, shame, inferiority, submissive behaviour	24 (moderate)
Goad and Parker (2020)	Observational	LD patients with high levels of self-criticism, shame, and associated distress (3 F: 3 M)	N=6	CFT group	None	11 weekly sessions	CORE-LD, adapted SoCS, SCS- SF	Low mood, self- criticism, shame	Self- criticism, shame	29 (moderate)
Gooding et al (2020)	Observational	Patients with persistent pain (1 F: 3M)	N=4	CFT group	None	12 two-hour weekly sessions	DASS-21, FSCRS, CPAQ, PDI	Mood, pain disability, pain acceptance	Self- criticism, self- reassurance	32 (good)
Grodin et al (2019)	Observational	Patients with military related PTSD (1 F: 21 M)	N=22	CFT group	None	12 sessions	PTSD checklist, STAXI-2, SCS, FCS	PTSD, anger	Compassion, fears of compassion	31 (good)

Study	Design	Population (Gender)	Ν	Treatment description	Control group	Frequency and type of sessions	Outcome measures	Treatment target	Mechanism of change measured	Quality Rating (Max score 40)
Irons and Heriot- Maitland (2020)	Observational	General public (37 F: 18 M)	N=55	CFT group	None	8 x 2.5-hour weekly sessions	ECR-S, SoCS FSCRS, SCS, CEAS, TPAS, WEWBS, DASS-21	Mental distress	Wellbeing, compassion to self and others	29 (moderate)
Judge et al (2012)	Observational	Patients referred to a Community Mental Health Team (16 F: 11M)	N=27	CFT group	None	12-14 two- hour weekly sessions	BDI, BAI, FSCRS, FSCS, ISS, OAS, SoCS, SBS	Depression, anxiety, stress	Self- criticism, shame, submissive behaviour, social comparison	24 (moderate)
Kelly et al (2017)	Randomised controlled trial	Outpatients with eating disorders (21 F: 1M)	N=22 (11 CFT: 11 TAU)	CFT group + TAU	TAU	12 weekly 90-minute sessions	EDE-Q, SCS, FCS, ESS	Eating disorder pathology	Shame, self- compassion, fears of compassion	30 (good)
Laithwaite et al (2009)	Observational	Forensic male inpatients in maximum security hospital with psychosis (19 M: 0 F)	N=19	Recovery After Psychosis group (based on CMT)	None	20 bi-weekly sessions over 10 weeks	SoCS, OAS, SCS, BDI, RSE, SIP- AD, PANSS	Depression, self esteem	Compassion to self, external shame	31 (good)

Study	Design	Population (Gender)	Ν	Treatment description	Control group	Frequency and type of sessions	Outcome measures	Treatment target	Mechanism of change measured	Quality Rating (Max score 40)
Lucre and Corten (2013)	Observational	Outpatients with personality disorder (7 F: 2 M)	N=9	CFT group	None	16 weekly sessions	SoCS, SBS, OAS, FSCRS, DASS-21, CORE	Anxiety, depression, stress	Self- criticism, self-attacking thoughts, feelings, behaviours	22 (moderate)
Matos et al (2017)	Randomised controlled trial	General public (84 F: 9 M)	N=93 (CMT 56: WLC 37)	CMT group	WLC	2-hour group session + written manual	CAAS, SCS, FCS, TPAS, OAS, FSCRS, DASS-21, PSS	Emotional, self- evaluation, psychopath ology, HRV	Flows of compassion, shame, fears of compassion, self- criticism, self- reassurance	29 (moderate)
McManus et al (2018)	Observational	Patients referred to a Community Mental Health Team (6 F: 7 M)	N=13	CFT group	None	16 weekly 2- hour sessions	FSCRS, FSCS, OAS, SCS, MHCS	Self- compassion , self- criticism, shame	Self- compassion, self- criticism, shame	23 (moderate)
Savari et al (2021)	Randomised controlled trial	Students with a diagnosis of major depression (30 F: 0 M)	N=30 (15 CMT: 15 control)	CMT group	Waitlist control	8 bi-weekly 90-minute sessions	BDI-II, ARS, FSCRS, FCS, SCS- SF,	Depression, anger, negative self- relating	Self- criticism, fear of compassion, self- compassion	33 (good)

Abbreviations - CFT: Compassion Focused Therapy; CMT: Compassionate Mind Training; HADS: Hospital Anxiety and Depression Scale; FSCRS: Forms of Self-Criticism/Self-Attacking and Self Reassurance Scale; SCS-SF: Self-Compassion Scale – Short-Form; FSCS: Function of Self Criticizing/Attacking Scale; OCDUS: Obsessive-Compulsive Drug Use Scale; DASS: Depression and Anxiety Stress Scale; DASS-21: Depression and Anxiety Scale short from; BISS: Body Image Shame Scale; CEAS: Compassion Engagement and Action Scale; OAS: Other as Shamer Scale; BDI: Beck Depression Inventory; BDI-II: Beck Depression Inventory 2; BAI: Beck Anxiety Inventory; SCI: Structured Clinical Interview; ESS: Experiences of Shame Scale; BSI: Brief Symptom Inventory; FCS: Fears of Compassion Scale; SSPS: Social Safeness and Pleasure Scale; FFMQ: Five-facet Mindfulness Questionnaire; SBS: Submissive Behaviour Scale; CORE-LD: Clinical Outcomes in Routine Evaluation – Learning Disability; ISS: Internalized Shame Scale; EDE-Q: Eating Disorder Examination Questionnaire; RSE: Rosenberg Self-Esteem Scale; SIP-AD: Self-image Profile for Adults; PANSS: Positive and Negative Syndrome Scale; CORE: Clinical Outcomes in Routine Evaluation; MHCS: Mental Health Confidence Scale; EAT-26: Eating Attitudes Test, SCS: Self-Compassion Scale; SoC3: Social Comparison Scale, IPAQ: International Physical Activity Questionnaire, PSQ: Participant Satisfaction Questionnaire, SIHD: Structured Interview for Hoarding Disorder; MINI: Mini International Neuropsychiatric Interview; SI-R: Saving Inventory – Revised; FIS: Frost Indecisiveness Scale; Brief COPE: Coping Orientations to Problems Experienced; DTS: Distress Tolerance Scale; SAM: Self-Ambivalence Measure; DEQ: Depressive Experiences Questionnaire; TOSCA: Test of Self-conscious effect; OQ-45: Outcome Questionnaire 45; RRQ: Reflection Rumination Questionnaire, SRV: Social Rank variables; CPAQ: Chronic Pain Acceptance Questionnaire; PDI: Pain Disability Index; STAXI-2: State-Trait Anger Expression Inventory 2nd Edition; ECR-S: E

2) Exploring relationships between articles

Quality Appraisal

The included studies were critically appraised using the CCAT. Quality ratings of included studies ranged from 22 to 37, meaning all studies were either 'moderate' or 'good' quality. Eleven (55%) of the studies were rated as 'good'. The ratings are presented in Table 1.

<u>Review Aim 1</u>: To identify and describe the mechanisms of change reported in CFT intervention studies.

Of the 20 eligible studies, only four specifically aimed to investigate 'mechanisms of change' (Judge et al., 2012; Ashworth et al., 2015; Cuppage et al., 2018; Fox et al., 2021). Despite this, one of these studies did not specifically investigate 'mechanisms of change' in the analysis (Ashworth et al, 2015). The synthesis of 'mechanisms of change' studies focuses on the three studies that did a change analysis (Judge et al., 2012; Cuppage et al., 2018; Fox et al., 2021). One was a non-randomised control trial (Cuppage et al., 2018), two were observational studies.

Cuppage et al, (2018) delivered a CFT intervention to people referred to a mental health service in Ireland, specifically focused on patients with high levels of shame and self-criticism linked to their mental health. Fifty-eight patients were in the CFT group and 29 received treatment as usual. The intervention delivered was one of the longest of all the studies included, they delivered 14 sessions of CFT, each lasting three hours. The sessions were twice per week for five weeks and then four weekly sessions. Participants were then offered sessions once per month for four months as a follow up. Final outcome measures were taken in the first of the follow up sessions. The authors found significant differences between groups for psychopathology, fears of self-compassion, and social safeness with the CFT group having greater improvements. No significant differences between groups were found for external shame, self-criticism or self-persecution. At two month follow up no significant differences were found from post-CFT group to two-month follow up but improvements were maintained. However only 57% of participants who completed the final measures went on to complete the follow up measures. To examine mechanism of change, the authors explored the

relationship between change in psychopathology and changes in self-criticism, shame, social safeness, and fears of self-compassion. They found significant positive correlations with medium and large effect sizes between changes in psychopathology and changes in self-persecution (r=.51), shame (r=.47), the self-criticism subfactor of self-correction (r=.30), and fears of self-compassion (r=.57) measured on Functions of Self-criticism Scale (FSCS) (Gilbert et al., 2004) and the fears of self-compassion subscale on the Fears of Compassion Scale (FCS) (Gilbert et al., 2011). A significant negative correlation was found with social safeness (r=-.34). This study quality was rated as 'good' (33/40) with strongest ratings for describing aims and objectives and information given on the process of data collection. It was found that despite information being given on the CFT intervention it was not likely enough information to be replicated. The study utilised a nonrandomised design, participants were allocated to the CFT group if available at the time or allocated to treatment as usual to wait for the start of the next group. Additionally, given the sample size, the study was only powered to detect large effects, therefore the mechanism of change analysis with self-criticism and fears of compassion should be interpreted with caution. The analysis used regression and correlation to evaluate the relationship between outcomes. It is difficult to say whether this is a true measure of 'mechanism of change' or just a common factor of change (Kazdin, 2007). Another limitation was that the timing of data collection mean that the authors were unable to determine which changes occurred first and therefore lacking the temporal precedence needed to determine a mechanism of change. Given Kazdin's (2007) framework, this study gives some early evidence on the next steps for mechanisms of change analysis.

Fox et al. (2020) investigated a CFT group in a university counselling service. A CFT manual suitable for a student population was developed and the study firstly focused on examining the feasibility and acceptability as a group treatment. A secondary aim was to evaluate change in outcomes separated into three categories; mechanisms of change (fears and flows of compassion), CFT outcomes (self-reassurance, self-criticism and shame) and mental health outcomes (psychiatric distress). The authors evaluated change at three time points (pre, mid and post group), with the hypothesis that early change in fear and flows of compassion would predict later outcomes in self-

reassurance, self-criticism and shame. Twelve weekly, two-hour sessions of CFT were delivered in a group.

The authors found improvements in fears and flows of compassion, self-criticism, shame, selfreassurance and psychiatric distress. The authors used Pearson's correlation analysis to evaluate the relationship between change in fears and flows of compassion and change in CFT outcomes. Kadzin (2007) stated that this type of temporal analysis is useful for mechanisms of change analysis. However using correlation analysis fails to address what may be common factors that lead to change in outcomes rather than identifying a causal relationship in outcomes. It is useful to note that there were temporal correlations, however in evaluating these it appears that most strong correlations in change happened at the same time rather than predicting a later change. They calculated correlations between all measures and sub-measures, the volume of correlations calculated is excessive for a feasibility study and there is no reference to power calculation in the study. Given only 36 participants completed the measures fully, it is likely that the study was underpowered to detect the changes presented.

In terms of the present review, Fox et al (2020) investigated what they considered mechanism of change outcomes (fears and flows of compassion) with what they considered CFT outcomes (shame, self-criticism and self-reassurance). The present review considered that both of these outcome groups were potential mechanisms of change with a view to understanding their effect on mental health outcomes. Therefore the Fox et al (2020) study does not provide evidence for that review question. However, the study does provide some useful areas for further investigation as it is clear there are components that have an impact on participant's outcomes.

The relevant outcome measures used were FCS, the Compassionate Engagement and Action Scales (CEAS) (Gilbert et al., 2017), Forms of Self-criticising/self-reassuring scale (FSCRS) (Gilbert, et al., 2004), and Test of Self-conscious affect (TOSCA) (Tangney et al., 2000). They did not report on the relationship of change with mental health outcomes, which was the key question as part of this review. The quality of this study was rated as 'good' (32/40), with particular strengths in

research design, background information and data collection methods. It was judged that the study could be replicable with the manual available. It was found that information on sample recruitment, and sample size analysis was limited.

In evaluating the Fox et al (2020) analysis, it is useful to see that there are some associations between constructs, however it may be that these constructs already overlap, such as fears of compassion and hated-self, it is possible that they have an underlying common factor. This could be true for a number of the associations found. It is however, useful that the authors carried out a temporal analysis. Given Kazdin's (2007) framework, this is a useful step in the process of identifying mechanism of change. However, the study found that most change appeared to happen at the same time, therefore the timing of change did not support the mechanism of change being the factor for later change in any of the associations. The sample size was insufficient for the temporal analysis needed. An additional finding with this study was that baseline scores for the student sample were different to expected scores from clinical and non-clinical populations from the literature. For flows and fears of compassion the sample scored between clinical and non-clinical scores that are typically found in the research. Additionally, in compassion to others, the sample scored closer to an expected post-treatment score based on previous research, it also suggest a potential for ceiling effects in this construct, which would impact on the change analysis. Selfcriticism was significantly higher than both clinical and non-clinical samples in the literature and psychiatric distress was at a similar level to clinical samples based on the literature. Therefore a student sample may respond differently to the general population.

Judge et al. (2012) delivered a CFT group in a community mental health setting. Seven groups were run, each lasting 12-14 sessions of two hours each. Participants were receiving care for a mental health condition and scored high on internal shame. The outcome measures were BDI, BAI, FSCRS, FSCS, Internalized Shame Scale (ISS) (Cook, 1996), the Other as Shamer Scale (OAS) (Goss et al., 1994), the Social Comparison Scale (SoComS) (Allan & Gilbert, 1995), the Submissive Behaviour Scale (SBS) (Allan & Gilbert, 1997). The authors investigated whether individual differences at baseline were associated with later change in scores as this can impact on

how compassion based therapies are received by individuals. This study was a very early CFT study and the correlations evaluated were again not the focus of the present review as the change analysis did not focus on the effect of the CFT but rather the effect of individual baseline scores. Change was evaluated by subtracting post scores from pre scores. Correlation analysis evaluated the relationship with change scores and baseline scores, with the aim of evaluating whether individual differences at baseline had an impact on the change in scores. Overall, the authors found that higher baseline depression and external shame were associated with greater overall improvements. No other correlations were significant. The authors also used diaries to measure self-critical and selfsoothing thoughts, however these measures are not validated.

The quality of this study was rated as moderate (24/40), this was due to a lack of reporting on design, treatment guide, sampling methods, ethical matters, and essential analysis such as patient flow. The authors were contacted for further information and their treatment protocol, but no response was received. This study lends support to the idea that people who experience low mood and external shame may particularly benefit from CFT. However, the lack of information reported on study design, the low sample size and lack of control mean that the results must be interpreted with caution. As with Kazdin's (2007) framework, this study gives some early indicators as to important mechanism of change that need to be evaluated further, however it does not provide useful information for the present review in terms of change analysis. Additionally, the study scored moderately in quality further reducing the information that can be gathered from it.

Mechanisms of Change Summary

The three studies that evaluated 'mechanisms of change' in CFT all did so very differently and with different aims. The most useful study to answer the questions of mechanisms of change in CFT as a mental health intervention was the Cuppage et al (2018). The studies provide some preliminary evidence that fears of compassion, flows of compassion, self-criticism, and shame may be change mechanisms worthy of investigating further but generally, there is a lack of good quality analysis in evaluating mechanisms of change in these studies and so these conclusions are tentative. Kazdin's (2007) framework describes the process of identifying mechanisms of change in mental health

treatments. These studies fit with the initial process of identifying potential mechanisms that need to be investigated further with more robust research design. Correlation analysis is a useful early-stage statistical analysis to provide information on the potential relationships between constructs. A useful next step would be to evaluate potential mechanisms of change at different time points during a treatment to investigate whether early change in one mechanism leads to later change in a mental health outcome. The mental health and CFT outcomes of all twenty studies can be found in Appendix 1.4.

Review Aim 2: To identify the common components of CFT interventions delivered.

Eighteen of the CFT studies detailed intervention components, two did not have enough information and authors were contacted. Matos et al (2017) shared a copy of their group manual, Judge et al (2012) did not respond to the request. Analysis is based on the nineteen studies that had the information available. Table 2 details each component reported in each of the studies. Psychoeducation on the CFT model and compassionate imagery were the most commonly reported components. CFT psychoeducation was delivered in all but one study, it was not included in the work of Laithwaite et al (2009) which had a different type of psychoeducation focused on psychosis. Gooding et al (2020) was the only study that did not report compassionate imagery as a component of their intervention, this was a small-scale (n=4) study focused on chronic pain, it is unclear why compassionate imagery would not have been used. Compassionate imagery involves visualisation of a compassionate person, animal, or object. It is a common experiential practice used in CFT.

Mindfulness training as a component of the CFT interventions was used in twelve of the nineteen studies (Beaumont et al, 2016; Carlyle et al, 2019; Carter et al, 2020; Chou et al, 2020; Fox et al, 2021; Frostadottir & Dorjee, 2019; Goad et al, 2020; Grodin et al, 2019; Lucre &Corten, 2013; Matos et al, 2017; McManus et al, 2018 and Savari et al, 2021). The mindfulness training in the studies was usually a focused task to learn how to pay attention in the present moment. The studies used a variety of specific mindfulness techniques such as mindful eating, breathing techniques,

body awareness, recognition of feelings, awareness of attention, guided meditation practices and utilising a mindful object. Soothing rhythm breathing was used in 10 of the 19 studies (Ashworth et al, 2015; Beaumont et al, 2016; Carlyle et al, 2019; Carter et al, 2020; Chou et al, 2020; Fox et al, 2021; Goad et al, 2020; Irons & Heriot-Maitland, 2020; Matos et al, 2017 and McManus et al, 2018). It was often used in conjunction with mindfulness practices. Soothing rhythmic breathing is skill that teaches people to use breathing to help regulate their emotions.

Practices aimed at increasing 'compassionate self' were defined in a variety of ways. Fifteen studies included specific exercises focused on self-compassion but how it was delivered varied (Ashworth et al, 2015; Beaumont et al, 2016; Carlyle et al, 2019; Carter et al, 2020; Chou et al, 2020; Cuppage et al, 2018; Fox et al, 2021; Frostadottir & Dorjee, 2019; Gilbert & Proctor, 2006; Goad et al, 2020; Irons & Heriot-Maitland, 2020; Kelly et al, 2017; Matos et al, 2017, McManus et al 2018 and Savari et al, 2021). Some studies utilised discussion and giving examples to facilitate increased awareness, some discussed the attributes a 'self-compassionate person' would have, some used 'chair-work', and some used a technique of creating a compassionate self-image, which was distinct from 'compassion focused imagery'. 'Compassionate letter writing' was delivered in ten studies (Beaumont et al, 2016; Carlyle et al, 2019; Chou et al, 2020; Fox et al, 2021; Gooding et al, 2020; Irons & Heriot-Maitland, 2020; Kelly et al. 2017; Laithwaite et al. 2009; McManus et al. 2018 and Savari et al, 2021). This exercise is often used as a way to cultivate compassion towards the self. Techniques focused on 'blocks' or 'barriers' to compassion were used in nine studies (Ashworth et al, 2015; Carlyle et al, 2019; Gilbert & Proctor, 2006; Goad et al, 2020; Gooding et al, 2020; Irons & Heriot-Maitland, 2020; Kelly et al, 2017; McManus et al, 2018 and Savari et al, 2021). The studies used psychoeducation and discussion on 'blocks to compassion' and then self-compassion exercises previously learned, to work with blocks. This was also an intervention that was often delivered later in the group as it allowed people to have time to practice the techniques and understand what difficulties they may be having. Participants in the Ashworth et al. (2015) study did work on understanding barriers to compassion in their one-to-one sessions following the group

sessions. This was alongside other interventions that they felt were more appropriately delivered within an individual therapeutic relationship.

'Formulation' was used in four studies (Ashworth et al, 2015; Chou et al, 2020; Lucre & Corten, 2013 and McManus et al, 2018). The studies varied in how formulation was delivered. Ashworth et al (2015) used formulation in the individual sessions, alongside the work on blocks to compassion, this was to allow again for individualised therapeutic work. McManus et al (2018) also delivered one individual formulation session as a one-off within the group framework. The other two studies (Chou et al, 2020; Lucre & Corten, 2013) both delivered formulation within the group more generally.

'Compassion towards multiple selves' was a component used in six of the studies (Beaumont et al, 2016; Carter et al, 2020; Chou et al, 2020; Fox et al, 2021; Irons & Heriot-Maitland, 2020 and Matos et al, 2017). Chou et al (2020) utilised 'chair-work' to work with multiple selves, this was the only study that reported 'chair-work' as a technique. The studies focused on understanding different parts of the emotional self, such as 'angry self', 'sad self' and 'anxious self' and then discussion and teaching on how to be compassionate towards those parts, utilising techniques learned in earlier sessions.

Understanding and working with 'self-criticism' was a component used in twelve studies (Ashworth et al, 2015; Beaumont et al, 2016; Carlyle et al, 2019; Carter et al, 2020; Cuppage et al, 2018; Gilbert & Proctor, 2006; Gooding et al, 2020; Irons & Heriot-Maitland, 2020; Kelly et al, 2017; Laithwaite et al, 2009; Lucre & Corten, 2013 and Savari et al, 2021). The techniques used to address self-criticism varied across studies. All but one study delivered specific psychoeducation and techniques to work on self-criticism. However, Beaumont et al (2016) had 'self-criticism' work as part of other components such as 'multiple selves' or 'compassionate letter writing'. In summary, the studies included in this review had a wide variety of treatment protocols. The number of components varied in each study and often the length and level of intervention varied.

Table 2CFT Components Reported in Studies

Study	Psychoeducation	Compassion focused imagery	Mindfulness	Soothing rhythm breathing	Compassionate self	Blocks and barriers	Formulation	Multiple selves	Self- criticism	Compassionate letter writing
Ashworth et al., (2015)	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	
Beaumont et al., (2016)	✓	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark	\checkmark	✓
Carlyle et al., (2019)	✓	\checkmark	\checkmark	\checkmark	✓	\checkmark			\checkmark	✓
Carter et al., (2020)	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark	\checkmark	
Chou et al., (2020)	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		✓
Cuppage et al., (2018)	\checkmark	\checkmark			\checkmark				\checkmark	
Fox et al., (2021)	\checkmark	\checkmark	\checkmark	✓	\checkmark			\checkmark		\checkmark
Frostadottir et al., (2019)	\checkmark	\checkmark	\checkmark		\checkmark					
Gilbert et al., (2006)	\checkmark	\checkmark			\checkmark	\checkmark			\checkmark	
Goad et al., (2020)	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark				
Gooding et al., (2020)	\checkmark					\checkmark			\checkmark	\checkmark
Grodin et al., (2019)	\checkmark	\checkmark	\checkmark							
Irons et al., (2020)	✓	\checkmark		✓	\checkmark	\checkmark		\checkmark	\checkmark	✓
Kelly et al., (2017)	\checkmark	\checkmark			\checkmark	\checkmark			\checkmark	\checkmark
Laithwaite et al., (2009)		\checkmark							\checkmark	\checkmark
Lucre et al., (2013)	\checkmark	\checkmark	\checkmark				\checkmark		\checkmark	
Matos et al., (2017)	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark					
McManus et al., (2018)	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark
Savari et al., (2021)	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark			\checkmark	\checkmark
Total	18	18	12	10	15	9	4	5	12	10

<u>Review Aim 3:</u> To describe the outcome measures used to evaluate change in people receiving CFT interventions.

Several measures were used in the included studies to assess mechanisms of change. (see Appendix 1.5 for a full list by study). The most commonly used CFT outcome measures in the included studies can be found in Figure 3. Of the measures used the Forms of Self-Criticism /Self-Attacking and Self-Reassurance Scale (FSCRS) was used the most often, used in twelve of the twenty studies (Ashworth et al, 2015; Caryle et al 2019; Chou et al, 2020; Fox et al, 2021; Gilbert & Proctor, 2006; Gooding, 2020; Irons & Heriot-Maitland, 2020; Judge et al, 2012; Lucre & Corten, 2013; Matos et al, 2017; McManus et al, 2018; Savari et al, 2021) . The FSCRS measures two aspects of self-criticism and one aspect of self-reassurance. This measure was designed to understand how people treat themselves when things go wrong and in particular the tendency to engage in self-criticism or self-reassurance in the face of problems. The measure has been found to be reliable and valid measure for the two forms of self-criticism and one of self-reassurance both in clinical and non-clinical populations (Baião et al, 2015).

The self-compassion scale (SCS) is a 26-item measure that with six subscales relating to selfcompassion. Three of the subscales are positive: self-kindness, common humanity, and mindfulness. Three of the subscales are negative: self-judgement, isolation, and over-identification. The negative items are reverse scored and together all subscales give a global self-compassion score. The subscales can also all be individually rated. The SCS was used in six of the included studies (Frostadottir & Dorjee, 2019; Grodin et al, 2019; Irons & Heriot-Maitland, 2020; Kelly et al, 2017, Laithwaite et al, 2009 and Matos et al, 2017). The short-form version was used in three of the included studies (Beaumont et al, 2016; Goad & Parker, 2020 and Savari et al, 2021). The short form version (SCS-SF) is a 12-item outcome measure, it has near perfect correlation with the longer version (Raes et al, 2011). Both measures have been found to be reliable and valid in evaluating self-compassion as a construct. As with the FSCRS, the SCS and SCS-SF measures different selfcompassion and self-criticism constructs within one measure.

Table 3

Mechanisms of Change Outcome Measures used each Study

Study	FSCRS	SCS/ SCS-SF	FSCS	OAS	CEAS	FCS	SoCS
Ashworth et al., (2015)	√						
Beaumont et al., (2016)		\checkmark	\checkmark				
Carlyle et al., (2019)	\checkmark						
Carter et al., (2020)				\checkmark	\checkmark		\checkmark
Chou et al., (2020)	✓						
Cuppage et al., (2018)			\checkmark	\checkmark	\checkmark	\checkmark	
Fox et al., (2021)	√				✓	\checkmark	
Frostadottir et al., (2019)		\checkmark					
Gilbert et al., (2006)	√		\checkmark	~			\checkmark
Goad et al., (2020)		√					\checkmark
Gooding et al., (2020)	✓						
Grodin et al., (2019)		✓				\checkmark	
Irons et al., (2020)	\checkmark	\checkmark			\checkmark		\checkmark
Judge et al., (2012)	✓		\checkmark	\checkmark			
Kelly et al., (2017)		✓				\checkmark	
Laithwaite et al., (2009)				\checkmark			\checkmark
Lucre et al., (2013)	✓			~			\checkmark
Matos et al., (2017)	\checkmark	\checkmark		\checkmark		\checkmark	
McManus et al., (2018)	√	\checkmark	\checkmark	~			
Savari et al., (2021)	\checkmark	✓				\checkmark	
Total	12	9	5	8	4	6	6

Abbreviations - FSCRS: Forms of Self-Criticism /Self-Attacking and Self Reassurance Scale; SCS/ SCS-SF: Self-Compassion Scale/Self-Compassion Scale – Short-Form; FSCS: Function of Self Criticizing/ Attacking Scale; OAS: Other as Shamer Scale; CEAS: Compassion Engagement and Action Scale; FCS: Fears of Compassion Scale FCS; SoCS: Social Comparison Scale

To measure external shame, the Other as Shamer (OAS) scale was used in seven of the studies (Carter et al, 2020; Cuppage et al, 2018; Gilbert & Proctor, 2006; Judge et al, 2012; Laithwaite et al, 2009; Lucre & Corten, 2013; Matos et al, 2017 and McManus, 2018). This measure evaluates the beliefs about how others evaluate an individual, with higher scores indicating higher levels of external shame. It is an 18-item self-report measure, there are three main domains relating to feelings of inferiority, emptiness and how people evaluate mistakes made (Goss et al, 1994). To measure internal shame, the Internalized Shame Scale (ISS) was used in one study (Judge et al, 2012). This is a 24-item measure that evaluates the trait of shame, which is self-evaluations of inferiority. The Test of Self Conscious Affect (TOSCA) third version, is a 16-item measure of a person's guilt-proneness and shame-proneness. This measure was used in one of the studies (Fox et al, 2021). The Experiences of Shame Scale (ESS) is a 25-item measure that evaluates a person's proneness to shame. It was used in one study (Chou et al, 2020).

The Fears of Compassion Scale (FCS) is a measure with three subscales, totalling 36 items. The three subscale focus on the flows of compassion; fear of compassion for self, fear of compassion from others and fear of compassion for others. This measure was used in six studies (Cuppage et al, 2018; Fox et al, 2021; Grodin et al, 2019; Kelly et al, 2017; Matos et al, 2017 and Savari et al, 2021). The Compassion Engagement and Action Scale (CEAS) is another measure of the three flows of compassion: compassion from others, compassion to others and compassion to self. It is a 36-item measures with three subscales for each domain and for each subscale there are two dimensions: engagement and action. The dimensions reflect a person's ability to engage with suffering and be motivated to work with it. This measure was used in three studies (Carter et al, 2020; Fox et al, 2021 and Irons & Heriot-Maitland, 2020). The Compassionate Attributes and Action Scale (CAAS) is another measure that evaluates the three flows of compassion; self-compassion, compassion for others and compassion for others. This measure was used in one study (Matos et al, 2017).

The Social Comparison Scale (SoCS) is an 11-item measure that asks a person to rate their self-perception of social rank in comparison to others. Lower scores suggest feelings of inferiority in comparison to others. This measure was used in seven studies (Carter et al, 2020; Gilbert & Proctor, 2006; Goad & Parker, 2020; Irons & Heriot-Maitland, 2020; Judge et al, 2012; Laithwaite et al, 2009 and Lucre & Corten, 2013). The Function of Self-Criticizing/Attacking Scale (FSCS) is a 21-item scale to measure why people think they criticise and attack themselves. The factor structure suggests two functions: for self-improvement or to harm oneself. This measure was used in five studies (Beaumont et al, 2016; Cuppage et al, 2018; Gilbert & Proctor, 2006; Judge et al, 2012 and McManus et al, 2018).

Mechanisms of Change Outcome Measures Summary

There are a variety of measures used to evaluate mechanism of change in CFT, however they cover some core domains: shame, self-criticism, self-compassion, fears and flows of compassion and social comparison. A number of other outcome measures were used in the included studies that were focused on specific or general mental health outcomes. (3) Assessing the robustness of the synthesis

(3) Assessing the robustness of the synthesis

Eighteen of the studies provided sufficient information to carry out the analysis. Treatment manuals were requested from two authors, Judge et al (2012) and Matos et al (2017). The manual received from Matos et al (2017) was sufficiently detailed to inform the analysis. Judge et al (2012) did not respond to the request which meant CFT components from their study could not be analysed as part of the synthesis. However, all other information was available in the main article to sufficiently synthesise.

Discussion

CFT has become increasingly popular, and it appears to be effective at improving people's mental health and wellbeing (Craig et al, 2020). The aim of this systematic review was to
synthesise the data on 'mechanisms of change' in CFT interventions. Mechanisms of change outcomes, components of CFT that could lead to change and the outcome measures used to evaluate change were reviewed.

Only four of the studies included in the review aimed to specifically evaluate mechanisms of change. Of the four, only three reported on a mechanism of change analysis and utilised correlations to understand mechanisms of change. Kazdin (2007) described the processes needed to understand a mechanism: strong association, specificity, consistency, experimental manipulation, timeline, gradient, and plausibility. The three studies found correlations with certain mechanism which informs the *strong association* required to identify a mechanism according to Kazdin's (2007) framework. All three studies measured different aspects of change. Correlations were found with changes in self-criticism, shame, and fears of selfcompassion with changes in psychopathology (Cuppage et al, 2018). Fears and flows of compassion was correlated with changes in shame, self-criticism, and mental health (Fox et al, 2021). Judge et al (2012) found lower baseline scores in depression and shame were correlated with larger changes in outcomes and higher anxiety at baseline was associated with less improvement in soothing thoughts. These correlations indicate that there are some connections between constructs, but further investigation is needed to replicate these associations. Interestingly *self-compassion* as a mechanism does not appear to have been directly investigated as a mechanism for change in mental health or overall wellbeing. Fox et al (2021) investigated flows of compassion which is a measure of self-compassion and found that in treatment, earlier changes in *self-compassion* predicted early change in *self-criticism*. This fits with previous research that suggests *self-criticism* and *self-compassion* are negatively related, however Gilbert et al (2011) also note that individuals higher in self-criticism find it harder to approach exercises intended to improve *self-compassion*. In terms of Kazdin's (2007) framework, *plausibility* is possibly the only other requirement that has been met, that is, it is plausible that the mechanisms identified relate to the outcomes. However, there is a lack of mediation analysis in the studies that would meet Kazdin's (2007) test for causal

mechanistic impact and in terms of the other requirements, there is not enough evidence to demonstrate mechanisms of change. Overall, there is a lack of systematic approaches to measuring change mechanisms, which adds to the difficulties in analysing change.

In terms the components of CFT, the highly varied protocols across the studies meant it was not possible to compare like for like. There were some commonalities in components; nearly all interventions included compassionate imagery and psychoeducation on the CFT model which indicates these are key components of the interventions.

The FSCRS and SCS were the most used CFT outcome measures. Of note, both scales aim to measure aspects of both self-compassion and self-criticism. It may be that these composite measures are indicated to easily measure multiple domains. It is clear from the outcome measures used that the mechanisms most investigated are areas of self-criticism and self-compassion. Therefore, we have more data on self-focused measures, researchers appear more directed towards understanding how people relate compassionately or self-critically to themselves. The scales that are more 'other' focused are used much less frequently, such as the CAAS, CEAS and FCS. However, it is only in the last year, the CAAS and CEAS were used, this may indicate a new line of research.

Strengths and Limitations

A strength of this review is that no published reviews to date specifically investigate mechanisms of change in CFT, therefore the evidence provided here should contribute to refining this evidence base. However, the lack of studies investigating mechanisms of change, especially related to mental health outcomes puts limits on the conclusions that can be drawn. The heterogeneity of eligible studies also limits the conclusions that can be drawn from the research at this stage. Because much of the included research is at the feasibility stage the investigation of change processes was rare (only three out of the included studies). Future reviews in this area could be strengthened by pre-registered on PROSPERO.

Future research

In terms of understanding the process of change in CFT it is important that the variability in treatment protocols is reduced. Manualising a CFT approach and subsequently investigating each component against a mechanism of change measure may deliver more useful information on what components work and how they work. There is increasing research into CFT as an intervention, given that twelve of the studies included in this review were from the last three years, this indicates the increasing popularity of research in this field. It is important that the next stages of research further refine the intervention and the research methods.

Conclusions

This review has identified that despite the aims of many trials, very few studies have actually investigated mechanisms of change in CFT. Also, there is high variability in the outcome measures used to evaluate mechanisms of change and in the CFT components delivered as part of an intervention. Due to study weaknesses such as small sample sizes, lack of consistency in treatment protocols, different populations and variety of outcome measures used means that robust conclusions cannot be drawn on mechanisms of change at this time.

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Chapter 2: Major Research Project

A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

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Prepared in accordance with the author requirements for Mindfulness (Appendix 1.1)

Plain Language Summary

Title: A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

Background: Compassion Focused Therapy (CFT) is a treatment that aims to work on people's shame and self-criticism. Transdiagnostic means that it can be used to treat different mental health conditions. This is a new treatment and little research has been done with older adults, however it shows promise for working age adults with anxiety and depression.

Aims and Questions: This study evaluated whether it is possible to deliver CFT as a treatment to older adults in a community mental health service. This study also aimed to find out if it is an acceptable intervention for older people and if there are any indications of changes that people experience from the intervention.

Methods: Participants were people over 60 years old with anxiety or depression, who were referred to the NHS mental health team in South Glasgow or East Renfrewshire. Participants were identified by their NHS worker, given information about the treatment and the research, and asked if they would like to meet for an assessment session. Participants then met with the CFT group facilitator (Clinical Psychologist) for an assessment session. Eligible participants were given information on the study and asked if they would like to participate. The CFT group ran for ten weeks, and the sessions were 90 minutes long. The participants completed questionnaires before the group, during the group and after the group. Participants were also invited to attend an interview after the group to discuss their experiences. Information on the number of people referred to the group and the number of sessions they attended was gathered. The interviews were transcribed and analysed. The questionnaire scores were analysed using statistics.

Main Findings and Conclusions: Two CFT groups ran and there were thirteen participants who started and ten who completed the sessions. The findings were that CFT is a treatment

that it is possible to deliver within an NHS older adult service. It was also found that it was beneficial for participants. There are a few areas that would be useful to investigate further in future research, such as the referral process and what aspects of the treatment lead to people to feel changes.

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Abstract

Objectives: Compassion Focused Therapy (CFT) is a relatively new intervention, particularly with the older adult population. In line with complex intervention development, this project aims to evaluate the feasibility and acceptability of CFT as an intervention for older adults with anxiety and/or depression.

Methods: This project used a mixed methods design, utilising outcome measures and semistructured interviews. The CFT group was delivered in an Older Adult Community Mental Health setting. Outcome measures were administered pre-, during and post-intervention, participants were then invited for an interview to collect their views. Feasibility factors such as recruitment and retention were evaluated. Outcome measures were analysed for treatment signals using non-parametric analysis. Thematic analysis was used to evaluate interview data.

Results: Thirteen participants started the CFT intervention and ten completed. The findings suggest CFT is an acceptable and feasible intervention for older adults. The results inform future research in this area with indicators for development. Research participation was varied, with participants wanting to participate but also finding the outcome measures to be onerous to complete.

Conclusions: It is unclear from this study whether CFT is a feasible and acceptable treatment intervention for older adults with anxiety and/or depression. Further research could address barriers to referrals within the CMHT setting. Additional research is also needed to identify mechanisms of change within CFT treatment.

Keywords: Compassion-Focused Therapy, CFT, Older Adults, Depression, Anxiety

Introduction

Compassion Focused Therapy development

Compassion focused therapy (CFT) is a psychological treatment that focuses on reducing shame and self-criticism, which are often transdiagnostic processes for people with mental health problems (Gilbert, 2009). CFT was developed to address perceived shortcomings in standard CBT approaches as one of the 'third-wave' of CBT approaches. People who experience high levels of shame find it difficult to feel kindness towards themselves (Gilbert & Proctor, 2006).

CFT Research Evidence

A recent meta-analysis found evidence that compassion-focused interventions improve outcomes for psychological wellbeing and functioning (Kirby, 2017). Compassion-focused therapy has been shown to reduce maintenance factors for distress, such as shame, selfcriticism, and fears of self-compassion (Cuppage et al, 2017; Gilbert & Proctor, 2006). But treatment outcome research in this area is still in its infancy, particularly with clinical populations. Two recent systematic reviews found that clear evidence of the effectiveness of CFT as an intervention is not yet available, but the intervention is well accepted and feasible within a mental health setting (Leaviss & Uttley, 2015; Craig, 2020). CFT has been researched in the treatment of depression, anxiety, psychosis, personality disorders, eating disorders and in non-clinical samples (Leaviss & Uttley, 2015). We know that standard treatments like CBT do not work for everyone, and it may be that CFT is suitable for subgroups of patients for whom CBT is less effective, for example because self-criticism and shame block the use of standard CBT techniques.

Psychological Treatment in Older Adults

The current psychological treatment standard for depression is CBT, behavioural activation, or Interpersonal Psychotherapy (IPT) (NICE, 2009) and for anxiety is CBT (NICE, 2011; The Scottish Government, 2014). There is strong evidence of the effectiveness of CBT in working

age adults for anxiety and depression; it has also been shown to be effective in older adults but with smaller effect sizes. The treatment guidelines do not differentiate their guidance for working age adults and older adults. A meta-analysis of CBT treatment for Generalised Anxiety Disorder (GAD) in older adults concluded that it is difficult to evaluate the effectiveness of standard CBT treatments in the research due to a smaller volume of research studies and the use of less robust research methodology (Kishita & Laidlaw, 2017). The suitability of compassion-focused interventions for older adults is very unclear, mainly due to lack of relevant research. Currently the only CFT research conducted with an older adult clinical sample was a study of CFT for couples experiencing dementia, which found improvements in anxiety, mood, and self-compassion for both the patients and their spouses (Craig, 2018). Additionally, one study has shown that older adults from the general population who have a higher level of self-compassion have better psychological wellbeing, and that self-compassion moderates the association between health and symptoms of depression (Homan, 2016). Therefore, increasing self-compassion may be beneficial in improving mood, anxiety, and wellbeing in older adults.

Developing and Evaluating Complex Interventions

The Medical Research Council's (MRC) 'Developing and Evaluating Complex interventions framework' lays out guidance on the process of the feasibility/pilot stage of researching interventions (Craig *et al*, 2008; Lancaster *et al*, 2004). There are generally four stages to development of an intervention: developing the intervention, feasibility/pilot stage, evaluation stage, and then implementation stage. The feasibility/pilot stage of intervention testing can provide information on the acceptability of the intervention, the level of recruitment and retention, the sample size required for research, the acceptability of measures and to understand how the intervention effects change, (Craig *et al*, 2008). This is done before intervention is evaluated fully in a clinical trial. Process evaluation is useful for understanding how interventions work in clinical practice and to consider the mechanisms of change (Moore, et al, 2015). Given the sparse literature addressing psychological therapies for older

adults despite high levels of need, there is a strong justification for applied research developing and evaluating new psychological therapies. Using the MRC framework as a guide, studies that attempt to specify potential therapeutic change mechanisms and early phase clinical trials are needed.

Aims

The primary aim of the current study is to explore the feasibility and acceptability of delivering a CFT group intervention for older adults referred to a CMHT. Secondary aims are to evaluate recruitment and retention of participants, evaluate acceptability of outcome measures, describe potential mechanisms of change involved in a CFT group intervention and evaluate any change in psychological wellbeing following the group intervention.

Methods

Design

This research employs a mixed methods design, consistent with the feasibility stage of the MRC Complex Interventions framework (Craig et al, 2008). There is no control group as the focus of the research is to gather feasibility information of a CFT intervention with older adults referred to a Community Mental Health Team (CMHT). Questionnaire data will be collected pre-group, during the group and post-group. Qualitative data will be collected following the group intervention in the form of semi-structured interviews.

Participants

Participants were eligible to participate if they were aged over sixty years old, experiencing significant symptoms of anxiety and/or depression that warranted referral to NHS Greater Glasgow & Clyde Older Peoples CMHTs within South Health and Social Care Partnership and East Renfrewshire Health and Social Care Partnership. Patients experiencing psychosis, cognitive impairment, current addiction, or risk of self-harm were excluded. As CFT is a

transdiagnostic treatment model, participants with a variety of mental health diagnoses were eligible, but most had anxiety and depression.

Sample Size

No *a priori* sample size was calculated, in keeping with the standard goals of feasibility studies to examine effect sizes that can be used to estimate sample sizes for future studies (Lancaster, et al., 2004). Julious (2005) suggests 12 participants per group is optimal. The present study aimed to recruit two groups of 12 participants. With the option of another group if recruitment did not meet this target of 24.

Procedure

Ethical Approval

Ethical approval (Reference: 19/ES/0043) was granted by East of Scotland Research Ethics Service on 24th May 2019. NHS Greater Glasgow & Clyde Clinical Research and development approved the project on 6th June 2019 (Appendix 2.1, 2.2 & 2.3). The study was pre-registered on clinicaltrials.gov (Identifier: NCT04039542).

Recruitment

The lead clinician (Principal Clinical Psychologist) approached staff members of the South Glasgow and East Renfrewshire Older Peoples Mental Health Team to advise them of the study. The staff were advised via multidisciplinary team meetings, emails, clinic room posters and discussions (Appendix 2.11). The lead clinician contacted potential participants and invited them to meet for an initial assessment. At assessment, the suitability of the CFT group intervention for the patient/potential participant was considered and if participants met inclusion criteria they were asked if they would like to participate. Participants were given the opportunity to participate in the group separately from participating in the research. They were informed that if they were also willing to participate in the research, they would be invited to meet with the lead researcher to discuss the project, ask questions and give written

informed consent. Participants were asked to complete the pre-intervention measures at this meeting if appropriate or prior to the group starting.

CFT group

The group consisted of ten 90-minute sessions delivered weekly, facilitated by a Cognitive Behavioural Therapist and a Clinical Psychologist experienced in the delivery of CFT. A CFT protocol for older people was developed by the Clinical Psychologist, with input from a Clinical Psychologist experienced in CFT. Participants were provided with a workbook covering the ten sessions and a CD of audio exercises used both in session and as homework practice. The sessions delivered can be found in Table 4. Participants were also asked to practice homework tasks to support their learning.

Table 4

CFT Session content

Session	Session Content
1	Introduction - soothing rhythm breathing and mindful check-in
2	Psychoeducation – understanding thoughts and emotions
3	Psychoeducation – introduction to CFT 'three systems'
4	CFT formulation
5	CFT formulation & the threat system – learning how to notice thoughts
6	Compassionate-self – what it is and learning how to cultivate compassion for self
7	Compassionate image and barriers to compassion
8	Multiple selves – angry self, anxious self, sad self, and compassionate self
9	Shame and Self-Criticism – functional analysis
10	Review and planning ahead

Measures

All measures administered were self-report measures. Participants were offered support to complete them if required.

Clinical Outcome Measures:

Patient Health Questionnaire (PHQ-9) (Spitzer, Williams & Kroenke, 2001) – A 9-item measure of depressive symptoms with an internal consistency of .89.

Generalized Anxiety Disorder (GAD-7) (Spitzer, Kroenke, Williams & Lowe, 2006) – a 7-item measure of anxiety symptoms with an internal consistency of .92.

Mechanisms of Change Measures:

Forms of self-criticising/attacking & self-reassuring scale (FSCRS) (Gilbert et al, 2004) – A measure of self-hatred, self-inadequacy, and self-reassurance. Used to evaluate the level of self-criticism a person experiences, along with the level of ability to reassure oneself. Internal consistency for the subscales; inadequate self .90, hated self .86, and reassured self .86.

Self-compassion scale (SCS) (Neff, 2003) – A measure of a person's ability to show themselves compassion. Six paired subscales: self-kindness – self-judgement; common humanity – isolation; mindfulness – overidentification. Internal consistency reported as .93.

Toronto Mindfulness Scale - Trait (TMS-T) (Davis et al, 2009) – A measure of mindfulness traits with two subscales: curiosity and decentring. Internal consistencies; curiosity .91 and decentring .85.

Other as Shamer Scale (OAS) (Goss et al, 1994) – A measure to evaluate external shame. Internal consistency reported as .92

Social Connectedness Scale – Revised (SoConS) (Lee & Robbins, 1995) – Evaluate people's feelings of connectedness to others. There are three factors: connectedness, affiliation, and companionship. Internal consistency reported as .92.

Measures were administered prior to the start of the intervention, then each measure was administered at one time point during the intervention and then again following the intervention. To evaluate the mechanisms of change; the *FSCRS, OAS, SoConS, SCS, TMS-T* were given after certain sessions when these specific processes were targeted in the session content to assess any change from a specific intervention. Details on which session measures were delivered and length of time to complete the measures is provided in Appendix 2.4.

Data Analysis

Quantitative Analysis

Given the small sample size for outcome measures, descriptive statistics were used. Medians and interquartile ranges are presented to describe patterns of measures of central tendency and distribution.

To assess for clinically significant change for each participant, Reliable Change Index (RCI) scores were calculated on the mental health measures (PHQ-9 and GAD-7). The formula used to calculate RCI (Evans, Margison, & Barkham, 1998) was:

$$RCI = \frac{X_2 - X_1}{S_{1\sqrt{1 - r_{xx}}}}$$

(Where X_{1} = baseline score, X_{2} = post-intervention score, S_{1} = standard deviation at baseline, r_{xx} = internal reliability of the measure).

Internal reliability calculations were based on estimates in the literature investigating older adult mental health:

- PHQ-9: Zhang et al (2020; $\alpha = 0.725$)
- GAD-7: Wild et al (2014; $\alpha = 0.82$)

Qualitative Analysis

Following the completion of the group, all participants were invited to complete a semistructured interview, guided by a Topic Guide, to discuss their experience (Appendix 2.5). The interviews were conducted by a Trainee Clinical Psychologist (writer) or a Clinical Associate in Applied Psychology from the Older People's Clinical Psychology Service, neither of whom delivered the intervention. The interviews were recorded and transcribed, and all patient identifiable data were anonymised. Interviews were analysed using 'Nvivo 12 Pro' software. The interviews were analysed using reflexive thematic analysis following the six-stage process of Braun and Clarke (2006). This approach was used as it is an accessible approach to qualitative analysis and it is not wedded to any pre-existing theoretical frameworks (Braun & Clark, 2012).

An inductive approach was used in the generation of codes, subthemes, and themes from the data. Stage one was to become familiarised with the data by listening to, transcribing, reading, and rereading the transcripts several times. The second stage involved generating initial codes of the data set and the third stage was to search for themes in the codes. In stage four the themes were reviewed and checked with the coded extracts. The fifth stage was to define and name the themes. Finally, the themes were refined and reported on. Preliminary themes were reviewed by a senior researcher to check on data interpretation.

Reflexivity

Researcher reflexivity is a key aspect of qualitative analysis, the process of reflection facilitates a deeper understanding of the impact of the researchers own beliefs on the data. (Finlay, 2002). In the present study the lead researcher utilised reflective writing in the interview, transcription, and analysis stages of the process. The lead researcher is a Trainee Clinical Psychologist with previous experience working psychologically with older adults in a mental health setting. This previous experience allowed for a deeper understanding of the

issues faced when utilising psychological therapies within this population. These biases were reflected upon during the interview process and in understanding the data.

Results

Two groups were originally planned for delivery in 2019, with the potential for a third group in 2020 if the recruitment target was not met. Thirteen individuals participated in the first two groups starting in June and September 2019. Given prior sample size goal of 24, a third group was planned for 2020. However, the COVID-19 pandemic meant that the third group did not run. All analysis is from data collected on the first two groups collected prior to the pandemic.

Recruitment

Recruitment was via the Community Mental Health teams referring to the Clinical Psychologist in the service. See Figure 4 for participant flow.

Sample Characteristics

In total 13 participants participated in the group intervention: 5 in the first group and 8 in the second group. Of the 13 participants 3 did not consent to participate in the research and complete questionnaires and an additional 1 did not consent to participate in the interviews following the group. Nine of the 10 who consented to participate in the research were female. The age range of participants was 65-83 with a mean age of 72.5 years. Table 5 details the diagnoses that participants were referred with and table 6 details the professionals that referred into the group.

Figure 2

Participant Flowchart



Table 5

Participant diagnoses

Diagnosed Mental Health Condition (ICD-11 diagnoses)	Number of participants
Generalised Anxiety Disorder	1
Recurrent depressive disorder	1
Mixed depressive and anxiety disorder	1
Anxiety or fear related disorders, unspecified	5
Depressive disorders, unspecified	5

Table 6

Professionals that referred participants

Referrer	Number of
	participants
Community Psychiatric Nurse (CPN)	5
Psychiatrist	7
Occupational Therapist	1

Attendance rates

Thirteen participants started the groups, 2 (22.2%) attended all ten sessions, 5 (55.5%) attended 9 sessions, 2 (22.2%) attended 8 sessions, 1 (11.1%) attended 6 sessions, 1 (11.1%) attended 4 sessions and 2 (22.2%) attended 1 session. Reasons for missing sessions and non-attendance were holidays, appointments, family illness, undergoing an operation, worsening mental health and anxiety about group attendance.

Group completion rates

Of the 13 participants, 12 started the group at the first session. One participant missed the first session due to being on holiday but started at session 2. In the first group, 2 participants

(40%) completed 6 or more sessions and in the second group 8 (100%) completed 6 or more sessions. Combined 77% completed 6 or more sessions.

Outcome measures completion rates

Of the 13 participants, 10 consented to completing outcome measures. Data on outcome measures are based on those 10. Figure 5 shows the completion rate for outcome measures at the three time points, pre-group, during group and post-group. The completion rates dropped off throughout the group from the pre-group completion. The questionnaires that had the poorest completion mid or post group were the Forms of Self-Criticism/Self-Attacking and Self-Reassurance Scale, the Self-Compassion Scale, and the Toronto Mindfulness Scale - Trait.

Figure 3



Outcome Measures Completion Rates

Abbreviations: PHQ-9: Patient Health Questionnaire 9; GAD-7: General Anxiety Disorder 7; FSCRS: Forms of Self-Criticism/Self-Attacking and Self Reassurance Scale; OAS: Other as Shamer Scale; SCS: Self-Compassion Scale; SoConS: Social Connectedness Scale; TMS-T: Toronto Mindfulness Scale - Trait

Quantitative Analysis

Given that this study was a feasibility study, it was not powered to detect change. Descriptive statistics regarding change are presented to show the changed in outcome measure scores pre-(Time 1), during (Time 2) and post-intervention (Time 3). See Table 7 for descriptive statistics including medians and interquartile ranges for outcome and mechanism of change measures across time points.

Table 7

Measure	N	Time 1 Median (IQR)	Time 2 Median (IQR)	Time 3 Median (IQR)
PHQ-9	6	15 (8-18)	10.5 (4.5-18.5)	14 (5-16)
GAD-7	6	13.5 (10-17)	7 (2-14.5)	12.5 (8-14)
FSCRS				
Inadequate Self	6	24 (15-29)	22.5 (10-29)	21 (17-26)
Reassured Self	6	16 (13-16)	14 (11-17)	12.5 (15.25)
Hated Self	6	5 (3-8)	8 (4-13)	6.5 (2-12)
OAS	6	21 (5-43)	11 (2-31.5)	30.5 (10-39)
SCS				
Self-kindness	6	11 (8-12)	12 (10-16)	11.5 (6-14)
Self-judgement	6	11.5 (7-14)	13.5 (7-14)	10.5 (6-15)
Common humanity	5	12 (11-13)	12 (8-12)	11 (9.5-16.5)
Isolation	6	7 (5-14)	11.5 (6-16)	7.5 (6-10)
Mindfulness	6	11 (10-13)	11.5 (11-13)	9 (6-14)
Over identified	6	10 (5-14)	8 (6-12)	8 (5-9)
Total	5	58 (54-84)	65 (48-89)	58 (42-68)
SoConS	6	31 (20-37)	34 (25.5-39.5)	25.5 (19-39)
TMS-T				
Curiosity	6	13 (9-18)	17 (6-17)	17 (10-24)
Decentring	5	15.5 (11-20)	15 (13-16)	16 (12-21)

Statistical Analysis of Outcome Measures

Abbreviations: PHQ-9: Patient Health Questionnaire 9; GAD-7: General Anxiety Disorder 7; FSCRS: Forms of Self-Criticism/Self-Attacking and Self Reassurance Scale; OAS: Other as Shamer Scale; SCS: Self-Compassion Scale; SoConS: Social Connectedness Scale; TMS-T: Toronto Mindfulness Scale - Trait

Table 8

Reliable Change Scores

Measure	Rel	Mean	SD	P4		P5			P7			
muuburu	ne <i>r</i>	moun	i SD	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI
PHQ-9	0.725	13.67	7.23	21	15	-1.58	15	13	-0.53	2	5	0.79
GAD-7	0.82	13.83	3.43	16	14	-1.37	11	8	-2.06*	12	14	1.37
14	D /		(D)		P 8			P11			P12	
Measure	Rel	Mean	SD	Pre	P8 Post	RCI	Pre	P11 Post	RCI	Pre	P12 Post	RCI
Measure PHQ-9	Rel 0.725	Mean 13.67	SD 7.23	Pre 18		RCI -0.53	Pre 8		RCI -1.85	Pre 18		RCI 1.32

Notes: Reliability was taken from older adult population for RCI calculations. Mean and SD were taken from baseline scores. Lower scores on both measures indicates improvement. * < -1.96 or > 1.96 significant at 0.05.

Reliable Change Index (RCI) scores were calculated for mental health outcome measures for individual participants (Table 8). These suggest that three of the six participants showed an improvement in anxiety from pre- to post-intervention. However, no significant change was found for any participants in mood. These patterns are treatment signals worthy of further investigation.

Sample size estimation

An aim of the current study was to estimate the sample size needed for a larger trial. Given the main outcomes of a mental health treatment would be improvements in mood and anxiety, changes on the PHQ-9 and the GAD-7 would be useful to define significant effect. In terms, of depression, none of the participants in this study moved from above the clinical range to below the clinical range (Kroenke et al, 2001). In terms of anxiety, Spitzer et al (2006) suggest a score of above 10 is within the clinical range. In the present study two of the six participants had a significant reduction in anxiety and moved from the clinical to non-clinical range. Due to a low sample size and only two participants having meaningful clinical change in anxiety effect size estimates should be investigated in later studies.

Qualitative Analysis

Semi-structured interviews were analysed using Thematic Analysis (Braun & Clark, 2006). The topic guide offered some basis for the themes expected from the analysis and some unanticipated themes emerged.

Sample characteristics

Seven participants attended interviews; all had completed over 50% of the sessions. One participant was male, and the remainder (n=6) were female. Two had participated in the first group and five in the second group. Two participants of the nine who consented were unable to schedule interviews.

Reflexivity

Five of the seven interviews were carried out by another researcher due to the lead researcher being on maternity leave. Although both researchers followed the same topic guide

(Appendix 2.5), there were differences in the style of interview. In reflecting on the process, similar themes emerged from the data, and it became apparent that the topic guide led the process. Notes from the interview and transcription phase were that participants seemed more able to be honest about the more negative experiences given the facilitators were not present.

Thematic Analysis

Four themes and twelve subthemes were identified, highlighted in table 8. The themes are further discussed and illustrated with extracts from the interviews.

Table 9

Themes	Subthemes				
Engagement in Learning	Struggling to understand				
	Working hard to learn				
	Challenges of implementation at home				
CFT Mechanisms	Compassion for others				
	Mindfulness practices				
	Supporting new awareness				
	Outcomes				
The Value of Group Dynamics	Facilitators				
	Enhancing mutual learning through discussion				
	Mutual acceptance leading to safety				
Helping Others Through Research	Research participation				
	Difficulties with questionnaires				

Thematic Analysis Themes and Subthemes

Theme 1: Engagement in Learning

Struggling to understand

There was a general sense that many participants struggled to engage with the concept of compassion. This seemed to relate to having little previous experience of the concept, particularly in relation to both their mental health and in applying compassion to themselves.

and another said:

"I had to sort of say to [facilitator 1], oh what's this compassion, that bit I really don't quite understand" (Participant 8, Line 79).

Another participant found they had difficulty in relating how the compassionate element affected their mental health.

"I mean compassionate self isn't a hard concept to understand em but in relation to yourself and the situation you're in, yeah I think it is quite a hard concept to you know focus on" (Participant 9, Line 199).

They went on to say that this was something that they were better able to grasp in later sessions and developed some insight into the impact on their mental health.

"Probably until the last two or three sessions I think I struggled with it." (Participant 9, Line 215).

One participant struggled to integrate the idea of compassion towards self as opposed to compassion for others.

"I understood it a little bit, but em not a lot but I understood it a little bit em more, but I always thought compassion was for what you give for other people" (Participant 16, Line 184).

Working hard to learn

There was a sense that the psychological model was a challenge in addition to the concept of compassion being difficult to grasp. Several the participants spoke of many years of psychiatric involvement and the medical model appeared entrenched in their ideas of their own mental health. Previous psychological involvement appeared to bridge some of that gap in understanding for those who had experienced it.

A few of the participants noticed a struggle to follow the psychoeducation side of the group.

"I found it a wee bit hard sometimes to take it in" (Participant 7, Line 98).

"It took me, yes em, eh there was quite a bit of concentration involved" (Participant 5, Line 133).

One participant felt that they should have known some of the work being taught in the group given their previous profession. There was a sense of shame at not knowing.

"I was a wee bit disappointed in myself that I didn't pick up, cos I was, I used to be quite a smart cookie" (Participant 5, Line 141).

However, some participants did find the material useful and were able to understand it and incorporate that knowledge into their life. One participant who had participated in other therapy groups discussed how the psychoeducation was different. On being asked what was most difficult, they said:

"Em, I think probably the first couple of sessions, just getting into the way of the ... different em descriptions of feelings and how they're put into groups. I think getting used to that em but after about two sessions and then reading at home... the book that we had to start with then it all started to sound familiar." (Participant 12, Line 156).

A further challenge to learning that became apparent were some age-related difficulties; memory and new learning can be harder for older adult populations. When asked what part of the group one participant found most difficult, the noticed it was their struggle to remember the tasks:

"I think it was following through the things after I'd left the group...I think it was just my memory, you know trying to remember, eh what we were doing" (Participant 7, Line 153).

Challenges of implementation at home

One area that many of the participants described struggling in some way was implementing the techniques learned in sessions to their day-to-day life. There were a variety of reasons for this. Some participants found the volume of work too demanding and there was a sense that it was overwhelming to even know how to start the work.

"You know because that book is like a bible, it's got so many pages in it and I've got things like that at home from way back, to be honest I didn't read it terribly much" (Participant 8, Line 497).

However, another participant noted that having the workbook was helpful at home,

"Afterwards, I put it down, it... you could read it at your own pace and then relate to what had been said and it all fell into place for me quite, you know easily" (Participant 12, 189).

One person explained that they didn't do any of the work at home,

"I didn't keep a journal and I didn't do any of the worksheets, the only thing I did was the questionnaires, em so I can't really say, I can't voice an opinion on that because I really didn't do any of the tasks, I mean mindfulness... unfortunately I didn't play those at home because I don't have a CD that's working at the moment" (Participant 9, Line 270).

Some participants were able to apply the tasks to their home life and this seemed to be done in varying degrees. One participant found the tasks relatively easy to complete at home, which seemed to be related to previous psychological work they had done. When asked if there were any difficulties in incorporating tasks into day-to-day life said:

"I didn't honestly work very hard to do them, which for me was good". (Participant 12, Line 315)

Participant 12 also reflected on the similarities to a previous group they had done on mindfulness and that experience supporting their experience of the CFT group.

"I've been to another mindfulness em class, but it wasn't compassion based.... there were some similarities to it, ... coming to this group made me realise how I don't have to think about certain things that I, that I'm going to do or try to do for my own wellbeing, it's, I'm automatically doing it" (Participant 12, Line 252).

This reflected a general trend in the group, people who had previously done some psychological work found engagement in the work of the group easier than those with no prior experience.

Theme 2: CFT Mechanisms

Compassion for others

One mechanism of CFT is developing compassion for others and in the group setting this allowed for that direct experience of giving compassion to others. One participant described feeling surprised by their experience.

"I thought I had lost being compassionate, I thought for a long time, ... I've no compassion left but listening to [facilitator 1] and then listening to these other people, I felt a great compassion." (Participant 5, Line 624).

The group process appeared to facilitate that experience. The shared understanding of mental health difficulties amongst the group members was apparent. That combined with the CFT teaching appeared to allow for compassion to flow amongst the group. Many participants described feeling an increased awareness of how those around them may be feeling in general.

"em we all sort of stand in the queue and think about the people in front of us or taking too long or whatever and we don't really appreciate that they've maybe got problems that we don't even know about or you know would find really hard to deal with sort of thing and I think you have tae em sort of stand back from yourself and you know try and be a bit more thoughtful and considerate and compassionate" (Participant 9, Line 139). There was a sense from participants of increased awareness of their own feelings and response to other people. Although some noticed challenges in implementing compassion towards themselves and found it easier to direct compassion towards others.

"I don't know about eh whether I would still be that same person, I think it does help you to be more compassionate towards other people, I can't say I'm more compassionate to myself, but I don't find lately I've had the same kind of change of emotions" (Participant 7, Line 394).

Mindfulness practices

Most participants discussed feeling a benefit from the mindfulness practices. Some only managed the practice during the sessions and some were able to add in some home practice. It appeared to be the most often utilised task. There was a sense that the guided element of the mindfulness tasks was beneficial. Several of the participants pinpointed the mindful check in at the start of the session as something they found particularly engaging and useful.

"I did always enjoy at the beginning ... where you had your ... checking in with your mind and body in a sort of meditation form ... I always enjoyed that and ... it really em prepared me for the rest of the session" (Participant 12, Line 33).

One participant reflected on an awareness of how their body was feeling during the mindful check in at the start of the sessions.

"You realise just how busy, or how kind of full... your mind was before ... the contrast between how you feel physically and emotionally, just for that few minutes. And you ... just think, I was so tense before". (Participant 4, Line 365).

One participant found the mindful check-in at the start of the session the hardest part, this appeared to be due to having to notice some challenging feelings.

"See the listening to the tape at the beginning, em I know I find that difficult, em my concentrations not good so I find it a bit difficult, and em although you didn't need to,

your, close your eyes and you, I didn't do that, because I don't like that" (Participant 16, Line 108).

Another participant noticed that the mindfulness practice became easier in later sessions, which appeared to be related to feeling safe within the group.

"It was a wee bit different, I managed to get, meditate a wee bit more towards the last couple of sessions (Participant 8, Line 106).

Supporting new awareness

One participant noted the relationship to their own feelings and the CFT three systems model and felt awareness of this developing.

"Feels like you're under threat all the time, the thoughts and your mind is just constant, so the one thing that em just gets pushed out of the system of the three is the one that you really need.... I mean that, that to me that was interesting that kind of balance." (Participant 4, Line 788).

On discussing learning about how the mind and body are connected in CFT, one participant said:

"It was very em quite enlightening, you know, and it also made sense, you know from my own experiences with my mind and my body em, reactions to certain things etc" (Participant 12, Line 20).

This theme was only described by two people both of whom had done previous psychological work. That awareness appeared to be in addition to their previous learning.

Outcomes

The outcomes within the group were varied, most people took very individual things away from the group. There was a sense that just being part of a group was beneficial. One participant noticed an increased confidence in speaking up with friends. *"I feel more confident doing it now because of some of this stuff"* (Participant 5, Line 416).

There was also a sense that some people noticed changes but were unable to pinpoint what that change was. When asked how things have been different since the group, one participant said:

"Eh I just feel more not so uptight all the time and eh I think the... notes of compassion made me think more about that and made me challenge things a wee bit more" (Participant 7, Line 367).

Another noticed small changes in cognitive processes that helped:

"Small shifts, small movements are just... really important to you, and even at the end of it you felt, even that your mind has shifted slightly, you feel it's something positive, something that you know you might be able to build on" (Participant 4, Line 890).

Another person noticed:

"I think I'm calmer, I don't get as frustrated and I don't seem to get as angry as I did before, em I think I'm probably coping better with most of my life and eh more relaxed about it" (Participant 9, Line 479).

Despite some struggles with the concepts delivered in the materials, there was a strong general sense that the group was beneficial to people and that most did feel some improvement in their mental health following it.

Theme 3: The Value of Group Dynamics

All participants talked about the experience of the group as beneficial and there was a strong theme of feeling heard by others and feelings that it was safe space to express themselves. <u>Facilitators</u>

All the participants gave feedback that they had a positive experience with the group facilitators. Participants described a felt sense of safeness with the facilitators and the
characteristics that came across in the interviews were the facilitators were kind, gentle, interested in their experience and listened to the participants.

"It was just, it was a nice group and I think... [Facilitator 1] himself just got such a nice manner, I think that makes the difference" (Participant 8, Line 890).

"I'd like to say that the professionals ... at this particular ... group, I found particularly... nice, and understanding and compassionate ... and I just want to say thank you to them" (Participant 12, Line 684).

"[Facilitator 1] helped ... he explained everything, and you know, you didn't feel silly... if you wanted to say something... you didn't feel stupid". (Participant 16, Line 57).

"It was definitely [Facilitator 1] and [Facilitator 2], I think... I think that it's important to have em facilitators, ... you know you know you feel are genuinely willing to listen" (Participant 4, Line 90).

This was the strongest theme from the analysis that the facilitators had a large positive impact on people's experience within the group.

Enhancing mutual learning through discussion

Several participants mentioned that they found others asking questions was beneficial. Others asking questions appeared to facilitate two functions; finding out information that they wanted to know but also allowing that space to not know things and feel safe in asking questions for themselves.

"Other people speaking or asking questions, helped me to think oh I might have asked that myself so the information ... made it more relaxing ... for me as an individual not to have to remember, oh I must ask this, I must ask that" (Participant 12, Line 385).

"Being part of the group allowed you to maybe discuss things that maybe weren't making sense" (Participant 9, Line 456).

Mutual acceptance leading to safety

Every participant talked about feeling a sense of support from the group. There was empathy displayed between group members and this seemed an important factor in all their positive experiences in the group.

"I found it fine, I like being part of a group rather than a one to one, ... I'm not good at feedback or anything like that, or saying how things are eh for me, at times, I like being part of the group where you didn't feel you had to speak out, but you were free to speak out" (Participant 7, Line 298).

One participant talked about the importance of feeling listened to.

"We all, as a group in general, like the other 7 people that were with me, em I found them all very em respectful, attentive eh there was a lot of em, everybody listened to everybody" (Participant 12, Line 428).

Many of the participants discussed feeling at ease in the group and able to be open without feeling that they had to speak.

"Without knowing anybody... got the feeling that everybody was listening and that sort of relaxed me quite a bit, ... we were able to speak if we wanted to" (Participant 12, Line 69).

Some participant described feeling a sense of safety amongst others who also had mental health problems, a shared understanding of their difficulties.

"Could feel there was, kind of empathy, between, the... the three of us, em.... I could see that we were all ... looking for the same thing... having depression and having problems" (Participant 4, Line 29). One participant in the smaller group, was aware of experiencing compassion from another participant. This appeared to be quite a powerful feeling for the person and lead to a sense of safety and connection within the group.

"I was very much aware of [xxx's] compassion to me" (Participant 5, Line 799)

On sharing a difficult story with the group, this participant then went on to say:

"It made me feel good, somebody had that towards me ... she was just straight in, holding my arm, that did impact me, that somebody could show me that" (Participant 5, Line 824).

This was the only participant to specifically mention experiencing compassion from others within the group, but others talked more generally about feeling safety and feeling heard within the group.

Theme 4: Helping others through research

Research participation

All the participants were asked their thoughts about participating in research, of those that were interviewed all expressed feelings of wanting to help and that it would be of benefit to others to participate.

"I never really thought about it I don't think of it as anything... I think research is em something that has tae happen if things are gonnae progress... if this sort of group helps people in the same situation as myself and it can be improved or whatever then I'm all for it, that's em something that I would think is worthwhile" (Participant 9, Line 498).

One person described a desire to find something that would help their mental health.

"I think doing the research is good... it would be good if they could find something that would help" (Participant 8, Line 1267).

This theme was strong across all participants. It is of note that there were people who did not consent to participate in the research but did participate in the groups. Therefore, the research sample is perhaps biased towards those who want to participate in research.

Difficulties with questionnaires

There was a sense of negativity towards completing the questionnaires. Most found them challenging or did not like doing them. This links in with the low level of completion data, with only five participants of ten completing all the pre to post outcome measures.

"I didn't mind completing them cos I realised it's for research and they want to know how you feel, that's why I was being honest and saying I did find them difficult ... I just answered them as honestly as I could, but I did think they were difficult" (Participant 8, Line 1124).

One participant struggled, thinking that answers would be different on different days.

"Em like most questionnaires I feel the same question is asked in different forms throughout, different ways worded, worded in different ways throughout the questionnaire, maybe twice three times or whatever ... I don't like it... I think depending on how you feel, day to day depends on how you fill in the questionnaire" (Participant 9, Line 522).

There was also a sense of fatigue at questionnaires and the volume of questionnaires asked of them generally:

"I think it's (laughs) I just feel like life is filled with questionnaires at the moment... and I just havnae got a lot of time for them" (Participant 9, Line 561).

"I don't like the questionnaires, em, although I think I filled in all the ones I was asked for except for the last ones I was given" (Participant 9, Line 37). The questionnaires were poorly received by most of the participants, there was a sense that there were too many questionnaires. Also, some of the questionnaires people appeared to find quite long and the questions challenging. This seemed to be focused more on the CFT outcome measures which involve more effort and time to complete.

Discussion

The primary aim of this study was to investigate the feasibility of a CFT group for older adults experiencing problems with depression and/or anxiety. In line with the *MRC Complex Interventions Framework* (Craig et al, 2008), the feasibility stage provides information that can inform a full-scale trial. This study focused on the questions of whether it was possible to recruit participants, retain participants in the intervention and assess participants via outcome measures. There was an additional aim to explore symptom focused outcomes and putative mechanisms of change. Participant's views were obtained to gain their perspectives of the intervention.

Recruitment

Twenty participants were referred to two groups and the recruitment period for each group was one to two months from a CMHT consisting of approximately 78 team members serving a population of approximately 51,500. It was not possible to determine how many potential eligible participants there were. Recruitment to the group proved challenging and in reflecting with the Clinical Psychologist who led the intervention, there appeared to be difficulties initially in CMHT staff finding suitable participants and difficulties in keeping the group in mind when planning treatment. Given that the second group had a higher referral rate, it is possible that CMHT staff were likely to refer once the group was available and visible a treatment option. Normalisation process theory (NPT) suggests that there are factors needed in the implementation of new interventions into routine practice (Murray et al, 2010). Referrals to the group require staff to understand and explain the treatment and to understand

the need of the intervention. It is possible, especially in the early stages of implementation that the perceived need of the intervention was low, resulting in less referrals.

Five people did not attend the assessment appointment, with no reasons given. A further two were not recruited from assessment, one chose not to do any psychological therapy at that time and the other was not interested in group therapy. Of note, several of the participants spoke of their longstanding psychiatric treatment but very few had previously engaged in psychological therapy. The findings from this study suggest that referrals to a CFT group in an older adult community mental health setting could be challenging, increasing awareness, and understanding within the CMHT may be beneficial.

Retention

Overall, the groups had an attrition rate of 23% (n=3). Reasons for dropout were that one required an operation, and two dropped out as their mental health prevented them from attending. As with recruitment, the second group was more successful at retention than the first, with all eight participants completing the group. In the first group that ran, three of the five participants dropped out of treatment. Overall, of those who did complete the group there were very few missed sessions (13%), this fits with findings that older adults are more likely than working age adults to complete therapy (Chaplin et al, 2014) and that therapy attrition rates are lower in older adults (Saunders et al, 2021). Where possible participants were given a chance to meet with the group facilitator to catch up on what was missed which, was well received within the group. The one participant who had consented to interview but dropped out was invited to share their views in the post-intervention interview, however declined due to worsening mental health. The present study indicates that over-recruitment to future research groups would be required.

Outcome Measures and Research

Participation in the research element of the project appeared well received, with some participants stating they would like to be involved to "help out" in principle. However, the

questionnaires were not well received, and completion of the final measures was low (60%). Of note, two people who completed the group did not consent to complete the final set of measures due to finding them too much work. The subtheme '*difficulties with questionnaires*' suggests that participants found them onerous and there was some struggle with conceptualising some of the questions. On reflection with the lead facilitator, it was noted that more help was offered to understand the 'Toronto Mindfulness Questionnaire – Trait' (TMS-T) and it was this questionnaire that one participant missed 5 questions. The perceived relevance of the measures may have been a factor in decisions to complete or not complete questionnaires. Future research may find benefit in reducing the number of outcome measures used to minimise data loss through fatigue from questionnaires.

Change Indicators

Thematic analysis indicated that the people's sense of safety in the group and felt sense of compassion from others in the group improved. There was also a sense of becoming aware of compassion towards others and being less reactive. It is possible that from the intervention participants learned to increase self-compassion and through the feeling of safety in the group, they found it easier to give and receive compassion, which in turn may have reduced external shame and anxiety. Interestingly, the subtheme '*Mutual acceptance leading to safety*' showed that the social connectedness of the group was important. It would be useful to investigate these mechanisms further and investigate change at different time points during the study. Little research has been carried out into the mechanisms of change in CFT, as highlighted in the previous chapter.

The CFT group was very positively received by all participants who were interviewed, however there is little evidence that it was the CFT components that related to their enthusiasm. The participant's enthusiasm may be related to psychological therapy core components, such as feeling heard, being able to speak about their experiences and interacting with kind-others. Six of the seven participants found the meditation useful, however only two

continued to practice outside of the sessions. The CFT psychoeducation material appeared to be variable in terms of how well people understood and remembered it. Thematic analysis suggested that often people were unsure of how to apply CFT to their daily lives. It was also identified that people who had previously experienced some form of psychological therapy found the CFT material easier to grasp and appeared to apply the principles in their daily life more effectively. Future research might look at the possibility of simplifying the material or having a CFT group following psychological work that focus on a person's thoughts. Additionally, the analysis showed that participants found having the opportunity to ask questions and have discussions with the facilitators helped to internalise the lessons learned. Reflections from the lead facilitator were that it may be useful to allow more time for discussion on what compassion is and the different ways it can be practiced facilitating integration into participant's lives. It was noted that later sessions could be a chance to reflect and consolidate previous learning rather than continuing with the introduction of more content.

Strengths and Limitations

This study utilised a mixed methods analysis to evaluate a CFT group intervention for older adults. This approach allows for participants' experiences of the intervention to be understood alongside the quantitative data. A limitation of this study was the low sample size, with initial recruitment being problematic. It would have been useful to run the third planned group to further evaluate recruitment and add to the sample size. We cannot tell if the pattern of recruitment, retention and data loss will generalise to another sample. An additional limitation was in the thematic analysis there was no earlier independent review of codes to check on reliability in the early stages of analysis.

Future Research

Future research could investigate further the barriers to recruitment from a CMHT as recruitment to the present study was a challenge initially. Additional awareness raising and

promotion within the team may be of benefit. Another aspect that would be useful for future investigation would be the reduction of outcome measures given the negative response to the volume of outcome measures used in the present study.

Conclusions

As this study was a feasibility study, the data can be used to inform choices about the next stage of research. The present study is unclear as to whether a CFT group is feasible and acceptable to an older adult population within a mental health setting. Further research is needed to evaluate the effectiveness of the intervention. The present study also suggests refinements to the protocol to make it more adaptable to the older adult population. Further consideration should be given to reducing the number of outcome measures delivered. There was generally a positive attitude to participation, which is promising for future research.

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Appendices

Appendix 1.1 Author Guidelines for Mindfulness Journal Aims and scope

Mindfulness seeks to advance research, clinical practice, and theory on mindfulness. It is interested in manuscripts from diverse viewpoints, including psychology, psychiatry, medicine, neurobiology, psychoneuroendocrinology, cognitive, behavioral, cultural, philosophy, spirituality, and wisdom traditions. *Mindfulness* encourages research submissions on the reliability and validity of assessment of mindfulness; clinical uses of mindfulness in psychological distress, psychiatric disorders, and medical conditions; alleviation of personal and societal suffering; the nature and foundations of mindfulness; mechanisms of action; and the use of mindfulness across cultures. The *Journal* also seeks to promote the use of mindfulness by publishing scholarly papers on the training of clinicians, institutional staff, teachers, parents, and industry personnel in mindful provision of services.

Examples of topics include:

- Mindfulness-based psycho-educational interventions for children with learning, emotional, and behavioral disorders
- Treating depression and clinical symptoms in patients with chronic heart failure
- Yoga and mindfulness
- Cognitive-behavioral mindfulness group therapy interventions
- Mindfulnessness and emotional regulation difficulties in children
- Loving-kindness meditation to increase social connectedness
- Training for parents and children with ADHD
- Recovery from substance abuse
- Changing parents' mindfulness
- Child management skills

• Treating childhood anxiety and depression

Instructions for Authors

Double-blind peer review

This journal follows a double-blind reviewing procedure. Authors are therefore requested to submit:

A blinded manuscript without any author names and affiliations in the text or on the title page. Self-identifying citations and references in the article text should be avoided.

A separate title page, containing title, all author names, affiliations, and the contact information of the corresponding author. Any acknowledgements, disclosures, or funding information should also be included on this page.

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink "Submit manuscript" on the right and upload all of your manuscript files following the instructions given on the screen.

Please ensure you provide all relevant editable source files. Failing to submit these source files might cause unnecessary delays in the review and production process.

Suggested Reviewers

Authors of research and review papers, excluding editorial and book review submissions, are allowed to provide the names and contact information for, maximum, 4 to 6 possible reviewers of their paper. When uploading a paper to the Editorial Manager site, authors must provide complete contact information for each recommended reviewer, along with a specific reason for your suggestion in the comments box for each person. The journal will consider reviewers recommended by the authors only if the reviewers' institutional email is provided. A minimum of two suggested reviewers should be from a university or research institute in the United States. You may not suggest the Editor or Associate Editors of the journal as potential reviewers. Although there is no guarantee that the editorial office will use your suggested reviewers, your help is appreciated and may speed up the selection of appropriate reviewers.

Authors should note that it is inappropriate to list as preferred reviewers researchers from the same institution as any of the authors, collaborators and co-authors from the past five years as well as anyone whose relationship with one of the authors may present a conflict of interest. The journal will not tolerate this practice and reserves the right to reject submissions on this basis.

Title Page

The title page should include:

The name(s) of the author(s)

A concise and informative title

The affiliation(s) and address(es) of the author(s)

The e-mail address, and telephone number(s) of the corresponding author

If available, the 16-digit ORCID of the author(s)

Abstract

Please provide of structured abstract of up to 250 words

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Structured Abstract

The structured abstract of up to 250 words with four labeled sections should containing the following, with sub-section headers in bold:

a. Objectives: Problem being addressed in the study

b. Methods: The participants, essential features of the study method

c. Results: The basic findings, including effect sizes and confidence intervals and/or statistical significance levels

d. Conclusions: What the authors conclude from study results

Text

Text Formatting

Manuscripts should be submitted in Word.

Use a normal, plain font (e.g., 12-point Times Roman) for text.

Use italics for emphasis.

Use the automatic page numbering function to number the pages.

Do not use field functions.

Use tab stops or other commands for indents, not the space bar.

Use the table function, not spreadsheets, to make tables.

Use the equation editor or MathType for equations.

Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

Footnotes

This journal does not allow the use of footnotes, except in reprinted papers.

Article length

Papers accepted for publication in this journal are 35 double-spaced pages, in 12-point font, inclusive of text, references, tables and figures. For manuscripts exceeding this length, authors should contact the Editor in Chief, Nirbhay N. Singh directly at nirbz52@gmail.com.

Terminology

• Please always use internationally accepted signs and symbols for units (SI units).

Scientific style

Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.

Please use the standard mathematical notation for formulae, symbols etc.: Italic for single letters that denote mathematical constants, variables, and unknown quantities Roman/upright for numerals, operators, and punctuation, and commonly defined functions or abbreviations, e.g., cos, det, e or exp, lim, log, max, min, sin, tan, d (for derivative) Bold for vectors, tensors, and matrices.

References

Citation

Cite references in the text by name and year in parentheses. Some examples:

Negotiation research spans many disciplines (Thompson, 1990).

This result was later contradicted by Becker and Seligman (1996).

This effect has been widely studied (Abbott, 1991; Barakat et al., 1995; Kelso & Smith, 1998; Medvec et al., 1999).

Authors are encouraged to follow official APA version 7 guidelines on the number of authors included in reference list entries (i.e., include all authors up to 20; for larger groups, give the first 19 names followed by an ellipsis and the final author's name). However, if authors shorten the author group by using et al., this will be retained.

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text.

Reference list entries should be alphabetized by the last names of the first author of each work.

Journal names and book titles should be italicized.

If available, please always include DOIs as full DOI links in your reference list (e.g. "https://doi.org/abc").

Journal article Grady, J. S., Her, M., Moreno, G., Perez, C., & Yelinek, J. (2019). Emotions in storybooks: A comparison of storybooks that represent ethnic and racial groups in the United States. Psychology of Popular Media Culture, 8(3), 207–217.

https://doi.org/10.1037/ppm0000185

Article by DOI Hong, I., Knox, S., Pryor, L., Mroz, T. M., Graham, J., Shields, M. F., & Reistetter, T. A. (2020). Is referral to home health rehabilitation following inpatient rehabilitation facility associated with 90-day hospital readmission for adult patients with stroke? American Journal of Physical Medicine & Rehabilitation. Advance online publication. https://doi.org/10.1097/PHM.00000000001435

Book Sapolsky, R. M. (2017). Behave: The biology of humans at our best and worst. Penguin Books.

Book chapter Dillard, J. P. (2020). Currents in the study of persuasion. In M. B. Oliver, A. A. Raney, & J. Bryant (Eds.), Media effects: Advances in theory and research (4th ed., pp. 115–129). Routledge.

Online document Fagan, J. (2019, March 25). Nursing clinical brain. OER Commons. Retrieved January 7, 2020, from https://www.oercommons.org/authoring/53029-nursingclinical-brain/view

Please note:

If you are citing journal articles by their DOI please make sure to also include the volume and page numbers, if already available, e. g. as follows: "Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. Journal of Molecular Medicine, 78(2), 74-80. https://doi.org/10.1007/s00109000086".

Appendix 1.2 Crowe Critical Appraisal Tool (CCAT)

					Ye
earch design (add	if not listed)				
Not research		Opinion Guideline Pamph	let		
Historical		T opinion T deidenne T Panipi	inex [
Qualitative		Ethnography Grounded the	ory Narrative case s	tudy	
Descriptive,	A. Cross-sectional Longitu	dinal Retrospective Prospect	ive Correlational	Predictive	
Exploratory, Observational		Survey Developmental Norm			
Observational		/post-test control group Solomo			mised two-factor
	experiment Placebo	controlled trial	25 254		
Experimental		t only Non-equivalent control gr e sample pre-test post-test [no Cor		ced (cross-over) Multiple time	series
	and the second se	t experimental (case study) Sim		group pre-test/post-test Inte	ractive Multiple baseline
		ubjects (Equivalent time, repeated			
Mixed Methods		al Concurrent Transformative			
3 Synthesis		review Thematic synthesis M	Neta-ethnography N	larrative synthesis	
Other					
iables and analysi	is				
ntervention(s) Tr	eatment(s), Exposure(s)	Outcome(s), Output(s)	Predictor(s) Meas	ure(s) Data analysis m	ethod(s)
Total size	Group 1	Group 2	Group 3	Group 4	Control
opulation, sample, setting					
ta collection (add if	not listed)				
a) (Primary Secondary	02.000000	30.0000000	a) Formal Informal	
	Authoritation Partison Anti	agonist	Interview	b) Structured Semi-structure	d Unstructured Itiple Self-administered
Audit/Review b)				a) Standardised Norm-ref	
Audit/Review b) / c) L	iterature Systematic	0.2			
Audit/Review b) / c) L a) F Observation b) S	Jiterature Systematic Participant Non-participant Structured Semi-structured		Testing	b) Objective Subjective	
Audit/Review b) / c) L a) F Observation b) S	iterature Systematic Participant Non-participant		Testing	b) Objective Subjective c) One-on-one Group Self	
Audit/Review b) / c) t Observation b) 5 c) 0	Jiterature Systematic Participant Non-participant Structured Semi-structured		Testing		
Audit/Review b) / c) L Observation b) 5 c) 0	Jiterature Systematic Participant Non-participant Structured Semi-structured	Unstructured			
Audit/Review b) / c) L a) i Observation b) s c) 0 ores	Jiterature Systematic Participant Non-participant Structured Semi-structured	Unstructured			-administered

Appraise research on the merits of the research design used, not against other research designs.

Category Item	Item descriptors [☑ Present; 🗷 Absent; ■ Not applicable]	Description [Important information for each item]	Score [0-5]
1. Preliminaries			
Title	1. Includes study aims and design		
Abstract (assess last)	1. Key information D 2. Balanced D and informative D		
Text (assess last)	Sufficient detail others could reproduce □ Clear/concise writing □, table(s) □, diagram(s) □, figure(s) □		
		Preliminaries	[/5]

Introduction		
Background	1. Summary of current knowledge 2. Specific problem(s) addressed and reason(s) for addressing	
Objective	1. Primary objective(s), hypothesis(es), or aim(s) 2. Secondary question(s)	
	Is it worth continuing?	Introduction [/5]

Design		
Research design	1. Research design(s) chosen 🗆 and why 🗆 2. Suitability of research design(s) 🗅	
Intervention, Treatment, Exposure	1. Intervention(s)/treatment(s)/exposure(s) chosen and why 2. Precise details of the intervention(s)/treatment(s)/exposure(s) for each group 3. Intervention(s)/treatment(s)/exposure(s) valid and reliable	
Outcome, Output, Predictor, Measure	1. Outcome(s)/output(s)/predictor(s)/measure(s) chosen and why 2. Clearly define outcome(s)/output(s)/predictor(s)/measure(s) 3. Outcome(s)/output(s)/predictor(s)/measure(s) valid and reliable	
Bias, etc	Potential bias D, confounding variables D, effect modifiers D, interactions D Sequence generation D, group allocation D, group balance D, and by whom D S. Equivalent treatment of participants/cases/groups D	
	Is it worth continuing?	Design [/5]

	is it worth continuing:	Design (/ 5)
. Sampling		
Sampling method	Sampling method(s) chosen and why a Suitability of sampling method	
Sample size	1. Sample size D, how chosen D, and why D 2. Suitability of sample size D	
Sampling protocol	1. Target/actual/sample population(s): description and suitability 2. Participants/cases/groups: inclusion and exclusion criteria 3. Recruitment of participants/cases/groups	
	Is it worth continuing?	Sampling [/5]

		1 00 1
. Data collection		ζ
Collection method	Collection method(s) chosen and why 2. Suitability of collection method(s)	
Collection protocol	I. Include date(s) D, location(s) D, setting(s) D, personnel D, materials D, processes D Method(s) to ensure/enhance quality of measurement/instrumentation D Manage non-participation D, withdrawal D, incomplete/lost data D	
	Is it worth continuing?	Data collection [/5]

	Is it worth continuing?	Data collection [/5]
5. Ethical matters		10 A
Participant ethics	1. Informed consent C, equity C 2. Privacy C, confidentiality/anonymity C	
Researcher ethics	1. Ethical approval D, funcling D, conflict(s) of interest D 2. Subjectivities D, relationship(s) with participants/cases D	
	Is it worth continuing?	Ethical matters [/5]

7. Results		
Analysis, Integration, Interpretation method	1. A.I.J. method(s) for primary outcome(s)/output(s)/predictor(s) chosen and why 2. Additional A.I.I. methods (e.g. subgroup analysis) chosen 3. Suitability of analysis/integration/interpretation method(s)	
Essential analysis	1. Flow of participants/cases/groups through each stage of research 2. Demographic and other characteristics of participants/cases/groups 3. Analyse raw data , response rate , non-participation/withdrawal/incomplete/lost data	
Outcome, Output, Predictor analysis	1. Summary of results and precision for each outcome/output/predictor/measure 2. Consideration of benefits/harms , unexpected results , problems/failures 3. Description of outlying data (e.g. diverse cases, adverse effects, minor themes)	

		Results [/5]
Discussion		
Interpretation	1. Interpretation of results in the context of current evidence and objectives 2. Draw inferences consistent with the strength of the data 3. Consideration of alternative explanations for observed results 4. Account for bias Q, confounding/effect modifiers/interactions/imprecision	
Generalisation	Consideration of overall practical usefulness of the study 2. Description of generalisability (external validity) of the study	
Concluding remarks	Highlight study's particular strengths C Suggest steps that may improve future results (e.g. limitations) G Suggest further studies	
		Discussion [/5]

9. Total		
Total score	1. Add all scores for categories 1-8	
7		T-1-1 [(40)

Total [/40]

Crowe Critical Appraisal Tool (CCAT) :: Version 1.4 (19 November 2013) :: Michael Crowe (michael.crowe@my.jcu.edu.au)

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Appendix 1.3 CCAT Ratings

$\stackrel{\text{CCAT}}{\longrightarrow}$	-	1.		2.	3	3.	4	4.	5	5.		6.	,	7.		8.		9.	Overall	
Question																			Quality	
Reference ↓	R1	R2	Rating																	
Ashworth et al., (2015)	4	4	5	5	3	3	4	4	3	3	4	4	3	3	4	4	26	26	65%	
Beaumont et al., (2016)	4	4	5	5	3	3	1	1	4	4	2	2	3	3	3	3	25	25	62.5%	
Carlyle et al., (2019)	5	5	5	5	5	5	3	3	3	3	4	4	5	5	3	3	33	33	82%	
Carter et al., (2020)	5	5	5	5	4	4	3	3	4	4	4	4	3	3	4	4	31	31	75%	
Chou et al., (2020)	5		5		4		5		4		3		4		5		35		87%	
Cuppage et al., (2018)	4	4	5	5	4	4	4	4	5	5	3	3	4	4	4	4	33	33	82%	
Fox et al., (2021)	4	4	5	5	4	4	3	3	5	5	3	3	4	4	4	4	28	28	70%	
Frostadottir et al., (2019)	4		5		5		5		4		5		4		5		37		92%	
Gilbert et al., (2006)	4	4	5	5	3	3	2	2	4	4	1	1	3	3	3	3	25	25	62.5%	

CCAT Question		1.		2.	3	3.	2	4.	:	5.		6.	7. 8.		7.				9.		9.		Overall Quality
Reference ↓	R1	R2	R1	R2	R1	R2	R1	R2	- Rating														
Goad et al., (2020)	4	4	5	5	2	2	3	3	5	5	3	3	5	5	3	3	30	30	75%				
Gooding et al., (2020)	4	4	5	5	3	3	2	2	4	4	5	5	5	5	4	4	32	32	80%				
Grodin et al., (2019)	3	3	5	5	4	4	2	2	5	5	4	4	4	4	4	4	31	31	77.5%				
Irons et al., (2020)	4	4	5	5	4	4	2	2	4	4	3	3	3	3	4	4	30	30	75%				
Judge et al., (2012)	4	4	5	5	2	2	2	2	4	4	3	3	2	2	3	3	25	25	62.5%				
Kelly et al., (2017)	4	4	5	5	4	4	3	3	4	4	2	2	4	4	5	5	31	31	77.5%				
Laithwaite et al., (2009)	4		4		3		5		4		3		3		5		31		77%				
Lucre et al., (2013)	5		3		3		1		2		1		3		4		22		55%				
Matos et al., (2017)	4		5		4		4		3		4		2		3		29		72%				
McManus et al., (2018)	3		4		3		2		2		1		3		5		23		57%				

CCAT Question	1	l .	2	2.	3	3.	4	I.	5	5.	6	5.	7		3	3.	9).	Overall Quality
Reference ↓	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	Rating
Savari et al., (2021)	4		5		4		5		4		3		3		5		33		82%

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
Ashworth et	Anxiety	Self-criticism	Self-reassurance			
al., (2015)	Significant reduction in anxiety on the HADS from pre- to post- treatment and this was maintained at 3 month follow up. Depression Significant reduction in depression from pre- to post-treatment and it was maintained at 3 month follow up.	Significant reduction on 'Inadequate self' and 'Hated self' subscales of the FSCRS scale, that was maintained at 3 month follow up.	Significant increase on 'self-reassurance' subscale of the FSCRS scale, that was maintained at 3 month follow up.			
Beaumont et		Self-criticism	Self-compassion			
al., (2016)		'Self-judgement' significantly reduced on the SCS from pre- to post-treatment.No significant effect was found for self- persecution and self-correction on the FSCS	Significantly increased on SCS from pre- to post-treatment.			
Carlyle et al.,	Opioid Use	Self-criticism	Self-reassurance			
(2019)	No significant main effect was found from pre to post treatment.	No significant main effect was found from pre to post treatment on the FSCRS.	No significant main effect was found from pre to post treatment on the FSCRS.			

Appendix 1.4 Outcomes for included studies

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
	Depression					
	There was a significant reduction on the					
	DASS from pre- to post-treatment but					
	no significant difference between					
	groups.					
	Anxiety					
	No significant effect of time or group					
	Stress					
	There was a significant reduction from					
	pre- to post-treatment but no significant					
	difference between groups.					
Carter et al.,	Body weight shame	External Shame	Self-Compassion			
(2020)	Significant improvement from pre to	Significant main effect of external shame	Non-significant main effect of self-compassion			
	post treatment on the BISS, this was	on the OAS, with a decrease from pre- to	on the CEAS from pre- to post-intervention.			
	maintained at follow up.	post-intervention.	Flows of compassion			
			No significant main effect of 'compassion to			
			others' or 'compassion from others' on the			
			CEAS from pre- to post-intervention			

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
Chou et al.,	Hoarding disorder symptoms	Shame	Self-reassurance			
(2020)	Significant decrease in symptom severity on the SI-R from pre- to post- treatment. There was a significant decrease in every symptom domain. In contrast CBT treatment had a marginal effect on symptom severity from pre- to post-treatment. Distress tolerance Significant increase from pre- to post- treatment on the DTS.	Significant reduction from pre-to post- treatment on 'self-ambivalence', 'shame about oneself 'and 'shame when making mistakes' on the ESS. Self-criticism Significant reduction from pre- to post- treatment on the FSCRS.	Significant increase from pre-to post-treatment on the FSCRS.			
Cuppage et al.,	Psychopathology	Fears of Self-compassion				
(2018)	Significant reduction from pre- to post- treatment on the GSI section of the BSI.	Significant reduction from pre- to post- treatment on the FSC. External shame Significant reduction from pre-to post- treatment on the OAS scale.				

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
		Self-correction Significant reduction from pre to post treatment on the FSCS. There were no significant differences between the CFT and TAU groups for self-				
		criticism, self-persecution, self-correction, and others as shamer scales.				
Fox et al., (2021)		Fears of CompassionSignificant reduction in 'fears of compassion', 'fears of compassion from other' and 'fears of compassion to others' on FCS from pre- to post-treatment, with medium and small effect sizes.Self-criticismSignificant reduction on 'hated self' and 'inadequate self' on FSCRS from pre- to post-treatment with medium effect sizes.Shame	Compassion Significant increase in self-compassion from pre- to post-treatment on the CEAS, with a large effect size Significant increase in 'compassion from others' from pre- to post-treatment, with a small effect size Reassured self Significant increase in 'reassured self' on the FSCRS from pre- to post-treatment, with medium effect size			

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
		Significant reduction from pre- to post- treatment on the TOSCA, with a medium effect size.				
Frostadottir et	Depression		Self-compassion			
al., (2019)	Significant reduction in depression on the DASS from pre- to post-treatment. Anxiety Significant reduction in anxiety on the DASS from pre- to post-treatment. Stress Significant reduction in stress on the DASS from pre- to post-treatment.		Significant improvement in self-compassion on the SCS from pre- to post-treatment, with a small effect size. However, this was improvement was not significantly different from the MBCT group. Pre-treatment rumination was found to have no significant interaction with self-compassion.			
Gilbert et al., (2006)	DepressionSignificant reduction in depression on the HADS from pre- to post-treatment.AnxietySignificant reduction in anxiety on the DASS from pre- to post-treatment.	Self-criticismSignificant reduction in 'self-persecution' on the FSC from pre- to post-treatment.Significant reduction on 'inadequate self' from pre- to post-treatment on FSCRS. p-	Reassured self FSCRS: Significant increase from pre (M=6.17, SD=6.40) to post treatment (M=19.83, SD=8.21)			

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
		value 0.07. Authors state significance level				
		set at 10% due to small sample size (n=6).				
		Significant reduction on 'hated self' on				
		FSCRS from pre- to post-treatment.				
		External shame				
		Significant reduction on external shame on				
		the OAS from pre- to post-treatment.				
		Social comparison				
		Significant improvement on the SoCS from				
		pre- to post-treatment.				
Goad et al.,	Mood	Social comparison	Self-compassion			
(2020)	CORE-LD was used to measure mood,	RCI calculated for individual scores on the	RCI calculated for individual scores on the SCS-			
	psychometric data are not available for	SoCS. 4 of the 6 participants showed	SF. All 6 participants showed significant			
	this measure so reliable and clinically	significant improvement from pre to post	improvement from pre to post intervention.			
	significant change cannot be calculated.	intervention.				

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
Gooding et al.,	Depression, anxiety, and stress	Self-criticism	Self-reassurance			
(2020)	DASS used to evaluate changes in mood. Results were reported in terms of triangulation within qualitative analysis. Only 3 of 4 participants completed questionnaires. No information on change in scores available.	FSCRS was used to evaluate changes in self-criticism. Results were reported in terms of triangulation within qualitative analysis. Only 3 of 4 participants completed questionnaires. Authors reported an improvement in scores.	FSCRS was used to evaluate changes in self- reassurance. Results were reported in terms of triangulation within qualitative analysis. Only 3 of 4 participants completed questionnaires. Authors reported an improvement in scores.			
Grodin et al., (2019)	 PTSD Significant reduction in severity on the PLC from pre- to post-treatment, with medium effect size. Anger Significant improvement on STAXI subscales 'trait anger', 'inward expression of anger' and 'inner control over anger', from pre- to post- intervention, with a small effect size. Non-significant results for state anger, outward expression of anger, outward control over anger. 	Fears of compassion FCS for others: Significant reduction on FCS subscales 'fear of compassion from others', 'fears of compassion for self' from pre- to post- intervention, with a small effect size. No significant results for self-compassion and fears of compassion for others				

Study	Mental Health	Mechanism of Change Outcomes				
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes			
Irons et al.,	Depression	Social comparison	Self-compassion			
(2020)	Significant reduction from pre- to post-	Significant improvement from pre- to post-	Significant improvement on SCS subscales			
	treatment on the DASS, with a medium	intervention on the SoCS, with a small	'mindfulness', 'kindness' and 'common			
	effect size.	effect size.	humanity' from pre- to post-intervention, with			
	Stress	Self-criticism	medium and large effect sizes.			
	Significant reduction from pre- to post- treatment on the DASS. Non-significant results for change in anxiety scores on the DASS.	Significant reduction on FSCRS subscales of 'inadequate self' and 'hated self' from pre- to post-treatment, with a large effect size. Significant reduction on SCS subscales of 'over-identification', 'self-judgement' and 'isolation' from pre- to post-intervention, with medium and large effect sizes.	Significant improvement on CEAS subscales 'self-compassion engagement', 'self-compassion action' engagement with compassion to others' and 'action in compassion from others' from pre- to post-intervention with small and large effect sizes. Non-significant results for action in compassion for others and engagement in compassion from others.			
Judge et al., (2012)	Depression: Significant reduction on BDI from pre-	Self-criticism Significant reduction on FSCRS subscales	Reassured self Significant increase in reassured self on FSCRS			
	to post treatment.	'inadequate self' and 'hated self' from pre-	from pre- to post treatment.			
	Anxiety:	to post-treatment, with a large effect size.				
		Significant reduction on 'self-persecution				
		on FSCS from pre- to post-treatment.				

Study	Mental Health	Mechanism of Change Outcomes					
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes				
	Significant reduction on BAI from pre- to post treatment.	ShameSignificant reduction of internalised shame on the ISS from pre- to post-treatment.Significant reduction in external shame from pre- to post-treatment.Social comparisonSignificant improvement on SoCS from pre- to post-intervention.Non-significant change in self-correction 					

Study	Mental Health	Mechanism of	² Change Outcomes
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes
Kelly et al.,	Eating pathology	Shame	Self-compassion
(2017)	Significant decrease in eating pathology in CFT group compared to TAU.	Decreased significantly in CFT + TAU group but did not change in the TAU group. Fears of compassion Significant reduction in fear of self- compassion and fear of receiving compassion. Self-criticism Significant improvement in negative scales of SCS, with a large effect size. Changes were significant in CFT+TAU group but not TAU group.	Significant improvement from pre- to post- intervention, with a medium effect size. Changes were significant in CFT+TAU group but not TAU group.
Study	Mental Health	Mechanism of Change Outcomes	
---------------	--	--	---------------------------------
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes
Laithwaite et	Depression:	Social comparison	Self-compassion
al., (2009)	Significant reduction in depression from pre- to post-intervention, with a medium effect size. This was maintained at 6 week follow up.	Significant reduction from pre- to post- intervention, with a medium effect size. This was maintained at 6 week follow up. External shame Significant improvement from pre- to post- intervention, with a small effect size. This was maintained at 6 week follow up.	No significant change was found

Study	Mental Health	Mechanism of Change Outcomes		
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes	
Lucre et al.,	Distress	External shame	Self-reassurance	
(2013)	 Significant improvement across CORE domains (wellbeing, symptoms, functioning and risk). All domains apart from 'risk' were maintained at 1 year follow up. Depression, anxiety, and stress No significant changes in depression, anxiety and stress measured by DASS. 	Significant improvement from pre- to post- intervention. This was maintained at 1 year follow up.Social comparisonSignificant improvement from pre- to post- intervention.Self-criticismSignificant reduction in self-hatred and a non-significant reduction in self- inadequacy.	Significant increase in self-reassurance.	
Matos et al., (2017)	DepressionSignificant reduction on depression on the DASS, over time but with no effect of group.AnxietyNo significant reduction in anxiety	Fears of compassion Significant reduction in 'fears of compassion for self' and 'fears of compassion for others' on the FOCS, with a significant effect of treatment group, and both with a medium effect size. 'Fears of compassion from others' was not	Flows of compassion Significant improvement on the 'three flows of compassion' on the CAAS across time, with a significant effect of treatment group on 'compassion for self' and 'compassion from others' subscales with a medium effect size. Self-compassion	
	Stress	significant.		

Study	Mental Health	Mechanism of	Change Outcomes
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes
	No significant reduction in stress.	Self-criticismSignificant reduction in self-criticism on theFSCRS with a main effect of treatmentgroup and a medium effect size.Significant reduction on the 'self-judgement' scale of the SCS, with a maineffect of treatment group and a mediumeffect size.No significant effect of 'isolation' or 'over-identification' on the SCSExternal shameNo significant reduction in external shameon the OAS.	Significant improvement on self-kindness subscale of the SCS, which had a main effect of treatment group, with a medium effect size. There was no significant difference of mindfulness or common humanity on the SCS. Reassured self There was no significant difference on reassured self on the FSCRS.

Study	Mental Health	Mechanism of	Change Outcomes
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes
McManus et al., (2018)		Self-criticismSignificant reduction in hated self and self- inadequacy from pre- to post-intervention.External shameSignificant reduction in external shame from pre- to post-intervention.Self-criticismSelf-judgement, isolation and overidentification all significantly improved 	No significant change in self-reassurance was found. Self-compassion Self-kindness, common humanity, and mindfulness all significantly improved on the SCS from pre- to post-intervention.

Study	Mental Health	Mechanism o	f Change Outcomes
	Outcomes	Self-criticism & Shame outcomes	Self-Compassion outcomes
Savari et al.,	Depression	Fears of compassion	Self-reassurance
(2021)	A significant reduction in depression scores on the BDI-II from pre- to post- intervention, with a large effect size. There was a significant interaction of group. Anger There were significant reductions in anger subscales on the ARS (angry afterthoughts, angry memories and understanding of causes). However, these were not significantly different from the control group. The significant decrease of thoughts of revenge had a significant interaction of treatment group.	There were significant reductions on the FCS subscales. There was a significant interaction effect with treatment group on 'fears of compassion for others'. Self-criticism There were significant reductions on inadequate self and hated-self subscales of the FSCRS. There was a treatment group effect of hated self.	There was a significant increase on the self- reassurance subscale of FSCRS, with a treatment effect of group treatment. Self-compassion There was a significant increase in the positive subscales of the SCS with a treatment effect of group.

 Abbreviations - HADS: Hospital Anxiety and Depression Scale; FSCRS: Forms of Self-Criticism/Self-Attacking and Self Reassurance Scale; SCS-SF: Self

 Compassion Scale – Short-Form; FSCS: Function of Self Criticizing/Attacking Scale; DASS: Depression and Anxiety Stress Scale; DASS-21: Depression and

 Anxiety Scale short from; BISS: Body Image Shame Scale; CEAS: Compassion Engagement and Action Scale; OAS: Other as Shamer Scale; BDI: Beck Depression

 Inventory; BDI-II: Beck Depression Inventory 2; BAI: Beck Anxiety Inventory; ESS: Experiences of Shame Scale; BSI: Brief Symptom Inventory; FCS: Fears of

 Compassion Scale; SSPS: Social Safeness and Pleasure Scale; CORE-LD: Clinical Outcomes in Routine Evaluation – Learning Disability; SCRS: Social Comparison

Rating Scale; ISS: Internalized Shame Scale; CORE: Clinical Outcomes in Routine Evaluation; MHCS: Mental Health Confidence Scale; EAT-26: Eating Attitudes Test, SCS: Self-Compassion Scale; SoCS: Social Comparison Scale; SI-R: Saving Inventory – Revised; DTS: Distress Tolerance Scale; TOSCA: Test of Selfconscious effect; STAXI-2: State-Trait Anger Expression Inventory 2nd Edition; ARS: Anger Rumination Scale; CAAS: Compassionate Attributes and Action Scales.

Date: Your Ref:

Our Ref:

Email:

Enquiries to:

Direct Line:

23 May 2019

DL/19/ES/0043

01382 383871

Mrs Diane Leonard

eosres.tayside@nhs.net



East of Scotland Research Ethics Service (EoSRES)

TAyside medical Science Centre Residency Block Level 3 George Pirie Way Ninewells Hospital and Medical School Dundee DD1 9SY

Professor Hamish McLeod Professor of Clinical Psychology University of Glasgow Gartnavel Royal Hospital Administration Building 1055 Great western Road Glasgow, G12 0HX

Dear Professor McLeod

Study title:	A Mixed Methods Feasibility Study of a Transdiagnostic
	Compassion Focused Therapy (CFT) Group for Older
	Adults
REC reference:	19/ES/0043
Protocol number:	GN19MH088
IRAS project ID:	255137

Thank you for your letter of 13 May 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair, together with other named members.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact <u>hra.studyregistration@nhs.net</u> outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

The Committee requested that further information is inserted into the Participant
Information Sheet informing the potential participants that they do not need to audio
recorded to take part in the study, and that it will be transcribed and they will be asked
to verify a written statement in these instances.



You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise). Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact <u>hra.studyregistration@nhs.net</u>. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites



The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

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

Document	Version	Date
Covering letter on headed paper [Ethics Response Letter]	1	13 May 2019
GP/consultant information sheets or letters [GP letter]	1.0	
Interview schedules or topic guides for participants [Topic guide for interview]	1.1	
IRAS Application Form [IRAS_Form_03042019]	1	03 April 2019
IRAS Checklist XML [Checklist_15052019]		15 May 2019
Participant consent form [Participant Consent Form]	1.2	
Participant consent form [Semi Structured Interviews]	1.0	16 May 2019
Participant information sheet (PIS) [Highlighted changes]	1.04	16 May 2019
Participant information sheet (PIS) [Semi Structured Interviews]	1.0	16 May 2019
Research protocol or project proposal [Highlighted changes]	1.02	16 May 2019
Summary CV for Chief Investigator (CI) [Hamish McLeod CV]		
Summary CV for student [Fiona McConnell CV]	1.0	31 January 2019
Summary CV for supervisor (student research) [John Hickey CV]		05 February 2019
Validated questionnaire [FSCSR scale]	1	
Validated questionnaire [Others as Shamer Scale]		
Validated questionnaire [PHQ-9]		
Validated questionnaire [GAD-7]	1	
Validated questionnaire [Social Connectedness Scale]		
Validated questionnaire [Toronto Mindfulness Scale]	1	
Validated questionnaire [Self-Compassion Scale]	1	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study



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

User Feedback

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

HRA Learning

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

19/ES/0043	Please quote this number on all correspondence	

Yours sincerely

for Mrs Natalle McInally Vice-Chair

Email: eosres.tayside@nhs.net

Enclosures:	"After ethical review -	 guidance for researchers" 	

Copy to: Miss Emma-Jane Gault, NHS Greater Glasgow & Clyde



Appendix 2.2 Ethics Approval with Additional Documents



East of Scotland Research Ethics Service (EoSRES)

Research Ethics Service

TAyside medical Science Centre Residency Block Level 3 George Pirie Way Ninewells Hospital and Medical School Dundee DD1 9SY

Ms Fiona McConnell	Date:	24 May 2019
Institue of Health & Wellbeing, University of Glasgow	Your Ref: Our Ref:	DL/19/ES/004
Admin Building, Gartnavel Royal Hospital	Enquiries to: Direct Line:	Mrs Diane Leo 01382 383871
1055 Great Western Road Glasgow, G12 0XH	Email:	ecsres.tayside

43 onard e@nhs.net

Dear Ms McConnell

Study title:	A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older
	Adults
REC reference:	19/ES/0043
Protocol number:	GN19MH088
IRAS project ID:	255137

Thank you for your email of 24 May 2019. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 May 2019

Documents received

The documents received were as follows:

Document	Version	Date
Participant consent form [Consent Form Semi Structured Interviews]	1.01	23 May 2019
Participant information sheet (PIS) [Participant Information Sheet Semi Structured Interviews]	1.01	23 May 2019

Approved documents

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

Document	Version	Date
Covering letter on headed paper [Ethics Response Letter]		13 May 2019
GP/consultant information sheets or letters [GP letter]	1.0	
Interview schedules or topic guides for participants [Topic guide for interview]	1.1	
IRAS Application Form [IRAS_Form_03042019]		03 April 2019
IRAS Checklist XML [Checklist_15052019]		15 May 2019
IRAS Checklist XML [Checklist_24052019]		24 May 2019



Document	Version	Date
Participant consent form [Participant Consent Form]	1.2	
Participant consent form [Consent Form Semi Structured Interviews]	1.01	23 May 2019
Participant information sheet (PIS) [Highlighted changes]	1.04	16 May 2019
Participant information sheet (PIS) [Participant Information Sheet Semi Structured Interviews]	1.01	23 May 2019
Research protocol or project proposal [Highlighted changes]	1.02	16 May 2019
Summary CV for Chief Investigator (CI) [Hamish McLeod CV]		
Summary CV for student [Flona McConnell CV]	1.0	31 January 2019
Summary CV for supervisor (student research) [John Hickey CV]		05 February 2019
Validated questionnaire [FSCSR scale]		
Validated questionnaire [Others as Shamer Scale]		
Validated questionnaire [PHQ-9]		
Validated questionnaire [GAD-7]		
Validated questionnaire [Social Connectedness Scale]		
Validated questionnaire [Toronto Mindfulness Scale]		
Validated questionnaire [Self-Compassion Scale]		

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

19/ES/0043 Please quote this number on all correspondence

Yours sincerely

Mrs Diane Leonard Assistant Co-ordinator

Email: eosres.tayside@nhs.net

Copy to: Ms Joanne McGarry, NHS Greater Glasgow and Clyde



SCOTLAND

East of Scotland Research Ethics Service (EoSRES)

Research Ethics Service

TAyside medical Science Centre Residency Block Level 3 George Pirie Way Ninewells Hospital and Medical School Dundee DD1 9SY

21 August 2019

Arlene Grubb

01382 383848

LR/AG19/ES/0043

eosres.tayside@nhs.net

Ms Fiona McConnell Institute of Health & Wellbeing, University of Glasgow Admin Building, Gartnavel Royal Hospital 1055 Great Western Road, Glasgow G12 0XH

Dear Ms McConnell

Study title:

REC reference: Protocol number: Amendment number: Amendment date: IRAS project ID:

A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults 19/ES/0043 GN19MH088 AM01 (REC reference only) 20 August 2019 255137

Date:

Email:

Your Ref:

Our Ref:

Enquiries to:

Direct Line:

Thank you for your letter of 20 August 2019, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notice of Non Substantial Amendment		20 August 2019
Cover email with additional documents	i.	21 August 2019
Participant information sheet (PIS) [Semi Structured Interviews Highlighted Changes]	1.02	30 July 2019
Participant information sheet (PIS) [Highlighted Changes]	1.05	25 July 2019
Research protocol or project proposal [Highlighted Changes]	1.03	30 July 2019

Statement of compliance



The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

19/ES/0043:

Please quote this number on all correspondence

Yours sincerely

Arlene Grubb Assistant Co-ordinator

Email: eosres.tayside@nhs.net



Measure	Administration sequence number	Session number to be delivered at	No. of items	Construct being measured	Est. completion time (mins)
PHQ-9	1	1, 5, 10	9	Depression	1 minute
GAD-7	2	1, 5, 10	7	Anxiety	1 minute
Forms of self- criticising/attacking & self-reassuring scale	3	1, 9, 10	22	Inadequate self Hated self Reassured self	4 minutes
Other as Shamer Scale	4	1, 5, 10	18	External shame	3 minutes
Self-compassion scale	5	1, 8, 10	26	Self- compassion	4 minutes
Social Connectedness Scale	6	1, 5, 10	20	Social connectedness	4 minutes
Toronto Mindfulness Scale - Trait	7	1, 7, 10	13	Mindfulness	3 minutes

Appendix 2.4 Outcome Measures Delivered

Appendix 2.5 Topic Guide for Semi-Structured Interviews

Semi-structured Interview Schedule

Introduction

Thank you for meeting with me to discuss your experience of the CFT group. We are looking at how feasible it is to deliver a compassion focused therapy group to older people. We're keen to know what worked well in the group and what could be changed for future groups.

Experience of the group

I'd first of all like to know about your experience of the group.

- How was the CFT group for you?
 - What parts of the group did you like? What was good about it?
 - What parts of the group did you not like? What wasn't good about it?
- What parts of the group did you find most difficult?
 - What was it that made it difficult?
- What would you change about the group?
- How did you find the CFT group tasks?
 - Were they beneficial/not beneficial?
 - Did they make sense?
 - Were you able to fit the tasks into your life? What were the difficulties of this?
- How was it being part of a therapy group? Did it feel supportive/ not supportive?
 - How did the group affect your experience?

Mechanisms of Change

- How have things been different for you since participating in the group?
 - Have there been changes in how you feel? Can you tell me about the changes?
 - Why do you think things have stayed the same for you?

Research

I'd like to know how you found being part of a research project

- What were your thoughts about participating in research? How did you decide to take part?
- How did you find completing the questionnaires?

Overall

- If we were to do the whole project again, what would you recommend would make it better?
 - What should we do again?

Thank you for answering my questions, I really appreciate it. Is there anything you would like to say that we haven't discussed?

Appendix 2.6 Major Research Project Proposal

A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

Fiona McConnell

Matriculation Number:

Academic Supervisor: Professor Hamish McLeod

Field Supervisor: Dr John Hickey

Date of Submission: 24th January 2019

Version number: v2.1

Word Count: 3,450

Abstract

Background

Compassion focused therapy (CFT) has been developed from the cognitive behavioural therapies to target the shame and self-criticism which are often high in people who experience mental health problems. The evidence base for CFT is still in its infancy but there is increasing and promising evidence that it is of benefit to people experiencing psychological distress. Currently, there has not been enough research on CFT as a clinical intervention for it to be recommended as a treatment. Research shows that the standard CBT treatment approach has smaller effect sizes in the older population that in working age adults. Further research is needed to evaluate CFT and its acceptability to older adults and whether CFT could be an acceptable alternative to CBT.

Aims

The aim of this project is to test the feasibility of a CFT group intervention for an older adult sample. Consistent with feasibility stage studies, focus will be on recruitment, retention of participants, acceptability of treatment and outcome measures. We will also explore preliminary signals for the effectiveness of the treatment and possible mechanisms of change.

Methods

A mixed methods feasibility study design will be used. Participants will be over 60 referred for psychological therapy for common mental health conditions such as depression or anxiety disorders. People with psychosis, addictions, cognitive impairment, or risk of self-harm will be ineligible. They will participate in a 10-week CFT group intervention and asked to complete outcome measures before, during and after treatment. Following the intervention, they will be asked to complete a semi-structured interview.

Application

The project aims to evaluate the feasibility of a CFT group treatment for the older adult population. Additionally, the project aims to evaluate the acceptability and effectiveness of

outcome measures to assess mechanisms of change from the treatment intervention in an older adult population. The project will aim to add to the evidence for CFT interventions within the older adult population.

Word count: 316

Introduction

Compassion Focused Therapy development

Compassion focused therapy (CFT) was developed through a combination of theories; evolutionary psychology, attachment theories, neurophysiology, and cognitive behavioural theories (Kolts, 2016). Originally developed by Paul Gilbert (2009) CFT focuses on reducing shame and self-criticism, which are often transdiagnostic processes for people with mental health problems. Gilbert found that although Cognitive Behavioural Therapy (CBT) was useful, that it was lacking for certain people who struggled to make positive change using traditional cognitive techniques. CFT was initially focused on shame and self-criticism and how to develop a kinder 'inner voice'. Shame is an emotionally painful state in which people evaluate themselves negatively as worthless, defective, or bad (Gilbert, 2010; Gilbert & Proctor, 2006). People who experience high levels of shame find it difficult to feel kindness towards themselves (Gilbert & Proctor, 2006).

CFT Research Evidence

There has been increasing evidence that compassion focused interventions improve outcomes for psychological wellbeing and functioning (Kirby, 2017). Compassion focussed interventions are varied and include Compassionate Mind Training, which is a specific group intervention using CFT; Mindful Self Compassion, which is a group with a similar format but with a stronger focus on meditative exercises and Compassion and Loving kindness meditations (Kirby, 2017). The interventions are similar, particularly their intended mechanisms of action. Compassion focused therapy has been shown to reduce maintenance factors for distress, such as shame, self-criticism, and fears of self-compassion (Cuppage *et al*,

2017; Gilbert & Proctor, 2006). Research in this area is still in its infancy, particularly with clinical populations. A 2015 systematic review of the evidence for CFT found that the research is still early in terms of the effectiveness, acceptability, and tolerability of CFT as an intervention (Leaviss & Uttley, 2015). However, evidence indicates that CFT is a promising intervention and has been researched in the treatment of depression, anxiety, psychosis, personality disorders, eating disorders and in non-clinical samples (Leaviss & Uttley, 2015). In a study investigating complex mental health problems, compassionate mind training was delivered; participants had a significant reduction in anxiety, depression, self-criticism, shame, inferiority, and submissive behaviour (Gilbert & Proctor, 2006). Leaviss and Uttley (2015) state that despite the evidence suggesting CFT is a beneficial intervention there is still insufficient evidence to show that it is more effective than the current standard treatments. Additionally, little research has focused on an older adult population.

Psychological Treatment in Older Adults

The psychological treatment standard currently for depression is CBT, behavioural activation, or Interpersonal Psychotherapy (IPT) (NICE, 2009) and for anxiety is CBT (NICE, 2011; The Scottish Government, 2015). There is strong evidence of the effectiveness of CBT in working age adults; it has also been shown to be effective in older adults but with smaller effect sizes. It is difficult to evaluate the effectiveness in the research with older adults due to less research and differing methodologies (Kishita & Laidlaw, 2017). Currently no research has been found to evaluate specific compassion interventions in older adults, however in a non-clinical sample, research has shown older adults who have a higher level of self-compassion have better psychological wellbeing, as measured by a psychological wellbeing scale and that self-compassion moderates the association between health and symptoms of depression as measured by the Depression Anxiety and Stress Scale-Short Form (Lovibund and Lovibund 1995; Homan, 2016). Additionally, self-compassion was found to be positively associated with wellbeing in older adults (Allen, Goldwasser, & Leary, 2011).

Developing and Evaluating Complex Interventions

This study will use the Medical Research Council's (MRC) Developing and Evaluating Complex interventions framework (Craig *et al*, 2008; Lancaster *et al*, 2004). The aim of the feasibility stage of intervention testing is to evaluate the acceptability of the intervention, the level of recruitment and retention, the sample size required for research, the acceptability of measures and to understand how the intervention effects change, (Craig *et al*, 2008).

Aims and Questions

The aim of the current study is to explore the acceptability of a CFT group for older adults, including the mechanisms of change of CFT in older adults, the tolerability and relevance of outcome measures and the feasibility of delivering of a CFT group intervention for older adults referred to the CMHT. Additionally, the study aims to estimate recruitment and retention of participants for future projects and to estimate effect sizes for future projects.

Research Questions

- Is a CFT group intervention acceptable for older adults referred to the CMHT?
- Is it feasible to deliver a CFT group intervention to older adults referred to the CMHT?
- What ate the estimated rates of recruitment and retention for future trials?
- Is a CFT group acceptable for older adults?
- Does a CFT group intervention improve psychological wellbeing in older adults?
- What are the potential mechanisms of change involved in CFT treatment?
- Do older adults find the outcome measures acceptable?

Methods

Participants

Eligible participants will be identified from NHSGGC HSCP South and East Renfrewshire Older People's Mental Health Service.

Inclusion Criteria:

- Age 60+
- Experiencing symptoms of depression and/or anxiety disorder
- Able to provide informed consent

Exclusion Criteria:

- Psychosis
- Addictions
- Cognitive impairment
- Risk of self-harm

Recruitment Procedure

Potential participants will be recruited from the older adult service within NHS GGC. Staff within the service will identify potential participants for a CFT group and if they agree to participate in the group, attendees will then be asked to participate in the study. Group attendees' inclusion in the group is not dependent on their participation in the study. Inclusion and exclusion criteria will be assessed, and eligible participants will be asked for their consent to participate in the project.

Outcome Measures

The lead clinician will administer outcome measures at beginning and end of the group programme. Additionally, measures will be used after specific sessions to assess the effect of specific interventions. Outcome measures to be used are (table 1):

Clinical Outcomes:

 Patient Health Questionnaire (PHQ-9) (Spitzer, Williams & Kroenke, 2001) – a 9 item self-report measure of depressive symptoms. Generalized Anxiety Disorder (GAD-7) (Spitzer, Kroenke, Williams & Lowe, 2006) – a 7 item self-report measure of anxiety symptoms.

Mechanisms of Change:

- Forms of self-criticising/attacking & self-reassuring scale (FSCRS) (Gilbert *et al*, 2004) a self-report measure of self-criticism and self-reassurance. Used to evaluate the level of self-criticism a person experiences, which is often linked to mental health problems. Additionally, it evaluates the ability to reassure oneself.
- Self-compassion scale (SCS) (Neff, 2003) a self-report measure measures a person's ability to show themselves compassion in the face of challenges.
- Toronto Mindfulness Scale Trait (Davis *et al*, 2009) a self report measure of mindfulness traits such as curiosity, acceptance and openness. Given the CFT group incorporates elements of mindfulness, this will be useful to measure.
- Other as Shamer Scale (Goss *et al*, 1994) a self-repost measure to evaluate beliefs a person has about other's evaluation of them.
- Social Connectedness Scale Revised (Lee *et al*, 1995) a self-report measure which evaluate people's feelings of connectedness to others. To measure whether the group itself has an impact on people's feelings.

Measure	Administration sequence number	Session number to be delivered at	No. of items	Construct being measured	Est. completion time (mins)
PHQ-9	1	1, 5, 10	9	Depression	1 minute
GAD-7	2	1, 5, 10	7	Anxiety	1 minute
Forms of self- criticising/attacking	3	1, 9, 10	22	Inadequate self	4 minutes

Table 1. Outcome Measures to be Used.

& self-reassuring				Hated self	
scale				Reassured self	
Other as Shamer Scale	4	1, 5, 10	18	External shame	3 minutes
Self-compassion scale	5	1, 8, 10	26	Self- compassion	4 minutes
Social Connectedness Scale	6	1, 5, 10	20	Social connectedness	4 minutes
Toronto Mindfulness Scale - Trait	7	1, 7, 10	13	Mindfulness	3 minutes

Design

As this is a feasibility study, a mix methods study design will be used. For the quantitative part of the study a within group design will be used to assess outcomes at baseline and posttreatment. Treatment acceptability will also be evaluated by semi-structured interviews following the intervention.

CFT Protocol

A group programme of CFT will run for 10 sessions lasting 90 minutes per session. The group has been developed by an experienced NHS Clinical Psychologist working with older adults. The group protocol has been developed from a previous group run in NHS GGC with working age adults (Judge, Cleghorn, McEwan & Gilbert, 2012). The group will be delivered by NHS clinicians and led by an NHS Clinical Psychologist. The sessions are as follows:

Session 1: Introduction, aims and soothing rhythm breathing

Session 2 & 3: Psychoeducation

Session 4: Formulation

Session 6: Compassionate Self

Session 7: Compassionate Image and barriers to compassion

Session 8: Multiple selves – responding with different emotions

Session 9: Shame and self-criticism

Session 10: Review, formulation and planning ahead

Participants will be asked to practice techniques and record their progress throughout the intervention. They will practice breathing and mindfulness techniques and keep a compassionate diary to support their learning.

Data Collection

All measures will be completed with participants in a pre-intervention meeting and at postintervention in the order indicated in table 1. The measures will also be repeated after specific sessions to evaluate any change from a specific intervention (session numbers shown in table 1). Demographic data will also be obtained to allow for a description of the data. The lead clinician will administer and collect the outcome measures at the end of the specified session. Attendance and dropout from the group will also be recorded for analysis.

Following the completion of the group, participants will be asked to attend for a semistructured interview to discuss their experience of the CFT group protocol. All those who consented to participate in the study will be asked to participate in the semi-structured interview. The interviews will be conducted by a trainee clinical psychologist (main researcher) who will be unknown to participants. Interviews will be based on a topic guide, which will focus on the participant's experience of the intervention and their thoughts for improvements. The interviews will be recorded and transcribed, and all patient identifiable data will be anonymised. The recordings will then be destroyed.

Data Analysis

Quantitative data will be analysed using SPSS; outcome measures will be analysed for changes in outcome measures before, during and after treatment. Descriptive statistics will be used to define the sample and evaluate attrition. Within subjects t-tests, or non-parametric equivalent will evaluate results pre and post intervention to explore change at a group level. For future studies a power calculation with be calculated to inform the recruitment and retention of participants.

Qualitative data will be analyses using Thematic Analysis (Braun & Clarke, 2006). Transcripts of interviews will be read to capture themes in responses and the themes will be applied to the transcript data to ensure the data is accurately evaluated.

Sample Size

As this is a feasibility study, a power calculation will not be done. It is an aim of this project to estimate recruitment and retention and to calculate appropriate sample sizes for future research, as per MRC guidelines on developing complex interventions (Craig, 2008). Effect sizes will be generated from this study which can be used to inform future research. Due to the group component of the intervention, it is likely that the groups will run with approximately 12 participants. It is planned that two groups will be run; therefore, it is estimated that 24 participants will take part in the study. If recruitment to the study is not as expected, then participants will be recruited from later groups scheduled. For the qualitative analysis, a purposive sample of those who completed and did not complete the intervention will be asked to participate in semi-structured interviews. For the qualitative component the sampling will be iterative to data saturation.

Health and Safety Issues

Potential health and safety issues may arise in the planning process. As CFT has little research in the older adult population it is possible that some adaptations are needed to adjust for this

cohort, for example, physical discomfort from the environment, length of sessions and complexity of homework. Careful consideration will be given to the needs of older adults to evaluate whether the protocol meets their needs.

All participants will have the project explained to them with potential outcomes. Information will be given in written format and participants will be asked to sign to consent to take part in the study. Additionally, it will be explained that participants can drop out at any time and their data destroyed. Participants will also be given the opportunity to access the report written from the project.

The groups will be run by two staff members (at least one will be a qualified clinician). The staff will be alert for any distress experienced by participants and will take steps to manage any distress. Standard NHS procedures will be used to log any adverse events, such as reporting on the Datix system. One facilitator is a Clinical Psychologist working in an Older Adult Community Mental Health Team in NHS Greater Glasgow & Clyde. The Clinical Psychologist has completed a doctorate in Clinical psychology and has experience of delivering psychological therapies, including CFT, in the community.

Groups will be run during normal working hours and standard NHS procedures will be followed for the safety of participants and staff.

Ethical Issues

An ethics application for the study will be submitted to the NHS Greater Glasgow and Clyde's Research Ethics Committee and the Research and Development Department.

Confidentiality will be discussed with participants in their initial meeting prior to the group and repeated at the start at the group. Participants will be informed of the limits of confidentiality. Participants will be informed that they can withdraw from the project at any time. All data collected will be anonymised. Data will be stored in line with the NHS Confidentiality Code of Practice Guidelines (2003), Caldicott Guidelines, the Freedom of Information Act (2000) and the General Data Protection Regulation (Data Protection Act, 2018).

Financial Issues

It is expected that the main costs will be paperwork for the study, including printing of outcome measures and handouts. A recorder will be borrowed from the University of Glasgow to record interviews.

Timetable

January 2019: Complete Ethics application

April 2019: Group 1 (10 weekly sessions plus data collection and interviews)

July 2019: Group 2 (10 weekly sessions plus data collection and interviews)

Early 2020: Data analysis and write-up will be completed

April 2020: Viva scheduled

Late 2020: Write up for publication

Practical Applications

The current study aims to evaluate the acceptability and feasibility of a CFT group in an older adult community mental health service. The practical applications for the service are that it will help inform whether a CFT group is a beneficial intervention. Additionally, it aims to provide data on the acceptability of outcome measures and effect sizes for future research. Also, the results of the study will contribute to the current CFT literature and provide initial research of CFT in older adults.

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Appendix 2.7 Participant Consent Form for Outcome Measures

IRAS ID: 255137

Consent form v1.2

April 2019

Greater Glasgow and Clyde



IRAS ID: 255137

Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

Name of Researcher: Fiona McConnell

Please initial box

- I confirm that I have read the information sheet dated...... (version.......) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from NHS Greater Glasgow & Clyde, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- I agree to my General Practitioner being informed of my participation in the study.
- I understand that the information held and maintained by NHS Greater Glasgow & Clyde may be used to help contact me or provide information about my health status.
- 6. I agree to take part in the above study.

Name of Participant	
Name of Person taki	

Date

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Date

Signature

Signature

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Appendix 2.8 Participant Consent Form for Semi-Structured Interviews

IRAS ID: 255137

Consent form Semi Structured Interview v1.01

University of Glasgow

IRAS ID: 255137

Study Number:

Participant Identification Number for this trial:

had these answered satisfactorily.

CONSENT FORM

Title of Project: A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults – Semi-structured Interviews

Nam	e of Researcher: Fiona McConnell			
			Please	e initial box
1.	I confirm that I have read the information sheet dated	(version) for the	
	above study. I have had the opportunity to consider the info	rmation, ask quest	ions and have	

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from NHS Greater Glasgow & Clyde, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4. I understand that the information held and maintained by NHS Greater Glasgow & Clyde may be used to help contact me or provide information about my health status.
- 5. I agree to participate in an interview following completion of the group.
- 6.
- a. I agree to be audio recorded for the interview following completion of the group or
- I do not agree to be audio recorded but rather have my responses be typed into a a written report for review by me.

Date	Signature
	Signature
	Date

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.



23rd May 2019

Appendix 2.9 Participant Information Sheet Outcome Measures

IRAS ID: 255137

Participant Information Sheet v1.05

25th July 2019





Participant Information Sheet

Study Title:

A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

Who is conducting the research?

The study is being carried out by:

- Fiona McConnell, Trainee Clinical Psychologist (NHS Greater Glasgow & Clyde)
- Professor Hamish McLeod (Supervisor University of Glasgow)
- Dr John Hickey (Clinical Psychologist, NHS Greater Glasgow & Clyde)

Invitation

You are being invited to take part in a research study. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. One of the research team will go through this information sheet with you and answer any questions that you have. This should take about 15 minutes. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

Compassion Focused Therapy (CFT) is a psychological therapy that uses various strategies to help people manage feelings of shame, self-criticism, anxiety and depression. Research shows that people who have a higher level of self-compassion have better psychological wellbeing. CFT can be an effective treatment for people with mental health difficulties. However, we need to understand more about the effectiveness, suitability and acceptability for people over 60 years old. The research will mainly occur from April 2019 until April 2020, your connection to the study will last around 4 months.

The study will be submitted as part of Fiona McConnell's research portfolio as part of her requirements for completion of the Doctorate in Clinical Psychology at the University of Glasgow.

IRAS ID: 255137

Why have I been invited?

We are looking for participants who are over 60 years old, are experiencing symptoms of emotional distress such as depression or anxiety. We asked clinicians working in older adult services in South Glasgow and East Renfrewshire to identify people who meet these criteria, would benefit from taking part in the CFT group and may be interested in taking part in this research. The referral information from the referrer was used by clinicians and Dr John Hickey to assess suitability for this type of intervention. By taking part in the study your routine care will not be affected.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the research. Your access to the treatment group is not affected whether you agree to participate in the research or not. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason. Regardless of whether you decided to participate or not, it will not affect any treatment you are currently receiving or any that you may need in the future.

What will happen to me if I take part?

As part of your initial meeting Dr John Hickey will explain the CFT group and will assess your suitability to participate in the group. Dr Hickey will also explain that the group is part of a research project and invite you to meet with Fiona McConnell (Trainee Clinical Psychologist) to discuss the research. Fiona McConnell will explain the research process and what is expected of you. When you are sure you would like to take part, Fiona McConnell will ask you to sign a consent form. You can withdraw your consent to take part in the research at any time.

You will also be asked to complete some questionnaires that ask questions about mood, thoughts and behaviours; these will take around 20 minutes to complete.

There will be 10 weekly group sessions and each group session will last for **90 minutes**. The sessions will take place at the same NHS clinic each week (Shawmill Resource Centre, Elderpark Clinic, or Eastwood Health Centre). Frequent breaks will available if required. If you become distressed during the sessions Dr John Hickey and the co-facilitator will be available for support.

The sessions will cover the following topics:

- Session 1: Introduction, aims of the group, soothing rhythm breathing practice and mindful checking in
- Session 2: Psychoeducation understanding thoughts and emotions
- Session 3: Psychoeducation Introduction to CFT 'three systems'
- Session 4: Formulation
- Session 5: Formulation & the threat system learning how to notice thoughts
- Session 6: Compassionate Self what it is and learning how to cultivate compassion for self
- Session 7: Compassionate Image and barriers to compassion
- Session 8: Multiple selves responding with different emotions angry self, anxious self, sad self and compassionate self
- Session 9: Shame and self-criticism

IRAS ID: 255137

Session 10: Review, formulation and planning ahead

You will be asked to complete some questionnaires again after certain sessions, which will take approximately 5 minutes. After the last session you will be asked to complete all the questionnaires again, these will take around 20 minutes to complete. Questionnaires will be given to you by Dr John Hickey. There are a total of 7 questionnaires which will be administered in the following order:

- 1. PHQ-9
- 2. GAD-7
- 3. Forms of self-criticising/attacking & self-reassuring scale
- 4. Other as Shamer Scale
- 5. Self-compassion scale
- 6. Social Connectedness Scale
- 7. Toronto Mindfulness Scale Trait

You will also be invited to attend a one-to-one interview at the same location that you attend the group, within 8 weeks of completing the group, where you can describe your experience of the group. The interview will either be done by Fiona McConnell or Morgan McDonald (Clinical Associate in Applied Psychology). If you do not complete all the sessions, we would still like to hear about your experience, so we will contact you to invite you along to an interview and you can come if you want to. This interview will last 30-60 minutes and will be audio recorded. It will be anonymised so although we might use some of your quotes, your identity will be concealed and kept confidential. If you become distressed in the interview Fiona McConnell or Morgan McDonald will be available to offer support if needed.

If you miss any sessions or dropout of treatment, this information will be recorded and used as part of the analysis of the group.

What are the disadvantages and risks of taking part?

There is minimal risk of harm involved in taking part in this research project. There is a time burden in that we ask you to complete some questionnaires that are additional to routine outcome monitoring. When filling out the questionnaires, sometimes difficult thoughts or feelings may arise. If you do express feelings or thoughts of suicide or other extreme forms of distress, Dr John Hickey will be available to talk to and provide appropriate support.

What are the possible benefits of taking part?

No specific benefit can be guaranteed; however, research has shown others with similar conditions report improvements in mood and wellbeing. Some people find the experience of participating in the research interesting. Others have also reported that they enjoy contributing and supporting the improvement of healthcare.

Will my GP be notified?

Yes, we will write to your GP to inform them of your participation in the research study.

What happens when the research study ends?

At the end of the research, you will no longer be asked to complete questionnaires and interviews, but you will continue to receive treatment within the Older People's Mental Health Service if required.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. You will be given a unique ID number which you will be asked to report on all questionnaires rather than any identifiable information. At the NHS site a document will be kept with you participant ID linked to your name and contact details. Your data from questionnaires will be collected on an anonymised data collection form, which will be stored at the NHS site until the group is completed. This anonymised data will then be transferred to the University of Glasgow network for data analysis. No identifiable information will be removed from the NHS site. Participant name and contact details will be stored on the NHS network site file for 10 years following the research. Anonymised data from the study will be stored with University of Glasgow for 10 years following the completion of the research.

If you decide to take part in the post-intervention interview, this will be audio recorded. This recording will then be transcribed, without your name being attached to it. Any identifiable information on the recording will be redacted from the transcript. The audio recording will then be deleted when the study is completed. Anonymous quotes from the interview may be used in the final report.

Personal information on the site file will be accessible to Fiona McConnell (Trainee Clinical Psychologist), Dr John Hickey (Principal Clinical Psychologist) and Morgan McDonald (Clinical Associate in Applied Psychology). Additionally, as the study sponsor NHS Greater Glasgow & Clyde may access your personal information to ensure the study is being conducted correctly.

General Data Protection Regulation (GDPR):

NHS Greater Glasgow & Clyde is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow & Clyde will keep identifiable information about you for 10 years after the study has finished.

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

You can find out more about how we use your information at https://www.hra.nhs.uk/

NHS Greater Glasgow & Clyde will collect information from you for this research study in accordance with our instructions. NHS Greater Glasgow & Clyde will keep your name, CHI number and contact details confidential and will not pass this information to University of Glasgow. NHS Greater Glasgow & Clyde will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from NHS Greater Glasgow & Clyde and regulatory organisations may look at your medical and research records to check the accuracy of the research study. University of Glasgow will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, CHI number or contact details.

NHS Greater Glasgow & Clyde will keep identifiable information about you from this study for 10 years after the study has finished.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of Fiona McConnell's requirements for the Doctorate in Clinical Psychology. The study may also be written up for publication in an academic journal. Participants will be offered the opportunity to receive a summary of the research upon completion of the study.

Data from the study may also be used to inform future development and research of Compassion Focused Therapy group treatments in older adults.

Travel expenses

Unfortunately we are unable to provide travel expenses as the sessions you will be involved in form part of your standard care.

Who is organising and funding this research?

The research is organised via the University of Glasgow and is sponsored by NHS Greater Glasgow & Clyde. There is no commercial funding associated with this research.

Who has reviewed the study?

The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Greater Glasgow & Clyde, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

If you have any further questions

IRAS ID: 255137

Participant Information Sheet v1.05

If you would like more information about the study and wish to speak to someone who is not closely linked to the study, please contact Professor Thomas McMillan, University of Glasgow, email: thomas.mcmillan@glasgow.ac.uk, tel no. 0141 2110354.

If you have a complaint about any aspect of the study

If you are unhappy about any aspect of the study and wish to make a complaint, please contact Fiona McConnell in the first instance. The normal NHS complaint procedure is also available for you. The contact for making a complaint in NHS Greater Glasgow & Clyde is: Glasgow City HSCP, Commonwealth House, 32 Albion Street, Glasgow, Gl 1LH. Phone: 0141 287 0130. Email: GCHPComplaints@ggc.scot.nhs.uk

Contact details

If you would like further information you can contact: Main Researcher (Trainee Clinical Psychologist):

Fiona McConnell University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow, G12 0XH

Research Supervisors: Dr John Hickey Clinical Psychologist Elderpark Resource Centre Elderpark Clinic 20 Arklet Road Glasgow, G51 3XR John.hickey@ggc.scot.nhs.uk Tel: 0141-577-7773 & 0141-232-7183

Thank you for reading this Information Sheet.

Professor Hamish McLeod University of Glasgow Institute of Wellbeing 1055 Great Western Road Glasgow, G12 0XH <u>Hamish mcleod@glasgow.ac.uk</u> Tel: 0141 211 3922

Appendix 2.10 Participant Information Sheet Semi Structured Interviews

IRAS ID: 255137

Participant Information Sheet Semi Structured interviews v1.02



Participant Information Sheet Semi-structured Interviews

Study Title:

A Mixed Methods Feasibility Study of a Transdiagnostic Compassion Focused Therapy (CFT) Group for Older Adults

Who is conducting the research?

The study is being carried out by:

- Fiona McConnell, Trainee Clinical Psychologist (NHS Greater Glasgow & Clyde)
- Professor Hamish McLeod (Supervisor University of Glasgow)
- Dr John Hickey (Clinical Psychologist, NHS Greater Glasgow & Clyde)

Invitation

You are being invited to take part in an interview following your participation in the Compassion Focused Therapy (CFT) group. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. One of the research team will go through this information sheet with you and answer any questions that you have. This should take about 15 minutes. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the interviews?

We are keen to hear your views of the CFT group that you participated in. By carrying out interviews we are able to find out more from you about what you found good and bad about the group, what you learned, what you found useful and how it was to complete the outcome measures and take part in the research. This is important as it helps us to adapt and learn from your feedback so that we can improve future CFT groups and research.

Why have I been invited?

We are looking for participants who participated in or dropped out of the CFT group. By taking part in the study your routine care will not be affected.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the interviews. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw

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from the study at any time without giving a reason. Regardless of whether you decided to participate or not, it will not affect any treatment you are currently receiving or any that you may need in the future.

What will happen to me if I take part?

You will meet with Fiona McConnell (Trainee Clinical Psychologist) who will explain the interview and if you agree to participate in the interviews you will be asked you to sign a consent form. The interviews will take place in the same place that you attended the groups in a private clinic room. You will be asked several questions on your experience of the group. It is expected that this interview will take 30-60 minutes. Fiona McConnell or Morgan McDonald (Clinical Associate in Applied Psychology) will carry out the interviews with you.

The interviews will be audio recorded if you consent to this. If you do not consent to your interview being audio recorded you will still be able to provide your opinions in an interview. Fiona McConnell or Morgan McDonald will make notes on your interview responses and write these into a report, they will then ask you to check to confirm the accuracy of your responses. The recordings will be anonymised so although we might use some of your quotes, your identity will be concealed and kept confidential. If you become distressed in the interview Fiona McConnell or Morgan McDonald will be available to offer support if needed.

What are the disadvantages and risks of taking part?

There is minimal risk of harm involved in taking part in the interviews. There is a time burden in that we ask you to spend 30-60 minutes participating.

What are the possible benefits of taking part?

No specific benefit can be guaranteed. Some people find the experience of participating in the research interesting. Others have also reported that they enjoy contributing and supporting the improvement of healthcare.

Will my GP be notified?

Your GP will have been notified that you have participated in the CFT group. We will not further notify them of you participating in the follow up interviews.

What happens when the research study ends?

At the end of the research, you will continue to receive treatment within the Older People's Mental Health Service if required.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. The recordings will be transcribed, without your name being attached to it. Any identifiable information on the recording will be redacted from the

transcript. The audio recording will then be deleted when the study is completed. Anonymous quotes from the interview may be used in the final report.

Personal information on the site file will be accessible to Fiona McConnell (Trainee Clinical Psychologist), Dr John Hickey (Principal Clinical Psychologist) and Morgan McDonald (Clinical Associate in Applied Psychology). Additionally, as the study sponsor NHS Greater Glasgow & Clyde may access your personal information to ensure the study is being conducted correctly.

General Data Protection Regulation (GDPR):

NHS Greater Glasgow & Clyde is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow & Clyde will keep identifiable information about you for 10 years after the study has finished.

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

You can find out more about how we use your information at https://www.hra.nhs.uk/

NHS Greater Glasgow & Clyde will collect information from you for this research study in accordance with our instructions.

NHS Greater Glasgow & Clyde will keep your name, CHI number and contact details confidential and will not pass this information to University of Glasgow. NHS Greater Glasgow & Clyde will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from NHS Greater Glasgow & Clyde and regulatory organisations may look at your medical and research records to check the accuracy of the research study. University of Glasgow will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, CHI number or contact details.

NHS Greater Glasgow & Clyde will keep identifiable information about you from this study for 10 years after the study has finished.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of Fiona McConnell's requirements for the Doctorate in Clinical Psychology. The study may also be written up for publication in an academic journal.

Data from the study may also be used to inform future development and research of Compassion Focused Therapy group treatments in older adults.

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Travel expenses

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Contact details

If you would like further information you can contact: Main Researcher (Trainee Clinical Psychologist):

Fiona McConnell University of Glasgow Institute of Health and Wellbeing 1055 Great Western Road Glasgow, G12 0XH

Research Supervisors: Dr John Hickey Clinical Psychologist Elderpark Resource Centre

Professor Hamish McLeod University of Glasgow Institute of Wellbeing

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Elderpark Clinic 20 Arklet Road Glasgow, G51 3XR John.hickey@ggc.scot.nhs.uk Tel: 0141-577-7773 & 0141-232-7183

1055 Great Western Road Glasgow, G12 0XH <u>Hamish mcleod@glasgow.ac.uk</u> Tel: 0141 211 3922

Thank you for reading this Information Sheet.

Appendix 2.11 CFT Poster

CFT Psychological Therapy Group Contact: Dr John Hickey – Shawmill and Elderpark OPCMHT's 2019

What is CFT?

- Compassion Focused Therapy
- Based on Evolutionary Psychology, Neurobiology, and the psychologies of cognition, emotion, behaviour and mindfulness to name a few
- Emphasis on addressing key emotions that can cause and/or maintain symptoms of depression and anxiety

What treatment is on offer?

- 10 week Compassion Focused Therapy group
- Work on understanding our "<u>tricky brain</u>" and how the difficulties that make us feel stuck are human difficulties – they are common –
- Work on strategies to address key emotions anger, sadness, fear
- Work on key problems of shame and self criticism "It's not your fault"

Practice relaxation and mindfulness based techniques

When can I refer patients for an assessment?

- Now!- contact Dr John Hickey
- Groups to start in June 2019 and in September 2019

Who might benefit?

- Able to commit to working over 10 weeks; in session and in between sessions
- Feeling stuck with symptoms of anxiety or depression or a particular life stressor