

**Being kind to ourselves: The feasibility and acceptability of  
Compassion Focused Therapy (CFT) to improve depression  
and anxiety in Dementia: A qualitative analysis**

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**University College London**

## **UCL Doctorate in Clinical Psychology**

### **Thesis declaration form**

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

Name: Ben Loe

Date: 11<sup>th</sup> June 2025

## Overview

Compassion Focused Therapy (CFT) is a promising third-wave Cognitive Behavioural Therapy (CBT) approach to support people with depression and anxiety. However, it is yet to be tested rigorously in the older adult population, specifically in people living with dementia. This thesis aimed to investigate the feasibility of a CFT trial for depression and anxiety in this population.

Part one is a systematic review and meta-analysis of third-wave CBT interventions for older adults. Studies that reported outcomes on depression, anxiety, quality of life or self-compassion were included. There were mixed findings and validity was limited by small sample sizes. Suggestions for future research is presented and discussed.

Part two constitutes a qualitative study exploring the feasibility and acceptability of group Compassion Focused Therapy (CFT) to support people living with dementia (PLWD) experiencing depression and anxiety. Framework analysis was used to analyse data gathered in interviews with caregivers of PLWD, CFT group facilitators and NHS senior management clinicians involved in the trial. This is a joint project with Shoshanna Freedman, Trainee Clinical Psychologist, who presents the data gathered from PLWD. This qualitative evaluation was embedded within a multi-site randomized controlled trial (RCT) which is still ongoing. My project is therefore also joint with Melissa Melville, PhD student, who will focus on the quantitative analysis from the main RCT when complete.

Part three outlines a critical appraisal of the process of conducting this research. This includes my interest in dementia and CFT, reflections on my involvement as a group facilitator in the CFT trial, and methodological challenges of the part two research.

## Impact Statement

The research presented in this thesis adds to the growing literature on third-wave Cognitive Behavioural Therapy (CBT) in older adults, particularly Compassion Focused Therapy (CFT) for people living with dementia (PLWD). The conclusions drawn from the Literature Review and Empirical Paper have applications both within and outside academic circles.

### **Literature Review**

The Systematic Review in this thesis builds upon two previous theses that investigated third-wave CBT. However, to the author's knowledge this is the first review that synthesised data from Randomised Controlled Trials (RCTs) using meta-analysis to investigate depression, anxiety, quality of life and self-compassion in older adult populations. The finding that interventions deploying more hours of therapy were no more effective than those with fewer has clinical implications pertaining to resource allocation and cost. The study also highlighted that there was limited available research and a lack of standardization in therapeutic approaches, with high heterogeneity between included studies potentially pointing to the lack of specification of treatment protocols and intervention delivery. Academic implications here are that more robust RCTs are needed, with an emphasis being placed on ensuring clear reporting of therapeutic protocols and subsequent deviations in order to enable robust statistical analysis. This review is in the process of being edited for publication.

## **Empirical Paper**

This study suggests that group CFT is a feasible and acceptable intervention to support PLWD with depression and anxiety. Moreover, the findings suggest that, overall; the trial processes were feasible and acceptable too. This has important academic implications as it suggests the appropriateness of a full-scale RCT and identifies numerous areas that the trial and intervention could be tweaked in order to bolster participant access, engagement and outcomes. Moreover, the role of the caregivers in dementia research and daily life is discussed, with research implications being pertinent to this demographic as well as PLWD. Given the mixed findings of current psychosocial interventions for PLWD, this has exciting clinical implications. People may be able to engage in a CFT group that not only provides social connection, but one that endorses openness and vulnerability in a way that existing interventions may not. The findings from NHS staff suggest that the intervention sits well within existing NHS service frameworks and therefore has the potential to be operationalised on a national level. Finally, I believe that the intervention should become more embedded within older adult memory services, as there are vital moral implications. It opens the door to therapeutic support for a frequently isolated population, and helps to promote compassion in a world that can often feel quite the opposite.

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## Part 1: Literature Review

### Effectiveness of Third-Wave Cognitive Behavioural Therapies for Older Adult Psychological Wellbeing: A Systematic Review and Meta-Analysis

## 1. Abstract

*Introduction:* 'Third-wave' Cognitive Behavioural Therapies (CBT) arose in response to limitations of CBT such as emotional avoidance and invalidation of experience, and focus on acceptance, mindfulness and values-based work. They are receiving growing attention in adults, but the evidence base in the older adult population is still lacking. Most existing reviews report measures of depression or anxiety, the latest of which being conducted in 2021, highlighting the need for an updated review. Additionally, there are arguments to suggest that quality of life and self-compassion should be included as measures of wellbeing rather than the focus being solely on symptom reduction, which no review has yet focused on. A synthesis of up-to-date Randomized Controlled Trials of depression, anxiety, quality of life and self-compassion in older adults is therefore warranted to evaluate the effectiveness of third-wave interventions in older adults.

*Objective:* To evaluate the effectiveness of third-wave CBT on improving depression, quality of life, anxiety and self-compassion in adults aged 65 or over.

*Methods:* MEDLINE, PsychInfo, Scopus, Proquest and Cochrane Central Register of Controlled Trials (CENTRAL) electronic databases were searched to identify Randomised Controlled Trials that reported a measure of depression, quality of life, anxiety or self-compassion in older adults.

*Results:* Twelve studies (n= 1009) were included in the review. Eleven were synthesised using a random effects meta-analysis, one was synthesised narratively. Third-wave interventions did not differ significantly from active, waitlist, treatment as

usual or no-treatment controls on measures of depression (SMD= 0.88 [-0.01; 1.78],  $p= 0.052$ ), quality of life (SMD= 0.10 [-0.22; 0.42],  $p= 0.454$ ) anxiety (SMD= -0.90 [-4.80; 3.00],  $p= 0.43$ ) or self-compassion ( $F[2, 240]= 2.12$ ,  $p= 0.12$ ). Intervention type was identified to be a significant moderator of effect size in depression, but this could be explained by control group and age variables.

*Conclusion:* Third-wave CBT interventions were not more effective than control interventions in improving depression, quality of life, anxiety and self-compassion in older adults, though small sample sizes limit the conclusions that can be drawn.

## 2. Introduction

Older adults report higher levels of psychological wellbeing compared to those under the age of 65 (Carstensen et al., 2011). However, there exist some particular challenges as people move through the lifespan, from ageism and preparing for end of life, to comorbid physical health difficulties and neurodegeneration. With numbers in this demographic increasing over recent decades, considerations of how best to support older adult psychological wellbeing are essential.

Despite older adults being more likely to be prescribed medication rather than psychological support (Gum et al., 2006) existing literature suggests that older adults may particularly benefit from psychological intervention (Laidlaw, 2021) with those aged 65 and above experiencing greater clinical improvement following psychological intervention than those under 65 (Saunders et al., 2021; Pettit et al., 2017). Most of the evidence base is focused on Cognitive Behavioural Therapy (CBT) for depression and anxiety, and demonstrates its effectiveness in reducing associated symptoms (Cuijpers et al., 2014; Hendriks et al., 2024). However, the Hendriks et al (2024) review highlights how the evidence base is still relatively small compared to adult research, the suggested benefits of CBT in this population are not maintained longer term, and when compared to other psychological treatments CBT was no more effective for reducing symptomatology. There are also issues with access to treatment in this population. Older adults are underrepresented in NHS psychological services (NHS Digital, 2022), something that the (NHS Talking Therapies Positive Practice Guide: Older People, 2024) suggest may be partly due to the lack of choice in treatment offered, indicating that services should not rely solely on CBT as the first line treatment.

Alternatives to CBT are therefore required for this demographic. There is evidence to suggest that so-called 'third-wave' CBT therapies may be preferable to older clients (Witlox et al., 2021). 'Third-wave' CBT can be described as targeting people's relationship to their thoughts rather than the content of the thoughts themselves, therefore incorporating context into the work more readily (Hayes & Hofmann, 2017). Examples of these approaches include Acceptance and Commitment Therapy (ACT) (Hayes et al., 2006), Mindfulness-Based Cognitive Therapy (MBCT) (Segal, Williams & Teesdale, 2012), Mindfulness-Based Stress Reduction (MBSR) (Kabat-Zinn, 1990), Compassion Focused Therapy (CFT) (Gilbert, 2009a) and Dialectical Behavioural Therapy (DBT) (Linehan, 1992).

These interventions have received some empirical support in the wider population (Öst, 2008; Schefft et al., 2023), though of the emerging evidence in the older adult literature findings are mixed; Helmes & Ward (2017) suggest the effectiveness of MBCT for those in residential care settings, while Thomas et al. (2020) find insufficient evidence for MBCT in alleviating symptoms of anxiety and depression in older adults. A systematic review and meta-analysis conducted by Kishita et al. (2017) reported a significant effect of ACT and MBCT on symptoms of depression and anxiety, while an unpublished systematic review by Oliani (2022) as part of a doctoral thesis found small positive effects of third-wave therapies on symptoms of depression and anxiety in a narrative review of case studies, Randomised Controlled Trials (RCTs) and quasi-experimental studies. A further unpublished doctoral paper mirrored these findings with another narrative review of exclusively RCTs (Perry, 2021).

Much like the wealth of available literature, the aforementioned reviews predominantly focus on depression and anxiety in older adults. While this is crucial given the prevalence of these disorders in this demographic (Pocklington, 2017; RCPsych, 2018), it could be conceived as being a limited perspective of older adult wellbeing. The Institute for Public Policy Research (IPPR, 2009) outlines five key areas related to healthy ageing: resilience, independence, health, income and wealth, and having a role and having time, which moves beyond constructs of depression and anxiety. Hussenoeder et al. (2021) present quality of life (QoL) as a valuable indicator of wellbeing in this age group, while self-compassion is presented as an important variable to consider due to its benefits for older adult functioning (Tavares et al., 2023) and its potential mediating role in QoL (Kim & Ko, 2018).

Consequently, the reviews and studies outlined above highlight the lack of a systematic review that is focused on third-wave therapies and:

- Only includes RCTs, which is important when thinking about the assignment of causality;
- Is synthesised using a meta-analysis rather than narrative review, which is important in drawing quantitative conclusions across studies;
- Views psychological wellbeing through a wider lens than merely depression and anxiety by incorporating QoL and self-compassion.

The present review therefore aimed to investigate the following research questions:

- What is the effectiveness of third-wave CBT interventions compared to control conditions in improving depression, anxiety, quality of life and self-compassion in adults over 65?

- What is the current state of the quality and strength of the RCT evidence base?

### 3. Methods

The present review was registered with PROSPERO (record number CRD42024558587) and has been written in line with PRISMA guidelines (appendix 1).

#### 3.1. Inclusion / exclusion

Table 1 summarises the inclusion and exclusion criteria.

Table 1. Inclusion and exclusion criteria

Inclusion	Exclusion
<ul style="list-style-type: none"> <li>• Participants had mean age equal to or greater than 65 (including studies focused on caregivers).</li> <li>• Third-wave CBT interventions including ACT, MBCT, MBSR, CFT, DBT, metacognitive therapy or schema therapy where the focus of therapy is changing relationships to thoughts not the thoughts themselves (Hayes &amp; Hofmann, 2017).</li> </ul>	<ul style="list-style-type: none"> <li>• Studies focusing on physical health comorbidities e.g. diabetes, or those focusing on insomnia or sleep difficulties.</li> <li>• Studies where cognitions are not targeted e.g. relaxation.</li> <li>• First or second-wave CBT interventions that focus on changing thoughts directly (e.g. CBT or Behavioural Activation).</li> <li>• Studies published prior to 2022.</li> </ul>

- 
- Studies that use reasonably adapted versions of these intervention approaches
  - Primary outcome of depression, anxiety, QoL or self-compassion as measured by validated psychometric test e.g. Geriatric Depression Scale or WHOQoL
  - Randomized Control Trials with appropriate control group and pre-post intervention measurements.
  - Written in English.
  - Participants could have diagnosed or suspected cognitive impairments e.g. dementia, Parkinson's or subjective cognitive decline.
  - Interventions delivered individually or in group settings, either face to face or remotely using videoconferencing software
  - Participants with and without clinical diagnoses of depression or anxiety.
  - Studies focusing solely on caregivers who were not aged 65 or above.
  - Protocols.
  - Not RCTs with pre-post intervention outcome measures
  - Comorbid mental health diagnoses such as psychosis or personality disorder.

Decisions around exclusion criteria were made in an attempt to preserve homogeneity in some areas. Studies utilising participants with comorbid mental or physical health diagnoses were excluded due to the potential differences in presentation and responses to intervention. This was similar for the age threshold criterion, which also aligned with NHS and World Health Organisation (WHO) policy definitions of older adults and with traditional societal frameworks such as retirement age and pension receipt. The decision to exclude studies published pre-2022 was driven by the recognition that the COVID-19 pandemic introduced substantial and lasting changes to both the wellbeing of older adults and the delivery of psychological interventions (Cuthbert et al., 2022; Job et al., 2022). Studies conducted early on in the pandemic (2020 – 2021) were likely to reflect emergency conditions with disrupted healthcare access (World Health Organisation, 2022), and differing psychological needs (Pujolar et al., 2022) which may not represent the current state of older adult wellbeing. Moreover, as the present review was an update and extension of previous reviews whose searches were run in October 2020 (Perry, 2021) and December 2021 (Oliani, 2022), a rationale to exclude studies pre-2022 emerged.

### 3.2. *Search strategy*

Scoping searches using Google Scholar were initially conducted to familiarise with the literature. MEDLINE, PsycInfo, Scopus, Proquest and Cochrane Central Register of Controlled Trials (CENTRAL) electronic databases were then searched on 5<sup>th</sup> July 2024 (MEDLINE, PsycInfo and Scopus) and 10<sup>th</sup> July 2024 (Proquest and CENTRAL), with no additional date parameters specified at this stage. Database selection was based on existing similar reviews (Kishita et al., 2017) and aimed to ensure coverage across medical, psychological, psychiatric, gerontologic and other multidisciplinary

clinical practices, as well as ensuring inclusion of an RCT-specific database (CENTRAL). Similar to Oliani (2022), Proquest was also included to provide access to grey literature.

Forward citation searching was used within the Web of Science database to identify any additional papers. Rayyan Artificial Intelligence software (Ouzzani et al., 2016) was used to compile the search results and de-duplicate studies.

The final search strategy used built on searches used in similar reviews such as Kishita et al. (2017), with three key searches being conducted, whereby search terms were combined using Boolean functions 'OR' and 'AND'. Keywords, titles and abstracts were searched within the databases, and for databases that facilitated the function, subject headings and MeSH headings were searched to provide a more comprehensive search of third-wave therapies and psychological outcomes. Due to slight discrepancies in the different databases, the searches were adjusted to conform to database requirements. See Table 2 for search terms, and see appendix 2 for details of search terms in each individual database.

Table 2. Database Search Terms for Systematic Review

Stage	Search Terms
1	(third adj wave) or CFT or (compassion adj focus?ed) or mindful* or MBCT or "mindfulness based cognitive therapy" or ACT or "acceptance and commitment therapy" or MCT or "metacognitive therapy" or DBT or "dialectical behavior therapy" or "schema therapy"

- 
- 2            anx\* or depress\* or dysph\* or wellbeing or (well being) or (quality of life) or (self compassion)
  
  - 3            (older adj adult) or elder\* or (old adj age) or (late\* adj life) or ag?ing or geriatric or (older adj people) or over 65

### 3.3. *Data Collection*

The primary author screened all articles using the Rayyan AI software whereby studies were manually excluded with the assistance of the AI-generated PICO (participant, intervention, comparison, outcome) model, a feature that highlights text relevant to the domain of interest. A second reviewer (RN) was recruited to screen 10% of the titles and abstracts, and then a further 10% sample of those shortlisted for full text screening. Any disagreements were discussed, and a third reviewer (SF) enlisted in the instance of continued disagreement.

Studies that met the inclusion criteria were exported from Rayyan for full text review into a Microsoft Excel spreadsheet where key information was extracted to check the suitability for inclusion against the inclusion and exclusion criteria. When the full text review was completed, data were extracted from the included studies using an excel form. This included study information such as the year of publication, author and country, as well as information on the study design such as treatments and control groups used, the length of the intervention and minutes per week that participants were engaged in treatment. Sample demographics including sample sizes in

experimental and control groups, mean age and gender were collected as well as the psychological outcomes of interest. Statistical methods used such as Intention To Treat (ITT) analysis and descriptive and inferential statistics at pre and post-intervention (means, standard deviations and effect sizes) were extracted, along with follow-up information where provided. Any information pertinent to bias was recorded and factored into the subsequent risk of bias analysis. In instances where studies had multiple outcomes, only those that were relevant to the present review were extracted (depression, anxiety, QoL and self-compassion).

#### *3.4. Risk of bias assessment*

Risk of bias was assessed using the Cochrane Risk of Bias (ROB 2) tool (see appendix 3). This tool assesses levels of risk across five domains: randomisation process, deviations from intended intervention, missing outcome data, measurement of the outcome and reporting the results.

#### *3.5. Data preparation*

Primarily using raw data extracted from the study results, pooled standard deviations (SD), standardised mean differences (SMD) and standard errors (SE) were calculated. Two studies (Javadzade et al, 2024; Giulietti et al, 2023) did not report means and standard deviations, only the mean differences. The pooled SD estimates for the BDI-II measure in these two studies were taken from the 'Schneider et al' study due to its low risk of bias and larger sample size. The estimated pooled SD SF-36 value in the 'Giulietti et al 2023' study was taken from existing literature (Park et al., 1998; Walters, 2004). For this reason, SMD and SE were precalculated in an excel spreadsheet and the subsequent meta-analyses were conducted using this precalculated data.

Some studies also utilised multiple control groups and therefore reported multiple SMDs and SEs. The decision was made to handle this by splitting the study into multiple parts so that each SMD had a unique row in the excel spreadsheet. Studies that utilised multiple control groups were split in a similar way; each comparison had a unique row in the excel spreadsheet denoted by 'a' and 'b', for example 'Sanchez-Lara et al 2023a' contained the SMD of the intervention with a control, and 'Sanchez-Lara et al 2023b' contained the SMD of the intervention with a different control. For this to be in line with Cochrane guidelines, the sample size of the control groups was divided by the number of comparisons (Higgins, Eldridge & Li, 2024). These studies were then eligible to analyse in the same meta-analysis.

Prior to analysis, the direction of effect sizes were adjusted so that all were harmonious. Negative mean differences on measures of depression and anxiety indicated an improvement in symptoms, whereas negative mean differences on measures of QoL and self-compassion indicated worsening of symptoms. For this reason, the mean differences for QoL and self-compassion measures were multiplied by -1 to correct for this.

### 3.6. *Analyses*

Once data extraction and preparation were complete, the complete excel spreadsheet was then imported to R Studios, which was used to conduct the analyses (see appendix 4 for full R script). The 'metafor' package was utilised in R to run all the meta-analyses (Viechtbauer, 2010). Firstly, to correct for small sample bias the Hedge's  $g$  adjustment was applied to the SMD and SE variables prior to conducting the meta-

analyses. Meta-analyses and forest plots were then generated. These utilised random-effects models due to the expected heterogeneity both within and between studies. In running these analyses, the  $Q$ ,  $\text{Tau}^2$  and  $I^2$  statistics were calculated as measures of observed heterogeneity, residual heterogeneity and between study heterogeneity respectively, where  $I^2$  was interpreted as 0% indicating no impact of study heterogeneity, 50% suggesting substantial impact of study heterogeneity, and 75% indicating considerable impact of between study heterogeneity on the calculated effect sizes (Higgins, 2003).

Following recommendations (Hartung, 1999), the Restricted Maximum Likelihood (REML) method for computing  $\text{Tau}^2$  was used due to its appropriateness for analyses involving small study samples and potentially high heterogeneity. Hartung-Knapp (HK) adjustments were also applied to the confidence intervals around this  $\text{Tau}^2$  estimate in order to reduce the chances of reporting false positives in analyses where the study sample size is small (Knapp & Hartung, 2003; Sidik & Jonkman, 2002).

Three meta-analyses were run: one for each outcome area of interest: depression, QoL and anxiety. The decision to conduct three separate meta-analyses was made in order to preserve true effects on each outcome type rather than combine into one and potentially lose clarity of the data. No meta-analysis was run for self-compassion because only one self-compassion study was identified. Instead, a narrative synthesis of this paper was performed.

Sensitivity analyses were then conducted. For each outcome measure of interest, the 'metafor' package in R was used to identify any statistical outliers and then re-run the

analysis with outliers removed. Given the nature of the review, it was also decided to run a sensitivity subgroup analysis on intervention type (e.g. Mindfulness Based Intervention [MBI], MBSR, MBCT) for the depression and QoL outcomes to investigate the presence of any differences in effect sizes across different third-wave interventions. This was not conducted for the anxiety outcome due to the small number of studies identified.

To explore potential sources of heterogeneity of any significant or significance-approaching effects found, a series of meta-regressions were then run to investigate whether extracted study characteristics were acting as moderators of the between study heterogeneity. Variables of interest were: amount of therapy received (measured by total hours), control type used, intervention used, outcome measure, risk of bias, use of Intention To Treat analysis (ITT), attrition rates, age, whether participants were residing in the community or not, and whether participants had diagnoses of dementia or not. Due to insufficient power, these meta-regressions were considered exploratory.

### *3.7. Certainty assessment*

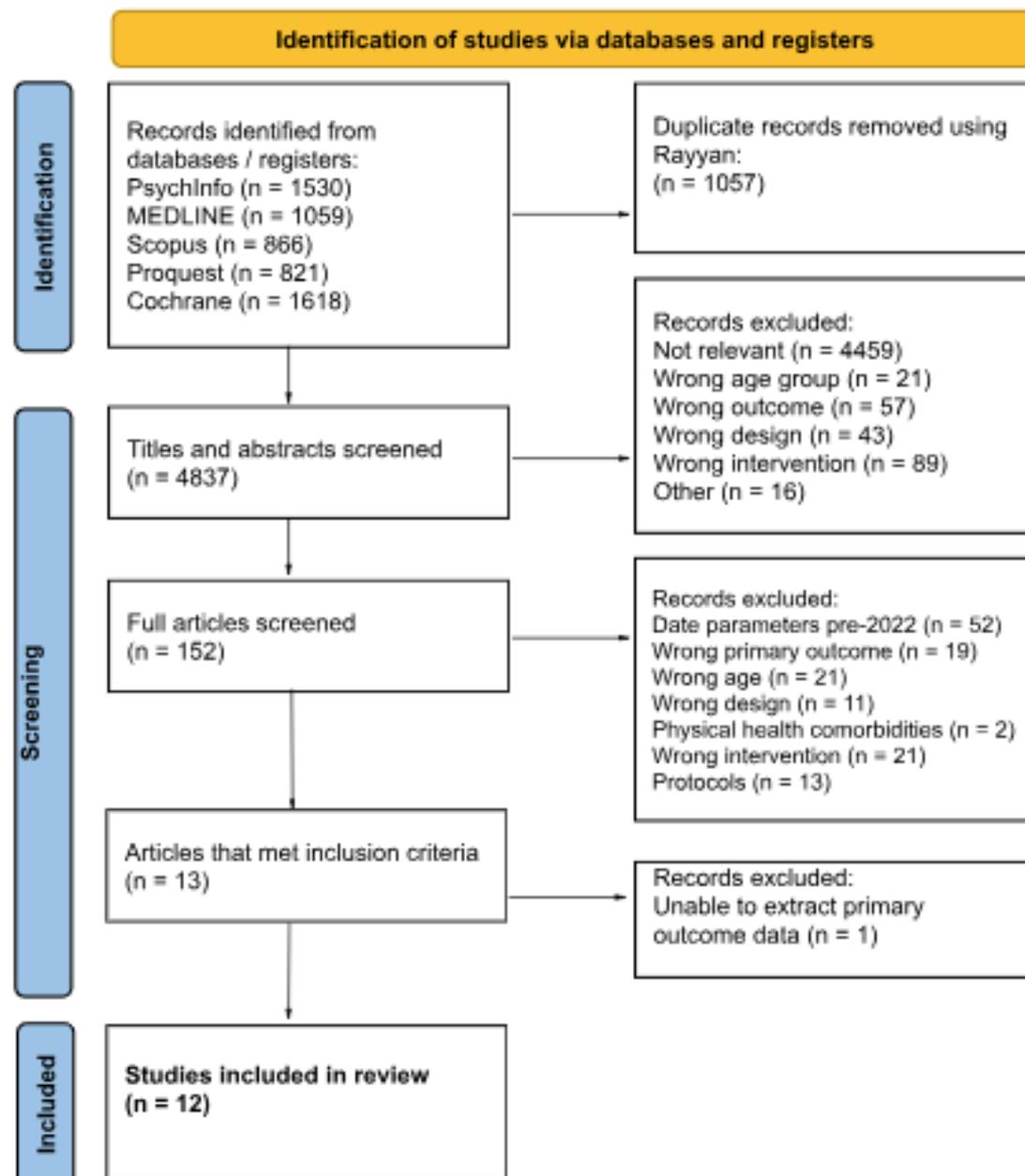
A certainty assessment was conducted on the findings following guidelines (Schünemann et al., 2019), the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework. This entailed grading the findings on a scale including very low, low, medium and high according to how certain the author felt in the finding. This would be upgraded due to factors such as having a large effect size, or downgraded according to limitations such as high risk of bias, small sample size or high heterogeneity.

#### 4. Results

The searches outlined above yielded 5894 studies (see Figure 1). 152 were identified as being potentially suitable for the present review. The second reviewer identified no additional articles at this stage (100% agreement). As the present review was an update and extension of previous searches whose searches were run in October 2020 (Perry, 2021) and December 2021 (Oliani, 2022), only trials from 2022 onwards were included, excluding a further 52 studies. From the remaining 100 studies, the primary reviewer identified 12 that met inclusion criteria, all of which provided necessary data to conduct a meta-analysis. The second reviewer identified an additional article that the primary author hadn't included (Hatch et al., 2023). After a discussion, this article was judged to meet inclusion criteria and was included ( $k = 13$ ). One study (Chintha et al., 2024) was thought to meet inclusion criteria, however was excluded due to the outcome measure of interest (depression) only being reported as a potential moderating variable for psychodynamic defence mechanisms. This study was therefore not included, leaving the total number  $k = 12$  (see Table 3).

Two studies (Quintana-Hernandez et al, 2023 and Schneider et al, 2024) used multiple outcome measures for depression; the Hamilton Depression Rating Scale (HDRS) the Beck Depression Inventory – II (BDI-II) and the Geriatric Depression Scale (GDS). As only one measure of a particular outcome could be used in each analysis, the HDRS was excluded in favour of the BDI-II and GDS to increase homogeneity, as other studies had also used these measures.

Figure 1. PRISMA Flow Diagram



Total participants included in review (n = 1009)

Number of additional articles identified by 2<sup>nd</sup> reviewer during title/abstract screening (n = 0)

Number of additional articles identified by 2<sup>nd</sup> reviewer during full article screening (n = 1)

Table 3. Summary of included studies

Outcome	Study	Third-wave therapy	Control	Age (Mean/SD)	Sample Size	Gender (F%)	Outcome measure	Total Therapy Hours	SMD (SE)
<i>Depression</i>	Giulietti et al (2023)	MBI	No treatment	82.85 (1.49)	44	31 (70.45)	BDI-II	24	13.3 (1.45)
	Javadzade et al (2024)	MBSR	No treatment	66.5 (5)	60	36 (60)	GDS	8	2.29 (0.33)
	Kabatas et al (2023)	MBSR	No treatment	76.04 (2.10)	48	13 (27.1)	GDS	8	0.71 (0.30)
	Ng et al (2022)	MAP	Health education	71.3 (1.64)	55	41 (74.5)	GDS	12	-2.69 (0.37)
	Noone et al (2023)	MBCT	TAU	77.3 (8.09)	20	15 (75)	PHQ-9	8	0.018 (0.46)
	Quintana-Hernandez et al (2023)	MBAS	Caretaking at home	82.64 (6.64)	152	66 (55)	GDS HDRS	96	2.326 (0.426)
	Sanchez-Lara et al (2023a)	CCT + Mindfulness	CCT alone	73.56 (2.47)	51	70 (73.68)	GDS	9	0.195 (0.308)

Outcome	Study	Third-wave therapy	Control	Age (Mean/SD)	Sample Size	Gender (F%)	Outcome measure	Total Therapy Hours	SMD (SE)
<i>Depression</i>									
	Sanchez-Lara et al (2023b)	Mindfulness	CCT alone	73.56 (2.47)	44	70 (73.68)	GDS	9	0.164 (0.319)
	Schneider et al (2024)	MCT	Cognitive remediation	71.51 (6.57)	80	58 (73)	BDI-II HDRS	8	0.634 (0.253)
<i>Quality of Life</i>									
	Chojak (2023)	ACT	PPI	75.6 (7.61)	100	80 (80)	WHOQoL-AGE	6	0.031 (0.200)
	Giulietti et al (2023)	MBI	No treatment	82.85 (1.49)	44	31 (70.45)	SF-36	24	5.058 (0.618)
	Noone et al (2023)	MBCT	TAU	77.3 (8.09)	20	15 (75)	QoL-AD	8	0.864 (0.480)
	Sanchez-Lara et al (2023a)	CCT + Mindfulness	CCT alone	73.56 (2.47)	51	70 (73.68)	WHOQoL-BREF	9	-0.138 (0.318)

Outcome	Study	Third-wave therapy	Control	Age (Mean/SD)	Sample Size	Gender (F%)	Outcome measure	Total Therapy Hours	SMD (SE)
<i>Quality of Life</i>									
	Sanchez-Lara et al (2023b)	Mindfulness	CCT alone	73.56 (2.47)	44	70 (73.68)	WHOQoL -BREF	9	0.075 (0.318)
	Schneider et al (2024)	MCT	Cognitive remediation	71.51 (6.57)	80	58 (73)	WHOQoL -BREF	8	0.484 (0.251)
<i>Anxiety</i>									
	Hatch et al (2023)	EFMT	WLC	67.7 (6.43)	45	39 (87)	GAI	9	-0.024 (0.298)
	Ng et al (2022)	MAP	Health education	71.3 (1.64)	55	41 (74.5)	GAI	12	-2.750 (0.376)
	Noone et al (2023)	MBCT	TAU	77.3 (8.09)	20	15 (75)	RAID	8	0.044 (0.460)
<i>Self-Compassion</i>									
	D'elia et al (2024)	CMBAS	Health self-management	72.7 (6.9)	147	95 (64.6)	SCS-SF	8	-0.052 (0.171)

Interventions: ACT = Acceptance and Commitment Therapy; CMBAS = Caring Mindfulness Based Approach for Seniors; MBI = Mindfulness-Based Intervention; EFMT = Emotion Focused Mindfulness Therapy; MBSR = Mindfulness Based Stress Reduction; MAP = Mindfulness Awareness Practice; MBCT = Mindfulness-Based Cognitive Therapy; MBAS = Mindfulness-Based Alzheimer's Stimulation; CCT = Computerized Cognitive Therapy; MCT = Metacognitive Training.

Control Groups: TAU = Treatment As Usual; PMR = Progressive Muscle Relaxation; WLC = Waitlist Control; PPI = Positive Psychology Intervention.

Outcome Measures: GDS = Geriatric Depression Scale (Yesavage et al., 1982); HDRS = Hamilton Depression Rating Scale (Hamilton, 1960); WHOQoL-BREF = Brief World Health Organisation Quality of Life Measure (The WHOQOL Group, 1998); BDI = Beck Depression Inventory 2 (Beck, 1961); PHQ-9 = Patient Health Questionnaire (Kroenke et al., 2001); RAID = Rating Anxiety in Dementia Scale (Shankar et al., 1999); QoL-AD = Quality of Life in Alzheimer's Disease (Logsdon et al., 2002); GAI = Geriatric Anxiety Inventory (Pachana et al., 2007); SF-36 = 36 Item Short-Form Survey Quality of Life Measure (Ware & Sherbourne, 1992); SCS-SF = Self-Compassion Scale Short Form (Raes et al., 2011); WHOQoL-AGE = World Health Organisation Quality of Life Measure in Older Adults (Caballero et al., 2013).

SMD = Standardized Mean Difference; SE: Standard Error of the SMD

#### 4.1. Risk of bias analysis

Using the Cochrane RoB-2 tool, five studies were judged as being at low risk of bias, two studies were deemed to be at medium risk of bias and four studies were judged to be at high risk of bias. See figure 2 for risk of bias assessment summary.

Figure 2. Risk of Bias Assessment

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
	Chojak (2023)	+	+	+	+	+	+
	D'Elia et al (2024)	+	+	+	+	+	+
	Giulietti et al (2023)	-	+	+	X	X	X
	Hatch, Finlayson & Kessler (2023)	+	+	+	+	+	+
	Javadzade (2024)	-	+	X	X	+	X
Study	Kabatas et al (2023)	+	-	+	X	-	X
	Ng et al (2022)	+	+	+	+	+	+
	Noone et al (2023)	+	+	+	+	+	+
	Quintana et al (2023)	+	+	X	+	-	X
	Sanchez et al (2023)	-	+	+	+	-	-
	Schlosser et al (2023)	+	+	-	+	+	-
	Schneider et al (2024)	+	+	+	+	+	+

Domains:  
D1: Bias arising from the randomization process.  
D2: Bias due to deviations from intended intervention.  
D3: Bias due to missing outcome data.  
D4: Bias in measurement of the outcome.  
D5: Bias in selection of the reported result.

Judgement  
X High  
- Some concerns  
+ Low

#### 4.2. Depression analysis

A random effects meta-analysis with Hartung-Knapp adjustments was first conducted with studies measuring depression as a primary outcome ( $k=9$ ). This revealed a non-

significant effect (SMD= 1.72 [-1.57; 5.0],  $p= 0.262$  with very high heterogeneity found between studies ( $I^2= 96.1\%$  [94.2%; 97.3%]). See Figure 3 for forest plot of this meta-analysis.

#### 4.2.1. *Sensitivity analysis*

Due to the high  $I^2$  value and the observable difference in the forest plot, tests to identify outliers were performed in R using the 'metafor' package. Two outliers were identified (Giulietti et al., 2023 and Ng et al., 2022), and after removing these outliers for their extreme effect sizes, a subsequent sensitivity analysis ( $k= 7$ ) revealed a small effect trending towards significance of treatment on pre-post intervention standardized mean differences in depression scores (SMD= 0.88 [-0.01; 1.78],  $p= 0.052$ ), indicating that third-wave interventions were close to having a statistically significantly larger effect from pre-post intervention on symptoms of depression compared to control groups. See figure 4 for forest plot of sensitivity analysis. However, heterogeneity remained high ( $I^2= 86.5\%$  [74.4%; 92.9%]).

#### 4.2.2. *Depression meta-regressions*

Although the overall model was not significant, there was very high heterogeneity and the sensitivity analysis removing the outliers approached significance. In line with recommendations (Baker et al., 2009; Spineli & Pandis, 2020), meta-regression models were then constructed to explore this heterogeneity. Mixed-effects regression models were created using Knapp-Hartung adjustments (utilised due to small sample size) to investigate potential moderating variables on effect sizes. The model included the seven studies of the filtered depression meta-analysis and used a random effects

structure to account for variability, while the Restricted Maximum Likelihood (REML) method was used to estimate Tau<sup>2</sup> statistics.

Control category (no treatment, treatment as usual (TAU) or active), intervention type (MBSR, MBI or MBCT), and mean age were found to be significant predictors of effect sizes. A test for residual heterogeneity revealed that a model containing these three variables was a good fit (log-likelihood= 0.622), contained no residual heterogeneity ( $I^2= 0\%$ ) and accounted for all effect size variability ( $QE$  (df=2)= 0.013,  $p= 0.994$ ). The amount of therapy received, risk of bias, use of Intention To Treat analysis (ITT), attrition rates, whether participants were residing in the community or not, and whether participants had diagnoses of dementia or not were not significant predictors of effect sizes.

Specifically, studies utilising a MBSR intervention were found to have significantly higher effect sizes than those using MBI interventions ( $\beta= 3.14$ ,  $SE= 0.05$ ,  $p< 0.01$ ), see Figure 5 for forest plot. No active control groups were associated with greater effect sizes compared to no treatment control groups ( $\beta= 2.34$ ,  $SE= 0.06$ ,  $p< 0.01$ ), and TAU control groups also showed a significantly higher effect size than no treatment control groups ( $\beta= 2.66$ ,  $SE= 0.05$ ,  $p< 0.01$ ). Meanwhile, mean age was found to be negatively associated with effect size ( $\beta= -0.16$ ,  $SE= 0.003$ ,  $p< 0.01$ ), suggesting that effect sizes diminished as participants got older. These results imply that intervention type, control group type and participant age all predict the effect sizes of studies.

Figure 3. Forest Plot of Meta-Analysis for Depression

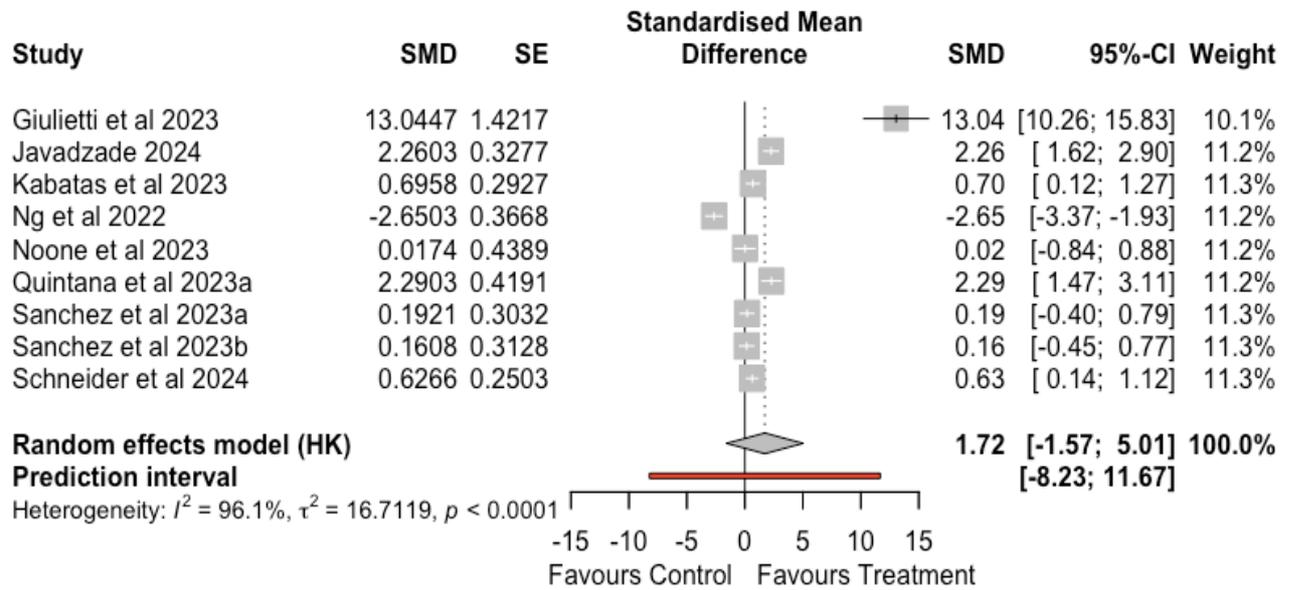


Figure 4. Forest Plot of Sensitivity Analysis for Depression With Outliers Removed

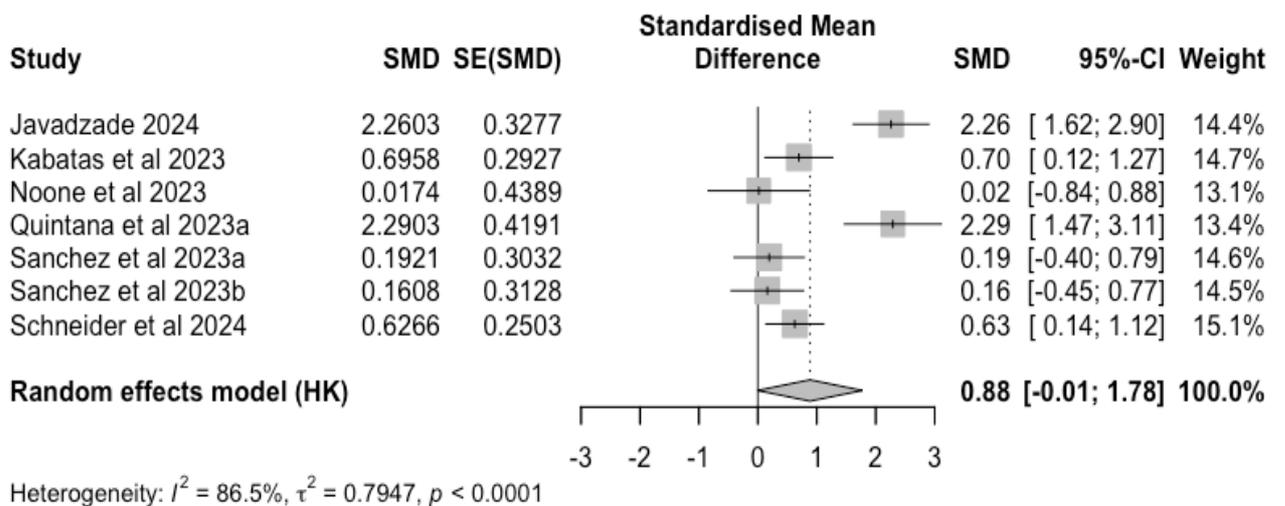
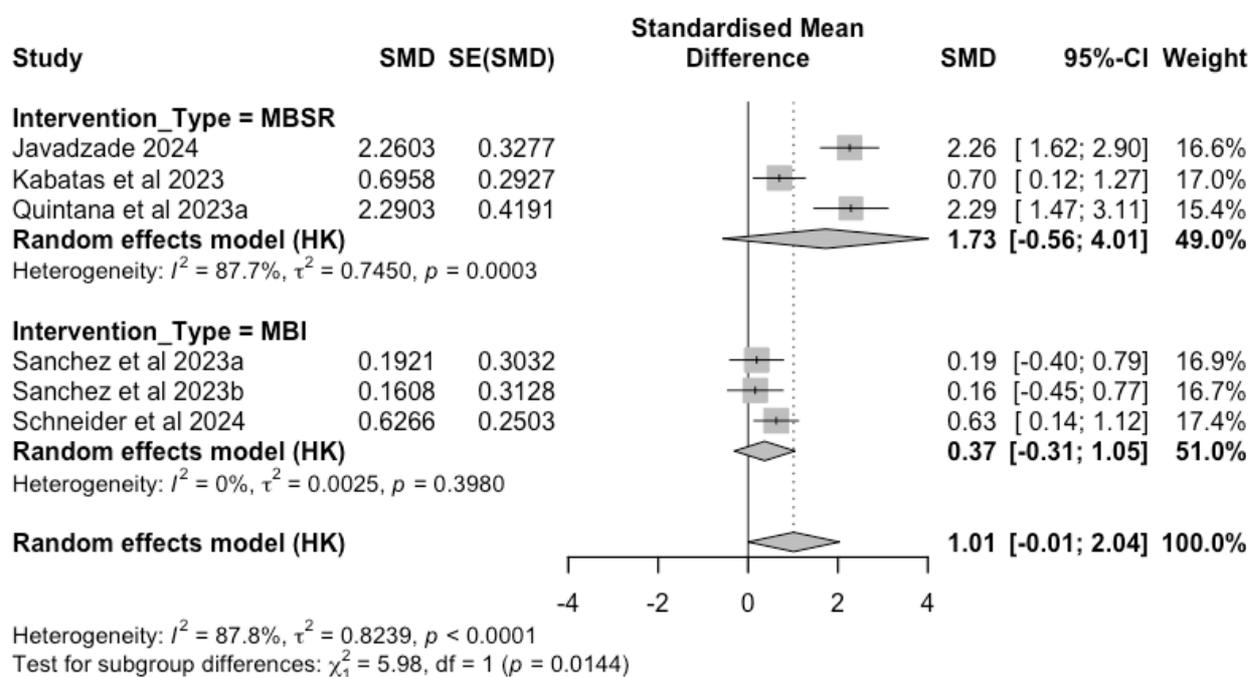


Figure 5. Forest Plot of Sensitivity Analysis of Intervention Type for Depression



### 4.3. Quality of Life analysis

An initial random effects meta-analysis for the QoL outcome was conducted on eligible studies ( $k = 7$ ) which revealed a non-significant effect (SMD= 0.82 [-0.827; 2.47],  $p = 0.269$ ) with high heterogeneity ( $I^2 = 91.5%$  [85.0%; 95.1%]). See figure 6 for a forest plot of this analysis.

#### 4.3.1. Sensitivity analysis

Further sensitivity analyses were conducted whereby the 'metafor' package was used to identify outliers, of which one was identified and removed 'Giulietti et al, 2023'. A further sensitivity meta-analysis was then conducted ( $k = 6$ ) which yielded a small non-significant effect of treatment on pre-post intervention standardized mean differences

in QoL (SMD= 0.10 [-0.22; 0.42],  $p= 0.454$ ) with low to moderate heterogeneity between studies ( $I^2= 28.5\%$  [0.0%; 70.6%]), indicating that the 'Giulietti et al, 2023' study accounted for a large portion of the heterogeneity in this analysis. See figure 7 for forest plot of sensitivity analysis.

#### 4.3.2. *Subgroup sensitivity analysis*

Due to sample size considerations, a meta-regression was not possible to investigate differences in effect sizes between studies utilising different third-wave interventions a sensitivity subgroup meta-analysis was carried out. Of the studies reporting QoL outcomes, there were a variety of interventions, including ACT ( $k= 1$ ), MBCT ( $k= 1$ ), MBSR ( $k= 1$ ) and MBI ( $k= 4$ ). Despite the small numbers in each group, it was decided to include all listed above due to the large sample sizes and low risk of bias. Following the removal of outliers (Giulietti et al, 2023), the number of MBI studies included was three. Non-significant effects were found for MBSR (SMD= -0.11 [-0.44; 0.22]), ACT (SMD= 0.03 [-0.36; 0.42]), MBCT (SMD= 0.83 [-0.07; 1.73]) and MBI (SMD= 0.18 [-0.62; 0.98]). A test for subgroup differences revealed a non-significant difference between intervention types ( $Q= 4.2$ ,  $df= 3$ ,  $p= 0.241$ ). Figure 8 shows the sensitivity analysis for ACT, MBCT, MBI and MBSR effect sizes.

#### 4.4. *Anxiety analysis*

A random effects meta-analysis was conducted for the anxiety outcome on eligible studies ( $k= 3$ , no outliers identified) which yielded a non-significant negative effect of treatment on the pre-post intervention standardized mean differences in anxiety scores (SMD= -0.90 [-4.80; 3.00],  $p= 0.43$ ) with high heterogeneity ( $I^2= 94.6\%$  [87.7%; 97.7%]). See figure 9 for forest plot of meta-analysis for anxiety. Due to the small

number of studies and variety of interventions utilised in these studies, no further sensitivity analyses were conducted.

Figure 6. Forest Plot of Meta-Analyses for Quality of Life

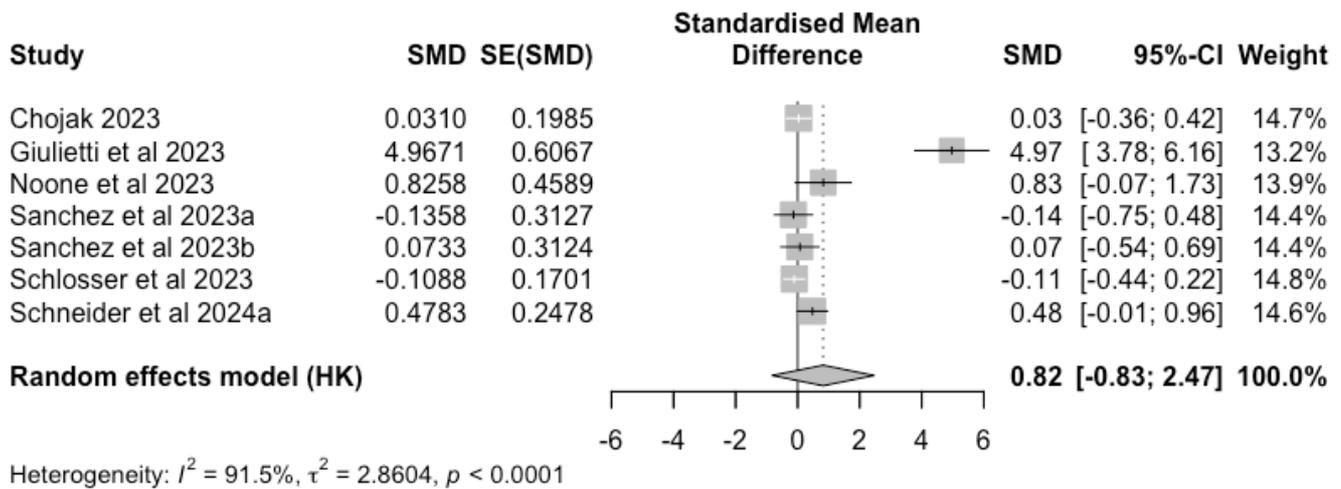


Figure 7. Forest Plot of Sensitivity Analysis for Quality of Life With Outliers Removed

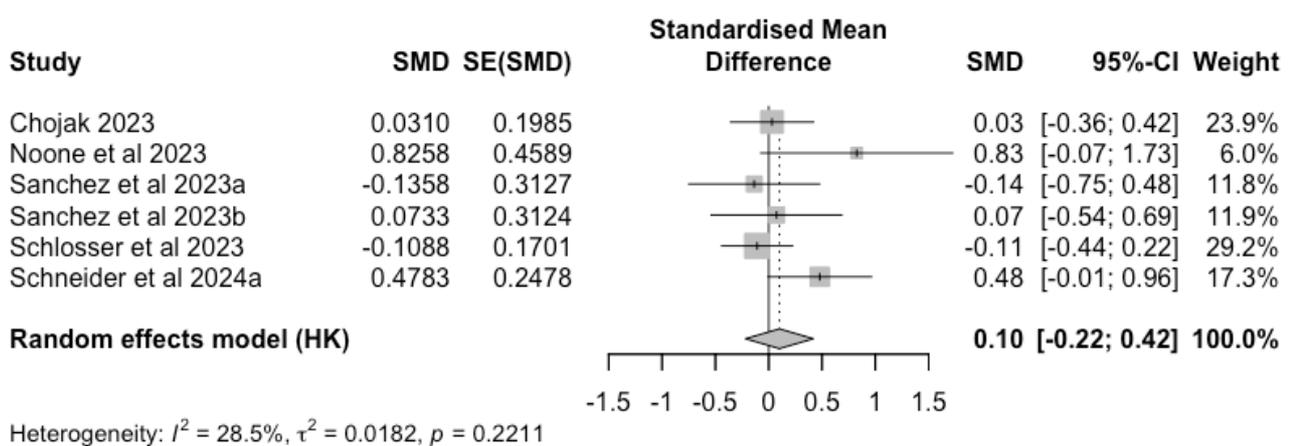


Figure 8. Forest Plot of Sensitivity Analysis of Intervention Type for Quality of Life

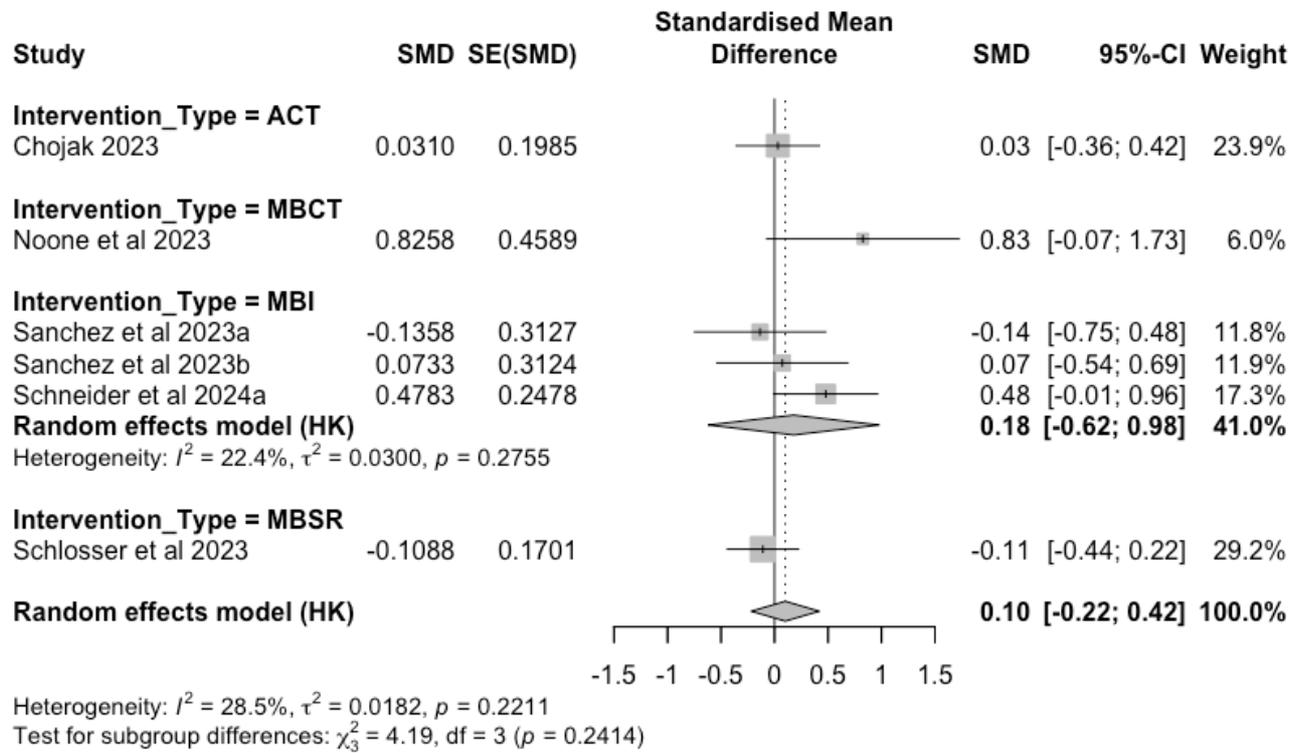
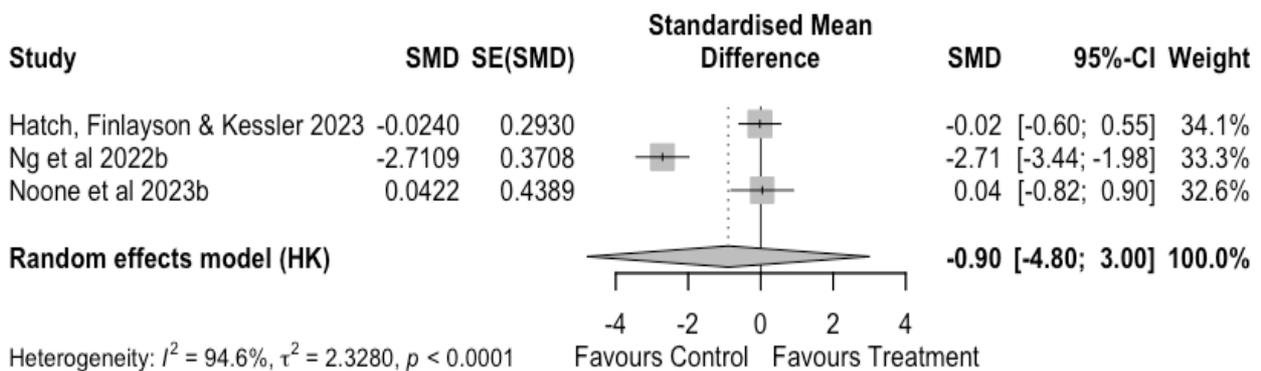


Figure 9. Forest Plot of Meta-Analysis for Anxiety



#### 4.5. Self-Compassion Narrative Synthesis

The D'Elia et al (2024) study was not included in any meta-analysis as it was the only self-compassion study that met the inclusion criteria. There was a significant increase in self-compassion from baseline to post-intervention in the Caring Mindfulness Based

Approach for Seniors (CMBAS) intervention group (estimated change= 2.00, [0.38; 3.61],  $p=0.02$ ) and a non-significant increase in self-compassion in the Health Self-Management Programme (HSMP) control group (estimated change = 0.69 [-0.94; 2.33],  $p= 0.40$ ). However the increase in self-compassion in the CMBAS group was not significantly different from the HSMP group ( $F[2, 240]= 2.12, p= 0.12$ ).

#### 4.6. Certainty Assessment

As highlighted before, Certainty of Evidence was assessed using the Grading of Recommendations Assessment Development and Evaluation (GRADE) (Guyatt et al. 2011; Schünemann et al. 2017). See Table 4 for the certainty assessment of the present review.

Table 4. GRADE Certainty of Evidence Table

Outcome	Number of Study-Arm Comparisons	Number of Participants	Effect Estimate [95% CI]	Certainty Assessment	Additional comments
Third-wave psychological therapies improve symptoms of depression in older adults relative to controls (moderate, non-significant result)	7	338	SMD = 0.88 [-0.01; 0.78]	Low	Downgraded for small study sample size, heterogeneity between studies and risk of bias. Upgraded due to smaller confidence interval after removal of outliers

Third-wave psychological therapies improve symptoms of QoL in older adults relative to controls (small non-significant result)	6	410	SMD = 0.10 [-0.22; 0.42]	Low	Downgraded for small study sample size and high between-study heterogeneity. Upgraded due to directness of included studies
Third-wave psychological therapies do not improve symptoms of anxiety in older adults relative to controls (small, non-significant result)	3	119	SMD = -0.9 [-4.80; 3.00]	Very Low	Downgraded for small study sample size and high between-study heterogeneity
MBSR yielded larger effects than MBI for improving symptoms of depression (statistically significant result)	7	338	MBSR SMD = 1.73 [-0.56; 4.01]  MBI SMD = 0.37 [-0.31; 1.05]	Very Low	Downgraded for very small study sample size and lack of significant difference when adjusted for control type and age

No differences in effect sizes for intervention types on QoL	6	410	See figure 8 for details of effect sizes for each intervention	Very Low	Downgraded for very small study sample size and very high between-study heterogeneity
Intervention type, control type and age predict effect sizes in depression outcome	7	338	Meta-regression (see paragraph hs)	Moderate	Downgraded for small sample of studies, upgraded for model fit and low heterogeneity

## 5. Discussion

### 5.1. Summary and Discussion of Findings

To the author's knowledge, this is the first systematic review and meta-analysis investigating RCTs of third-wave CBT in the improvement of symptoms of depression, anxiety, QoL and self-compassion in the older adult population. Findings were mixed, and validity of results hindered by a small sample size. Contextual strengths, limitations and implications are discussed.

This review found that third-wave CBT interventions such as ACT, MBSR and MBCT did not lead to significant improvements in symptoms of depression relative to controls. Heterogeneity was high in the depression meta-analysis, which points to potential sources of variability in the included studies. Meta-regressions indicated that age,

control category and intervention type may account for the high heterogeneity, with studies that use MBSR vs MBI, active controls, and younger age showing more impact on depression outcomes, though the very small sample limits the power of these meta-regressions. After the removal of outliers in the depression meta-analysis, heterogeneity was lowered slightly and the depression outcome did approach conventional levels of significance ( $p= 0.052$ ). Third-wave interventions did not lead to significant improvements in QoL, and despite the removal of outliers substantially reducing the heterogeneity and no significant effects being found between intervention types, this non-significant effect remained. Third-wave CBT did not significantly improve symptoms of anxiety in older adults, though the small pool of three studies included is a stark limitation to the generalisability of this conclusion. The narrative synthesis highlights how third-wave CBT interventions positively impacted self-compassion levels in older adults, but were not significantly more effective than control in doing so.

The lack of significant effects and high heterogeneity potentially indicate a lack of true effect between third-wave interventions and outcomes. However, this contrasts with existing literature (Kishita et al., 2017; Helmes et al., 2017) and may instead point to the challenges of combining different third-wave CBT interventions in a meta-analysis. The depression outcome approaching significance following the reduction of heterogeneity indicated that third-wave CBT interventions may be effective in the reduction of depression symptomatology given a pool of more homogenous trials. The data may indicate that better specified and conducted interventions that follow specific protocols (for example MBSR compared to MBI, the latter of which is a relatively unspecified approach) that utilise active control groups lead to better effects in

depression. However, for QoL and anxiety it is possible that individual factors differing between trials impacted outcomes as indicated by very high heterogeneity. While no significant differences were found between intervention types in QoL outcomes, the power of this sensitivity analysis was very low, rendering mechanistic or protocol differences between interventions plausible sources of heterogeneity (Dimidjian et al., 2016). This may also be the case for anxiety outcomes due to the variability in intervention factors and small sample size, although the direction and significance of the effects may suggest a true non-significant finding. This highlights the need for greater understanding of the relationship between third-wave therapies and QoL or anxiety within older adults.

The lack of significant findings contrasts with some existing meta-analytic reviews of specific third-wave approaches. Li & Bressington (2019) reported a significant difference between MBSR and waitlist controls on depression and anxiety symptoms in older adults, while qualitative findings present that older adult anxiety and depression is reduced by MBCT (Hazlett-Stevens et al., 2019; Ye et al., 2024). Moreover, the lack of significant difference in effect sizes between third-wave interventions and control conditions deviates from what might be predicted from findings in the general population (O'Connor et al., 2018). However, many of these reviews also suffer from limited power, and therefore contrasts should be interpreted with caution, particularly when considering how the depression effect size approached statistical significance. The non-significant effect of third-wave interventions on anxiety levels in older adults also goes against findings in this demographic (Kishita et al., 2017) as well as implications from research in the general population (Nandarathana & Ranjan, 2024). The present findings support the idea that research into older adult

mental health should consider a broad range of outcomes that better encapsulate a measure of wellbeing rather than just depression and anxiety in order to better understand the mechanistic influences of different interventions. The small sample size and high heterogeneity observed across the findings are essential to consider for all of these results, as discussed in the limitations section.

Initially, it appeared that Mindfulness-Based Stress Reduction (MBSR) led to significantly greater improvements in symptoms of depression compared to Mindfulness-Based Interventions (MBIs), however regression analyses revealed that effect sizes were higher when active and TAU control groups were used rather than no-treatment control groups, and became smaller as the age of participants increased. This highlights that the type of control group being used and the mean age of participants were important moderators of the observed differences between MBSR and MBI for depression outcomes. Intervention length was considered as a potential moderating variable (Ost et al., 2008). Importantly, the length of interventions in the present review was not found to moderate effect sizes, meaning that effects were not significantly smaller in shorter interventions, which thus has implications for the application of these interventions in real-world settings such as in resource allocation and costs.

It is important to note that four of the twelve studies included were judged to be at a high risk of bias, which given the small sample size may have skewed results. However, sensitivity analyses were conducted in an attempt to mediate for this, and risk of bias was not found to be a significant moderator of effect sizes in the meta-regression analyses.

## 5.2. *Strengths & Limitations*

A main strength of the present review was the inclusion of RCTs. In their previous meta-analysis into the same field, Kishita et al (2017) posited that the current evidence base of third-wave CBT interventions with older adults lacked RCTs, and the current review therefore aimed to rectify this. The search strategy was also robust: a large number of articles were screened, meaning that relevant studies were unlikely to have been missed from the search. Comprehensive statistical analyses were also conducted, such as the transformation of Standardised Mean Differences using the Hedge's  $g$  transformation to account for small sample size. Despite further reducing the sample size, sensitivity analyses were also conducted to ensure that outliers did not skew findings, and while very underpowered, the subgroup analyses highlighted potential moderating variables that help understanding of intervention effectiveness.

There were several limitations, some of which have previously been alluded to. Possibly the primary limiting factor was the small sample size. As highlighted in section 4, the decision was made to restrict the publication inclusion criteria to 2022 and after, and provide an update to previously written reviews. This was in part due to the impact of the COVID-19 pandemic and how wellbeing may have been uniquely affected, particularly in older adults (Xiong et al., 2020), and also due to the absence of date parameters in the search yielding too many studies to allow for a comprehensive review. While exclusion of studies pre-2022 made an up-to-date review possible, it limited statistical power, much like reviews in the extant literature.

The heterogeneity of the studies also impacted the statistical power of the analyses conducted. The decision was made to include depression, anxiety, QoL and self-

compassion as measures of wellbeing in order to offer a more rounded insight into the effectiveness of third-wave interventions, and due to the transdiagnostic aims of these interventions (Hayes & Hofmann, 2017). Conducting separate meta-analyses for these outcomes impacted the sample size further, resulting in meta-analyses that lacked power. This was particularly the case for the anxiety meta-analysis which contained only three studies with small numbers of participants and yielded 95% confidence intervals (-4.8; 3.0), highlighting statistical uncertainty of the finding. Power was further reduced in the sensitivity analyses when groups were subdivided, therefore rendering the conclusions drawn more exploratory in nature. The small sample size may have led to the lack of significant findings from the depression, anxiety and QoL analyses, and given that the depression meta-analysis approached conventional levels of significance ( $p= 0.052$ ), it may be that the small sample size led to a missed effect. The field would benefit significantly from further RCTs being conducted in order for future reviews to be able to analyse these outcome domains separately and carry out sensitivity analyses without hampering the power too drastically.

However, a noteworthy consideration was the suitability of RCTs in evaluating psychosocial interventions in older adults. Third-wave interventions are complex, contextual and often relational, and may be mediated by factors such as therapist skill, participant motivation and group dynamics. RCT designs may not capture these variables, which may limit understanding of how the interventions effect change in actual clinical practice (Craig et al., 2008). Moreover, these potential issues may be exacerbated in older adult research. Older adults may differ in many ways, for example in cognitive capacity and physical health, and by striving for increased homogeneity

RCT designs may lose important information about intervention effectiveness. Qualitative research on the other hand may provide rich data on contextual and relational factors of interventions (Yardley et al., 2021). This may be particularly important when evaluating third-wave approaches for older adults as it enables deeper, more individualised investigation of a heterogeneous population. Therefore in addition to a growth of RCT research in the field, qualitative and mixed-method paradigms should be encouraged to provide rich data regarding feasibility and acceptability of third-wave interventions for older adults.

In addition, heterogeneity was high in the anxiety meta-analysis ( $I^2= 94.6\%$ ), and despite the removal of statistical outliers, heterogeneity remained high for depression ( $I^2= 86.5\%$ ) though not for QoL ( $I^2= 28.5\%$ ). This was an expected limitation given the inclusion criteria and diversity of inter-study design but is noteworthy in the interpretation of findings. One source of heterogeneity as yet not discussed was the inclusion of study participants with and without clinical diagnoses of mood disorders or neurological disorders. Some studies focused on participants with dementia (Giulietti et al., 2023; Noone et al., 2023; Quintana-Hernández et al., 2023), or with subjective cognitive decline (D'elia et al., 2024; Schlosser et al., 2023), others required participants to score over particular thresholds on mood outcome measures (Ng et al., 2022; Hatch et al., 2023; Javadzade et al., 2024) or have formal diagnoses (Schneider et al., 2024), while others did not require scores above any diagnostic thresholds (Chojak, 2023; Kabataş Yıldız & Orak, 2023; Sanchez-Lara et al., 2023). Moreover, the inclusion criteria utilised was a mean age over 65, meaning younger participants may have been involved. Studies were therefore investigating the effects of interventions on participants who potentially differed greatly in their experiences of

depression, anxiety, QoL or self-compassion as a result of their age or potential diagnoses. That being said, some existing reviews investigating the effects of third-wave interventions on wellbeing also included studies of participants scoring above a particular clinical threshold, as well as others involving participants that were not (Perkins et al., 2023); (O'Connor et al., 2018), and to exclude such studies from analysis in this early stage of life of the older adult third-wave CBT field would hinder development of the evidence base.

Further limitations pertained to the small number of anxiety and self-compassion studies that met inclusion criteria. Possible explanations of this underrepresentation of anxiety studies could be due to the date parameters that were introduced, or may be indicative of wider methodological difficulties of anxiety measurement in older adults due to an increase in comorbid factors like physical health difficulties or grief (Lutz & Van Orden, 2020), and the different presentation and reporting of anxiety in older adults compared to younger adults (Balsamo et al., 2018). The lack of studies identified that reported measures of self-compassion potentially points to its incipience as a measure of interest within this demographic, and lack of well-validated measuring scale (Tavares et al., 2024), likely impacting the inclusion of self-compassion as a more commonplace outcome of interest. The lack of available studies in the present review that focus on anxiety or self-compassion limits the ability to draw conclusions of any weight regarding the effectiveness of third-wave CBT on both these domains in older adults, though presents potential avenues for future research.

### 5.3. *Research Implications*

The present review highlights the nascence of the older adult third-wave CBT intervention field, and need for more robust RCTs in order to draw any strong conclusions regarding effectiveness. A recommendation would be to ensure that outcome measures of older adult wellbeing are not limited to psychopathological determinants of mental health such as depression, and to incorporate additional measures of domains such as QoL and self-compassion. In the absence of significant effects of these outcomes in the present review, a growth of evidence here would offer a more holistic view of older adult wellbeing.

This review also identifies gaps for specific third-wave intervention approaches. Only one study included in this review investigated the effectiveness of ACT (Chojak et al., 2023), while no RCTs were found that investigated Compassion Focused Therapy (CFT) or Dialectical Behaviour Therapy. DBT has extensive evidence for the treatment of borderline personality disorder and emotion regulation, but has a limited literature base in older adults due to the majority of participants being young women (Panos et al., 2014), despite an early RCT showing promise for its effectiveness in the alleviation of depression symptoms in older adults (Lynch et al., 2003). While CFT has shown promise in clinical populations (Craig et al., 2020), there is only recent emerging evidence for its use in older adult populations (Altavilla & Strudwick, 2022; Craig et al., 2018), none of which are RCTs. This presents challenges in the extent to which findings from the current review can be extended to the entire 'third-wave' field, but nevertheless presents opportunity for future research to focus on broadening the third-wave landscape.

The lack of studies reporting anxiety and self-compassion measures may be a product of the theoretical underpinnings of third-wave CBT interventions. They focus less on psychopathology and more on the associated processes of change (Adler et al., 2024), which in the absence of well-validated measures of self-compassion may explain the increased prevalence of QoL measures yielded in the initial search. Depression, on the other hand, is a well-understood, comprehensively researched topic in older adult mental health (Hu et al., 2022), which may explain its frequent appearance as an outcome of interest instead of anxiety for which the research base in older adult populations remains relatively thin (Gonçalves & Byrne, 2012). Therefore, in order to draw any robust conclusions regarding the effectiveness of third-wave CBT interventions in alleviating symptoms of anxiety, more robust RCTs are required that are sensitive to the methodological challenges outlined in section 5.2. Despite the present review including one study of self-compassion, its potential moderating role in older adult wellbeing (Gao et al., 2024) warrant further research attention, particularly in the context of further CFT.

Given the high residual heterogeneity identified in the present review and the heterogenous landscape of older adult psychosocial research, future studies should aim to build on these findings by exploring specific mediating variables. This might involve separating clinical and non-clinical samples, distinguishing between levels of cognitive impairment, or examining cross-cultural differences in treatment effect, as these factors may impact mechanisms of change and observed effects. Moreover, it would be useful to examine across intervention delivery formats such as face-to-face compared with virtual interventions, or individual compared with group-based interventions to better understand mechanisms of change within these third-wave

interventions, as elements like group dynamics may play a central role in facilitating or hindering the magnitude of effect seen. Given that age was found to be a significant moderating variable impacting intervention effectiveness, further investigation could look into the mechanisms underlying the impact of age on therapeutic outcome in third-wave older adult interventions. Ecological validity may be enhanced by focusing on embedding future studies within community or healthcare settings to enhance understanding of how these interventions might be extended to clinical practice.

#### *5.4. Clinical Implications*

A key takeaway from the review is that third-wave interventions were found to improve symptoms of depression and QoL in older adults, though not statistically more so than control conditions. Third-wave approaches could be promoted to support people of this demographic, but further evidence is needed to establish whether they are more or less feasible and acceptable than alternative psychosocial interventions such as Cognitive Behavioural Therapy (CBT). However, the evidence base for CBT in older adults is mixed, particularly in research using active controls (Hall et al., 2016), and also when compared to working-age adults, (Kishita & Laidlaw, 2017). Third-wave interventions may therefore offer an appealing alternative.

A greater understanding of cultural influences on third-wave intervention effectiveness is essential to the growth of the field. The majority of studies included in this review were from Western, Educated, Industrialized, Rich and Democratic (WEIRD) nations with a predominantly White British participant base. The way in which depression, QoL, anxiety and self-compassion are conceptualised across the world is likely to differ vastly, and the role in which older adults play in society differs greatly across cultures.

The psychosocial challenges encountered by older adults across the world are myriad and therefore the tenets of third-wave interventions may require adaptation when working clinically.

The amount of therapy received by participants, or therapy 'dose', was not found to be a statistically significant moderator of effect, meaning much longer interventions were not significantly more effective than shorter ones. This has important practical implications for people engaging with these interventions. With shorter interventions, people do not have to commit to prolonged periods of time engaging in a treatment. This may suit some older adults who experience physical or cognitive limitations as well as those who are restricted by time, for example when having to take particular medication during the day. Moreover, it makes it easier to find consistent locations to run interventions in the community, such as in health clinics or community centres, and would overall lead to more cost-effective interventions that could be integrated alongside an individual's additional commitments.

Age, however, was found to be a significant moderator of depression effect sizes whereby as participants got older, interventions were less effective in alleviating symptoms of depression. Again, this points to the benefit of shorter interventions that do not lead to diminished effects over time, but also to adaptations that may need to be considered. These may include adaptation of material according to cognitive capacity, or to the structure of interventions whereby additional focus may need to be placed on socialisation or practical support. Moreover, modifying the metrics of improvement by incorporating measures of QoL or self-compassion rather than simply

honing in on symptom reduction may be important to alleviate these age-related moderator effects, as much older adults may experience more change here.

## 6. Conclusion

Third-wave CBT interventions lead to small, non-significant improvements in depression symptoms and quality of life in older adults. More robust research is required to build a comprehensive evidence base, including different therapeutic approaches as well as broader measures of older adult wellbeing. Studies could also focus on the effects of different interventions and moderating variables such as control group and age.

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## Part 2: Empirical paper

Being kind to ourselves: The feasibility and acceptability of Compassion Focused therapy (CFT) to improve depression and anxiety in Dementia: A qualitative analysis

## 1. Abstract

### *Objective*

To explore the feasibility and acceptability of a) group Compassion Focused Therapy (CFT) to support people living with dementia (PLWD) experiencing depression and anxiety and b) an RCT design within this context.

### *Method*

A qualitative evaluation was embedded within a multi-site randomized controlled trial (RCT). Semi-structured interviews were conducted with 17 participants, including caregivers, CFT group facilitators, and NHS senior management clinicians. Framework analysis was used to identify key themes.

### *Results*

Two meta-themes, Intervention Processes and Trial Processes, were extracted to organise subsequent themes and subthemes. Within Intervention Processes, five themes emerged: Benefits and Challenges of Group Format, Intervention Delivery, Knowledge and Understanding, Psychological Impact, and Systemic Integration. Within Trial Processes, four themes emerged: Trial Experience, Cognitive Difficulties, Psychological Influences and Outcomes, and Systemic Integration. Participants highlighted the importance of the group setting in fostering emotional safety, peer support, and motivation. While some CFT exercises were described as helpful, challenges included cognitive impairments, difficulty retaining material, and limited communication between PLWD and caregivers. Barriers such as session timings and complexity of materials also impacted accessibility and engagement. Caregivers and NHS staff offered numerous insights into how the intervention could be better tailored for future implementation.

### *Conclusions*

CFT shows promise as a group intervention for improving mood in PLWD. Tailoring the approach to dementia-specific needs, enhancing caregiver involvement, and addressing systemic barriers will be essential for future investigation.

### *Keywords*

Compassion Focused Therapy, Dementia, Depression, Anxiety, Feasibility, Caregiver Involvement, Qualitative Research

## 2. Introduction

With an ageing population, the prevalence of dementia in the UK is steadily rising. In 2014, around 850,000 people lived with dementia in the UK (Prince et al., 2014), in 2024 the number was estimated to be 982,000, and by 2040 it is predicted that 1.4 million people will be afflicted by dementia (Alzheimer's Research UK, 2024). Within the multitude of challenges presented by a diagnosis of dementia, depression and anxiety are found to be highly prevalent in this population. Between 20-37% of people living with dementia (PLWD) have diagnosable depression and many more experience depressive symptoms (Kuring et al., 2020), while a similar number was found for anxiety, with between 37% - 41% of PLWD meeting diagnostic criteria (Leung et al., 2021). Moreover, increased rates of depression and anxiety are seen in caregivers of PLWD (Watson et al., 2018).

The impacts of both depression and anxiety are myriad. They can significantly reduce quality of life, accelerate cognitive decline and increase the instance of behavioural disturbances (Orgeta et al., 2015a), as well as leading to cognitive deterioration and withdrawal from daily activities (Kwak et al., 2017). People often lose basic skills, entering a negative cycle of decline and disability, high physical dependency, relationship and behavioural problems, and premature care home admission, all of which detrimentally impact an individual's ability to live independently (Gibbons et al., 2002). Despite some identified benefits of diagnosis such as promoting empowerment in decision making (Mitchell et al., 2013), receiving a diagnosis of dementia has been compared to a grief reaction, alongside a loss of autonomy, self-esteem and sense of

identity (Aminzadeh et al., 2007), often leading to an increase in depression and anxiety symptomatology in both the PLWD and their caregivers.

Pharmacological interventions have minimal evidence of efficacy for people of this demographic. The National Institute for Health and Care Excellence guidelines for dementia state that antidepressants should not be routinely offered for depression in mild-to-moderate dementia, unless indicated for a pre-existing severe mental health problem (NICE, 2018). This is evidenced by Cochrane reviews of high quality randomised controlled trials (RCTs) which concluded that antidepressants in dementia are ineffective (Dudas et al., 2018; Pai et al., 2025) There is minimal evidence for the use of anxiolytic or antidepressant medication to treat anxiety in PLWD, and yet benzodiazepines are frequently prescribed for anxiety in later life despite their association with increased falls and delirium (Olfson et al., 2015; Pary et al., 2019).

The evidence for existing psychosocial interventions is more hopeful, but remains mixed. Various approaches including Cognitive Behavioural Therapy (CBT), interpersonal therapy and counselling have been suggested to significantly reduce symptoms of anxiety and depression in PLWD (Orgeta et al., 2015b), however this evidence is weakened by unclear quality of the included studies and methodological issues such as heterogeneity of diagnoses. Further reviews posit that while psychosocial treatments for both depression and anxiety in people with dementia have limited effectiveness (Noone et al., 2019), factors such as depression, anxiety and caregiver wellbeing could be important intervention targets (Hopkinson et al., 2019).

'Third-wave' Cognitive Behavioural Therapies (CBT) are an emerging group of psychological approaches that arose in response to limitations of CBT. One of particular interest is Compassion Focused Therapy (Gilbert, 2009b) which focuses on developing compassion to both self and others and simultaneously reducing levels of self-criticism and shame. PLWD have been reported to experience stigma and shame (Cheston & Christopher, 2019), as well as anxiety, disgust and a sense of inferiority (Gilbert, 1998). A previous systematic review concluded that CFT improves mood symptomatology and self-compassion in adult clinical populations, and was deemed to be acceptable and feasible when delivered in a group format (Craig et al., 2020). Group-based interventions are consistently highlighted for their importance in normalising difficulties and promoting hope (Marmarosh et al., 2005) as well as improving social integration (McDermott et al., 2019) which is particularly important in PLWD. In this population, CFT interventions have been found to improve quality of life, and symptoms of depression and anxiety (Collins et al., 2018), as well as self-compassion (Craig et al., 2018). The Craig et al. (2018) case-control pilot, testing an individual CFT programme in seven PLWD, revealed that clinical improvements were seen in supporters of PLWD, and that the intervention was liked by participants.

A recent qualitative metasynthesis also reported group-based CFT to be highly acceptable among clinical populations (Garrett et al., 2025). Qualitative analysis of feasibility and acceptability such as this is strongly recommended in the development of interventions (Craig et al., 2008). It helps to show how participant context interacts with the intervention (Yardley et al., 2021) and to identify any deviations from protocols (O'Cathain et al., 2019), as well as potential mechanisms of change and ideas for future implementation (Moore et al., 2015). Importantly, it also places importance on

participant experience of the intervention which is essential to consider in the design of an emerging intervention (Yardley et al., 2021).

Gathering multiple perspectives in qualitative research develops deeper understanding of phenomena (Denzin, 2011) and therefore evaluating the experiences of caregivers and NHS staff involved in the trial in addition to PLWD is vital for informing trial feasibility and acceptability. Dementia caregivers play a central role in the lives of PLWD and yet the impact of interventions on this subgroup is frequently overlooked (Goto et al., 2023) despite caregivers providing valuable insights into trials that might otherwise be lost with a sole focus on PLWD. Caregivers can lend insight into their own experiences of a trial (Turjamaa et al., 2020) or indeed the assumed perspectives of PLWD that may not be communicated due to cognitive or physical impairment (Silverman, 2020). NHS staff can also offer insight into participant factors such as barriers to engagement, intervention logistics including manual adherence and challenges with delivery (Pope, 2020) as well as perspectives on service implementation and policy (Braun & Clarke, 2019).

A National Institute for Health and Care Research (NIHR) funded research team aimed to build on the pilot study conducted by Craig et al. (2018) by conducting a multi-site feasibility Randomised Controlled Trial (RCT) of group-based CFT for mood in PLWD. Alongside this trial was a qualitative study investigating participant experience of the trial, which as aforementioned is crucial for intervention development (Craig et al., 2008). While a separate paper compiled by my research partner (SF) was focused on qualitative data acquired from PLWD themselves, this study gathered perspectives of

caregivers of PLWD, CFT group facilitators and NHS senior management clinicians. This was to gain insight into the feasibility, acceptability and mechanisms of change of the group CFT intervention and the trial process itself.

This paper therefore aimed to explore the following research questions:

- a) Perspectives on the CFT intervention according to caregivers of PLWD receiving the intervention and group facilitators:
  - i) How do group facilitators and caregivers of PLWD receiving the intervention perceive the feasibility and acceptability of the group-based CFT intervention for PLWD?
  - ii) What do group facilitators and caregivers of PLWD receiving the intervention identify as the barriers and facilitators to PLWD engagement and participation with the CFT intervention?
  - iii) What do group facilitators and caregivers of PLWD receiving the intervention perceive to be the mechanisms of change and outcomes for PLWD receiving the CFT intervention?
  - iv) What do group facilitators and caregivers of PLWD receiving the intervention identify as future recommendations for the delivery of the CFT intervention?
  
- b) Perspectives on the RCT process according to caregivers of PLWD receiving the intervention, caregivers of PLWD receiving Treatment as Usual (TAU), group facilitators and NHS senior management clinicians:

- i) How do caregivers of PLWD in both the intervention and TAU groups, group facilitators and NHS senior management clinicians perceive the feasibility and acceptability of conducting and being involved in an RCT of CFT for PLWD?
- ii) What do caregivers of PLWD receiving the intervention or TAU, group facilitators and NHS senior management clinicians perceive to be the barriers and facilitators to recruitment, access and engagement with the trial?
- iii) What do caregivers of PLWD receiving either intervention or TAU, group facilitators and NHS senior management clinicians identify as outcomes of trial involvement for themselves, and what future recommendations do they make for the design of a fully powered RCT?

### 3. Method

#### 3.1. *Ethics*

Ethical approval was sought and approved by the London Riverside REC (Ref: 23/LO/0535) and the Health Research Authority (HRA) via the Integrated Research Application System (IRAS ID: 327086) on 11.08.2023 (see appendix 5). Research and Development approval was gained from each participating site.

### 3.2. *Design*

The present report is of an embedded qualitative study within a main multi-site parallel Randomised Controlled Trial (RCT). In the main study, PLWD were allocated to either the Compassion Focused Therapy (CFT) plus Treatment as Usual (TAU) group or the TAU (alone) group. Qualitative semi-structured interviews were then conducted with PLWD in both the intervention and control groups, their caregivers, CFT group facilitators and NHS senior management clinicians. The perspectives of PLWD will be evaluated in a separate report to the present one. Henceforth the focus of this report will be on the perspectives of group facilitators, caregivers and NHS senior management clinicians, with some details of the main trial provided for context.

### 3.3. *Recruitment and Setting*

Four sites were involved in this study: two in London, one in the Central South of England and one in the Midlands. The aim was to interview a range of participants from the different sites in order to capture a variety of views from those involved with the different groups. A purposive sampling strategy was implemented using site factors (representation across all four sites) and role factors (caregivers of PLWD in both the treatment and control groups, group facilitators and NHS senior management clinicians from each participating site). Within the context of this study, a 'caregiver' was defined as the primary person who provided emotional and practical care and support for the PLWD. Given the number of participants available to the researchers, aims were to interview approximately ten caregivers and eight group facilitators and NHS personnel, but following extant guidelines the sample size was determined using the number of group participants and caregivers available and information power (Malterud et al., 2016). Table 1 details brief inclusion criteria.

Table 1. Inclusion Criteria

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#### CFT main trial participants

- Met Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type (American Psychiatric Association, 1994)
- Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR) (Morris, 1997)
- Experienced symptoms of depression and/or anxiety as determined by either a Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) score of  $\geq 8$ , a HADS score between 5-7 accompanied by caregiver reported PLWD low mood, or by substantial psychological distress as judged by a clinician or researcher, independent of HADS score
- Had capacity to consent to take part in research
- Could communicate in English,
- Had access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group
- Not participating in another interventional research programme concurrently
- Aged 18 and over
- People could be included with or without a caregiver.

#### Interview participants

- Were the caregiver of a PLWD in either the CFT or TAU group (they did not have to have attended the caregiver workshop, see below for details) OR
- Had facilitated a CFT group OR
- Were an NHS senior management clinician involved in assisting with set-up of the groups in localities or in making referrals to the group

### 3.4. Procedure (main trial)

Below is a brief outline of the procedure of the main trial for context.

Baseline assessments were conducted by researchers separate to the group facilitators. Attempts were made to conduct each site's assessments within two weeks to reduce the time between baseline assessment and commencement of the Compassion Focused Therapy (CFT) group. Participants were subsequently randomised to either the CFT or Treatment As Usual (TAU) group using a block randomisation process, with each site serving as a block. This was carried out between June 2024 and January 2025 by N.WORTH University of Bangor (Russell et al., 2011). In line with established interventions for PLWD, blocks contained approximately ten participants (Spector et al., 2003).

#### 3.4.1. Control Group

Those allocated to the control arm of the study received treatment as usual, which usually involved continued medication such as donepezil and visits to memory clinics or GPs.

#### 3.4.2. Compassion Focused Therapy for Dementia Group

Those allocated to the experimental group received a twelve-session tailored CFT intervention for PLWD that took place at community sites and was delivered by psychologists trained in CFT. Prior to the first session, caregivers were invited to attend a caregiver workshop which aimed to orientate caregivers to the intervention and what it would entail. Here they were informed that PLWD would be encouraged to

practice CFT exercises outside the sessions and that it would be helpful for them to assist with this. They were provided with a resource pack which contained the CFT exercises that would be covered in the group, however instructions for completion of CFT exercises and contextual information around CFT tenets were not included. In some groups, participants were given a CD containing recordings of CFT exercises. Along with handouts of session summaries, reminders for home-task completion were sent directly to PLWD rather than to caregivers to promote a sense of autonomy in group involvement.

Following recommendations for groups with PLWD (Spector et al., 2012), the intervention was split into three phases. Phase 1 involved setting up and introducing CFT, including psychoeducation on emotion regulation systems, formulation and goal setting. Phase 2 teaches people techniques to develop self-compassion, including imagery and the writing of compassionate letters. Phase 3 teaches techniques to tolerate difficult feelings, focusing on ending and maintaining benefits. Content was adapted for PLWD, such as making each session a standalone to adapt for memory impairments, and increasing the frequency of summaries to assist with concentration and attention (Charlesworth et al., 2015) (see appendix 6). Caregivers of those allocated to the CFT group were also offered a caregiver workshop. A manual adapted from (Craig et al., 2018) was used to guide facilitators through the three phases and was intended to be deployed flexibly.

### *3.5. Procedure (current study)*

Each caregiver, group facilitator and NHS senior management clinician involved in the trial was invited to an interview with a researcher. This included caregivers of those

assigned to the control group. Interviews were carried out by three researchers working on the trial: two clinical psychology doctoral trainees (one female (SF) and one male (BL) and a PhD student (female, MM)). BL and SF facilitated one of the London CFT groups and therefore did not conduct interviews with anyone who had been in this group. Participants were aware that the interviewers were researchers on the trial as well as their respective professional and educational roles, and were reminded of the aims of the trial through the administration of the information sheets (appendices 7 and 8). No additional information about the interviewers was communicated to participants, and no field notes were taken by interviewers.

Interviews took place between August 2024 and March 2025, with exact dates depending on when each group was completed; interviews were offered following the termination of each group, with efforts made to conduct interviews soon after to assist with recall. All interviews with caregivers took place either at participant homes or local community sites, and all group facilitator and NHS senior management clinician interviews took place via videoconferencing software. Consent was obtained at the beginning of each interview, with consent forms signed at each in-person interview and verbal consent provided for each online interview (appendix 9). Interviews were recorded via Dictaphone or inbuilt computer recording software and lasted approximately between fifteen to sixty minutes depending on the level of detail provided in participant answers.

### *3.6. Data Collection*

A semi-structured interview schedule was developed in line with established process evaluation frameworks (Moore et al., 2015; O’Cathain et al., 2019), building on

interview schedules utilised by previous studies of CFT for dementia (Craig et al., 2018) with additional input from a Patient and Public Involvement (PPI) group. This group consisted of five individuals who had all previously engaged in psychosocial interventions for dementia either as a PLWD or a caregiver. In one of the group's regular meetings, researchers shared an early version of the interview schedule and attendees provided feedback on different sections of the schedule and its overall structure, leading to changes in wording, order and length. In addition to demographic information, the guide included questions relating to how participants became involved with the trial, what they thought about different components, experiences of being involved, thoughts on impact, and what they thought could be improved. Participants were encouraged to report both positive and negative experiences of the trial. Appendices 10, 11, 12 and 13 contain the full interview schedules for caregivers of PLWD in the intervention and control groups, group facilitators and NHS senior management clinicians.

### *3.7. Attrition*

As stated in section 3.5., everyone who consented to participate in the trial was approached for interview. All six facilitators available to be interviewed were included. Four senior management clinicians were approached, three of which did not respond to interview requests. Of the twenty caregivers who consented to participation (eleven intervention group, nine control group), ten did not complete an interview either because they agreed to an interview but were then uncontactable despite multiple attempts (three in control group, one in intervention group), or were contacted and agreed to an interview but an appropriate date for interview could not be arranged (three in control group, three in intervention group).

### 3.8. *Analysis*

Qualitative Framework Analysis (FA) (Ritchie & Spencer, 1994) was used to analyse participant responses. FA was used primarily due to its structural approach lending to efficient comparison of themes within and across groups, enabling more nuanced understanding of the perspectives of caregivers, group facilitators and NHS senior management clinicians (Gale et al., 2013). FA is particularly suited to the combination of deductive and inductive approaches whereby both a priori themes and emerging participant responses shape the analytic framework (Ritchie & Spencer, 1994). The five stages of FA (Ritchie & Spencer, 1994) were followed for analysis:

1. Familiarisation
2. Identifying and developing a framework
3. Indexing
4. Charting
5. Interpretation

Recordings were transcribed manually by researcher BL and psychology undergraduate student DV before being read multiple times by BL with preliminary notes and codes being identified. In cases of ambiguity as to the tone or context of a participant's response, the recordings were listened to again in order to assist with understanding emotional context. Conversations were held regularly with project partner SF to discuss any emerging themes and researcher perspectives on the data. The initial framework developed consisted of themes derived from the research

questions specified in section 2. A 'miscellaneous' category was included for themes that initially did not fit appropriately into the other categories. This framework was applied to the first 25% of transcripts and 138 codes were generated. These preliminary codes were shared with the PPI group who provided feedback on the codes and emerging themes and offered insight into the language used in the coding process. These codes were used to iteratively refine the framework to ensure that participant experience shaped its structure while ensuring its continued alignment with the research questions. The refined framework was applied to subsequent transcripts within the indexing phase and resulted in the five themes presented in section 4. A summation for each participant was conducted in the charting phase and then examined to identify similarities and differences across caregivers, facilitators and senior management clinicians, and interpretations are detailed in section 4. Appendices 14 and 15 provide the coding tree and an excerpt of the thematic framework matrix respectively.

### *3.9. Epistemology*

The nature of FA is such that the epistemological position held depends on the research question. The present research paradigm is one that takes a critical realist approach. The multiple realities of the caregivers, facilitators and NHS senior management clinicians were gathered in the interviews and were viewed as their 'true' experiences, pertaining to a relativist perspective of different experiences of the CFT trial with an aim to use FA to compare themes within and across these groups. No interpretation of deeper latent meaning of interview answers was undertaken, only the explicit written language was analysed relative to feasibility and acceptability. However, when using these different viewpoints to plan a future full-scale RCT, the

researchers took a realist approach by aiming to identify one overall version of reality about how the trial could be delivered. It was acknowledged that this version may not be perfect or complete as it is shaped by the researchers' own limitations and perspectives (Guba & Lincoln, 1994).

### *3.10. Researcher Characteristics*

Reflexivity was an essential consideration throughout the study, particularly during administration and interpretation, and was maintained through writing a reflexive journal. At the time of the study, I was a 30-year-old White male in my third year of a Clinical Psychology Doctorate course at University College London. The interviews were being carried out as part of my research project, and I had facilitated one of the London groups and therefore had preconceived ideas around the findings I hoped to see: that CFT might be an effective intervention for low mood and anxiety in older adults living with dementia. I am drawn to the transdiagnostic application of CFT and frequently use it in my wider clinical practice and therefore have an appreciation for the therapeutic role it can play in tackling shame, particularly in those with dementia where stigma plays a pivotal role (Nguyen & Li, 2020a), but I also thus have pre-established ideas as to the way CFT works and may be subject to confirmation bias. While neither me nor SF had existing relationship with participants, MM did have pre-existing professional relationships with participants as their point of contact for the trial.

## 4. Results

Table 2 provides demographic information for the 17 participants interviewed. Two meta-themes were extracted. In the first, five themes and nine subthemes were

identified. In the second, four themes and six subthemes were identified, as detailed in Table 3. To promote transparency and easier identification of patterns across themes, the number of participants to which the code applied is represented in brackets (X/Y), where X refers to the number of participants to which the code was applied, and Y refers to the number of participants the theme was relevant to (Dey, 2003; Stenius, 2017). For the purposes of brevity, caregivers of PLWD in the CFT intervention group will be referred to as 'intervention caregivers', caregivers of PLWD in the TAU group as 'control caregivers', and in section 4.2. group facilitators and NHS senior management clinicians will be referred to collectively as 'NHS staff'. All themes were relevant across the participant groups, but there was occasional disagreement between them on how the themes presented.

Table 2. Participant Demographic Information

	Age (Mean)	Sex (% F)	Ethnicity (% White British)	Relationship to PLWD
<b>Caregivers</b>				
<i>CFT Group</i>	81	M	White British	Husband
	76	M	White British	Husband
	45	M	Mixed: White British & Black Caribbean	Son
	48	F	White British	Daughter
	66	F	White British	Wife
	73	M	White British	Husband
	79	F	White British	Wife
<i>Control Group</i>	70	F	White British	Friend
	38	F	Black British / African	Daughter
	80	M	White British	Husband
	(65.6)	(50.0)	(80.0)	
<b>Facilitators</b>				
	33	M	White Irish	Group Co-Facilitator*
	28	F	White British	Group Co-Facilitator
	48	F	Mixed: White & Asian	Group Secondary Facilitator**
	57	F	White British	Group Primary Facilitator
	34	F	White British	Group Primary Facilitator
	27	F	White British	Group Secondary Facilitator
	(37.8)	(83.3)	(66.7)	
Senior Management Clinician	62	F	White British	Coordinated Trial Setup at Site
Overall Mean	55.6	64.7	76.5	

- \* Co-facilitator is used where facilitators described their roles in the group as equal
- \*\* Primary / Secondary facilitator is used where facilitators adopted different levels of responsibility

Table 3. Summary of Meta-themes, Themes and Subthemes

Meta-theme	Theme	Subtheme	Example Codes
Intervention Processes	Benefits and Challenges of Group Format	Group Setting and Dynamics	Interpersonal difficulties, Group vs Individual, Facilitator Dynamics
		Shared Experience and Socialisation	Peer Support, Emotional Vulnerability, Socialising
	Intervention Delivery	CFT Content and Delivery	CFT Exercise Positives, Pacing, Homework Challenges
		Session Resources Practical Elements	Exercise Limitations, Resource Adaptations, Manual Limitations Session Timings, Transport, Session Number
	Knowledge and Understanding	Cognitive Difficulties Learning About Compassion and Dementia	Recall and Retention, Cognitive Engagement Understanding of Compassion, Limited Implementation, Caregiver Workshop
Psychological Impact	-	Increased Compassion, Positive Impact on Mood, Self-Care	
	Systemic Integration	Support Structures Communication and Awareness	Caregiver Involvement Awareness of Processes, Clarity of Communication, Reminders
Trial Processes	Trial Framework	Operational Setup and Delivery Training and Preparedness	Setup difficulties, Assessment Experience, Group Allocation CFT Training, Supervision Benefit
	Cognitive Difficulties	-	Assessment Difficulties, Trial Understanding
	Psychological Influences and Outcomes	Motivation for Trial Involvement Caregiver Burden	Previous Experience, Trial Interest, Motivational Outcomes Increased Caregiver Burden
	Systemic Integration	Support Structures Communication and Awareness	Formal Support, Professional Involvement, Caregiver Involvement Awareness of Processes, Clarity of Communication

## 4.1. *Intervention Processes*

### 4.1.1. *Benefits and Challenges of Group Format*

#### Group Setting and Dynamics

Overall, group facilitators and intervention caregivers felt that PLWD participation with a group was a positive element of the intervention. Despite some citing the group format as a perceived barrier to PLWD engagement with the group at the beginning (3/13), it was outlined as one of the main perceived reasons for PLWD engagement with the trial in the first place due to being more desirable than a one-to-one intervention (11/13). However, one intervention caregiver and one group facilitator suggested that a combination of both, particularly at the beginning, may have helped reduce PLWD anxiety of participating in a group.

*Caregiver 1: I thought she probably would respond better to something in a group rather than one-on-one because one-on-one puts you under a sort of extra pressure.*

*Caregiver 6: She is socially quite anxious. Put her in a group of people she doesn't know, she will not say a word. So had she had a one-to-one to start with and talk through a bit more of what it was going to be all about, then that may have helped her.*

Intervention caregivers felt that the size of the groups was appropriate and suggested that between three to four would be a good minimum number to facilitate conversation, and six to eight would be an appropriate maximum number to manage group

dynamics. Within the sessions, however, intervention caregivers and group facilitators perceived the group dynamics to be challenging for PLWD (6/13). Individuals were reported to dominate the space which led to a sense that other group members may not have been able to get what they wanted from the group.

*Facilitator 1: it was quite frustrating for the other participants... they didn't have the same cognitive difficulties that he did, and they were quite eager to talk about their own experiences. So that lead to problems with the dynamic of the group, and some of the participants got quite angry at one stage...*

#### Shared Experience and Socialisation

Some intervention caregivers and group facilitators (4/13) emphasised their beliefs that PLWD would benefit from being around similar others, and that for intervention caregivers this was a factor influencing their desire for PLWD to be involved in the group. Moreover, these participants outlined perceptions that being around similar others helped PLWD to create a sense of safety whilst completing some of the exercises in the group.

*Caregiver 9: I just thought that would be a good way for her to meet other people that are going through the same conditions.*

*Caregiver 5: seeing (others) do the breathing was good for him. He's not the kind to dive in without feeling like there's judgement*

Almost all intervention caregivers and group facilitators emphasised their perception that peer support in a safe space was an important mechanism of change for PLWD (11/13), something that these participants in turn believed assisted in PLWD completing CFT exercises due to the feeling of connectedness.

*Facilitator 5: No matter how many times we (facilitators) could have said or talked about that, it was something about having the other participants say it that was meaningful.*

*Caregiver 3: You can also bounce off other people and recognise that you're not in this journey alone. Other people are going through the same thing. I think it's always a bit of a relief when somebody else discloses something and it relates to you. It's almost like a weight off your shoulders.*

Socialisation was found to be a relevant factor for engagement, participation, mechanisms of change, outcome and future recommendations. Intervention and control caregivers and group facilitators spoke about how the trial potentially offered an opportunity for PLWD to socialise and mingle which they otherwise might not be doing, even in the control group.

*Caregiver 4: For them, it's their social, it's like an enhancement, having a conversation with someone else... it gives mum a chance to get out of these four walls.*

*Interviewer: You said that you feel that X is benefiting even though she wasn't in the treatment group?*

*Caregiver 8: Yes, because she's meeting people and she's able to express herself and obviously assist in your process.*

However, the time constraints of the CFT sessions meant that social interaction was at times perceived to be a barrier to group content being covered. Adaptations were made whereby 15 minutes of dedicated social time was added onto the start of the group so they could then “*hit the ground running*” (Facilitator 4).

#### *4.1.2. Intervention Delivery*

##### CFT Content and Delivery

Several intervention caregivers and group facilitators suggested the CFT exercises were an important mechanism of change in some way for PLWD (11/13), with group facilitators more likely to report a variety of exercises and techniques they felt were useful for PLWD such as compassionate letter writing, everyday self-compassion or repetition of CFT concepts across multiple sessions. Intervention caregivers exclusively spoke about their perception that breathing exercises were useful for PLWD (4/7). However, several barriers to PLWD engagement with CFT exercises were also identified. One facilitator shared that a PLWD disliked the loving-kindness exercise due to finding the repetition of compassionate mantra as “*far too religious and spiritual*” and that it made her “*feel like a preacher*” (Facilitator 4), highlighting the role of PLWD cultural and religious backgrounds in their engagement with CFT exercises. Some group facilitators shared their opinions that some CFT exercises

were too long (2/6) and thus hindered PLWD engagement. Moreover, three facilitators specifically labelled the 'Old-Brain, New-Brain' and goal-setting topics as potentially hard for PLWD to engage with.

*Facilitator 3: The three circles model – it was absolutely an anchor, really integral and something that we revisited quite often... But some exercises were very long, and I think because the majority of the patients are older, they also have dementia, that they struggle with it being so long. I don't understand why we have the ten-minute one for dementia.*

*Facilitator 4: And they said, well of course we've got an old brain, we're in like our 70s and 80s. And I went, ok, I hadn't expected that really, but that was how they had interpreted that.*

The majority of intervention caregivers felt that PLWD engagement was enhanced by the face-to-face nature of the intervention (6/7), though one caregiver (Caregiver 4) highlighted how online offers are vital to enhance accessibility.

According to group facilitators, adaptations to the delivery of CFT exercises and topics were made across all groups (6/6), and several were suggested for future groups including slower pacing and shorter exercises to help with engagement. Flexibility in the delivery of exercises was cited by intervention caregivers and group facilitators as being an important mechanism to PLWD engagement and change (9/13).

*Caregiver 5: I said to him, 'Tell them you don't want to write anything down. Tell them it makes you feel anxious'. And after that, I don't think any of them wrote anything down. He just carried on with the talking, and he was better with that.*

### Session Resources

There was agreement across all group facilitators (6/6) and some intervention caregivers (2/7) in detailing issues with resources used in the group; beliefs were that they were too complicated or confusing for PLWD, particularly regarding language and length. Group facilitators emphasised further challenges in applying the manual due to a lack of clarity around which topics and exercises were expected to be delivered in each session. However, the availability of the session recordings was cited by intervention caregivers as being a helpful way for PLWD to understand and practise the material (4/7). Suggestions were made for future trials that focused on increasing clarity of the resources and effectively organising documents and resources in preparation.

*Caregiver 2: I looked at (PLWD)'s folder and it was quite complicated. I don't know if she felt it was quite overwhelming... for me, I mean, it looked quite formidable.*

*Facilitator 3: Change the fonts, make certain things bold so it's clear. Have different sections, and then each resource for that session, rather than maybe all the resources at the end.*

### Practical Elements

Many of the adaptations listed above were driven by time limitations. Timings were mentioned by every intervention caregiver and group facilitator, occasionally as being adequate, but more frequently as being a sizeable barrier to change (10/13). Group facilitators particularly highlighted the challenges of fitting session content into the allocated time.

*Facilitator 1: I think just time was always so thin we were kind of battling with it... we were really stuck to the hour, which made it challenging I think.*

As a result, most group facilitators felt the sessions should be 1.5 hours (4/6) but that the number of sessions was appropriate (4/6). Intervention caregivers on the other hand indicated that they thought 1 hour was adequate but that the number of sessions could increase (4/7).

Transport was another practical challenge verbalised by some intervention caregivers and group facilitators (5/13). PLWD reliance on travelling to sessions was at times seen as a barrier and led to lateness, and two intervention caregivers voiced their discomfort at having to drive. Participant proximity to the group is therefore an important factor to consider during trial design.

*Caregiver 10: Once the lady rang up and told me it was the control group I thought 'oh that's good' because driving through (area) is not the most brilliant thing.*

### 4.1.3. Knowledge and Understanding

#### Cognitive Difficulties

Some group facilitators and intervention caregivers perceived PLWD cognitive difficulties to be potential barriers to engagement with the intervention, particularly relating to comprehension of group content and retention of topics session-to-session (3/13).

*Facilitator 1: They sometimes struggled being able to remember to practice and understand the conceptual ideas, and I think recall between sessions – I think those were things we were aware of that had been kind of challenging.*

*Caregiver 4: It is a real struggle for her to do the most simplest of words or read numbers and understanding instructions, and obviously actually seeing things even though it's like right in front of her.*

#### Learning About Compassion and Dementia

There were mixed opinions on learning outcomes from the intervention. Group facilitators felt that compassion was hard for some people to engage with, but was generally deemed to be a helpful thing for PLWD to bolster an understanding of (4/6). Intervention caregivers spoke less about compassion knowledge and more about understanding dementia (3/7), although this was caveated by others citing the caregiver's workshop as not imparting enough information about dementia (2/7).

*Caregiver 7: Certainly, you know, I have got a bit more understanding – you have to say things so many times and you shouldn't get cross about having to repeat it.*

Some group facilitators and intervention caregivers expressed scepticism around the extent to which they believed PLWD were able to implement things beyond the CFT sessions (4/13), particularly in completing homework tasks. However, two intervention caregivers spoke of implementing breathing exercises into their own routine (Caregiver 3 and Caregiver 5), and a facilitator had applied learning about CFT into their wider clinical practice.

*Facilitator 5: The group found it a bit harder to then apply when it came to saying, OK, well, how can you, like, embody some of these concepts in your everyday life? It just kind of fell back to the same.*

*Facilitator 6: I've already considered integrating it in different sessions already, like I use the safe place imagery with somebody and facilitate in a compassionate kind of voice with somebody else.*

#### *4.1.4. Psychological Impact*

All intervention caregivers and group facilitators perceived PLWD to have some positive experiences of the CFT group, however there were differences in the way intervention caregivers and group facilitators reported perceived improvements in PLWD psychological outcomes such as mood, compassion, acceptance, anxiety and

frustration. Group facilitators seemed to report more substantial improvements (5/6). While two intervention caregivers did perceive there to be improvements in PLWD anxiety, frustration and compassion (Caregiver 7 and Caregiver 5), the overall picture from these caregivers was that they generally only perceived subtle changes, if at all (5/10). Intervention caregivers did, however, outline that they felt that PLWD enjoyed the sessions (5/7) and returned home happy (2/7).

*Facilitator 5: The soothing, compassionate circle had grown. So this one guy's was really tiny at the start, and his drive circle was really, really big. But by the time we came to looking at those again, they'd levelled out to be similar... And one woman in the group, hers was noticeably more compassionate, it was much bigger.*

*Caregiver 4: I'd say she's pretty much on target... nothing's changed... It's not made her worse or better for it... I know she still gets anxious because sometimes she'll get a bit shaky.*

Intervention caregivers and group facilitators reported that they felt that PLWD engagement in the group led to PLWD reintegrating with things they used to enjoy doing, recapturing a sense of normality in their daily lives (6/13), as well as perceiving small improvements in PLWD self-care (4/13).

#### 4.1.5. Systemic Integration

##### Support Structures

The role of the caregiver was illuminated as a crucial factor influencing access, engagement and change (9/13). According to intervention caregivers and group facilitators, caregivers helped to provide transport and emotional safety to PLWD, and at times promoted engagement with inter-session tasks like homework or listening to recordings. Intervention caregivers who reported being more involved in the trial process tended to also report more substantial positive improvements in the PLWD they supported.

*Facilitator 5: I know one person's carer was a lot more involved and helped listen to the recordings and sort of gave a lot more prompting*

### Communication and Awareness

A core challenge identified across intervention caregivers and group facilitators was a lack of communication across the system. Both groups of interviewees perceived there to be limited communication between PLWD and caregivers during the trial (10/13) and felt that difficulties embedding learning from the group was due to over-reliance on PLWD sharing things with caregivers. In fact, many intervention caregivers stated that they had limited knowledge of what went on in the sessions (5/7) and that closer involvement should be a change made in future trials.

*Caregiver 2: We had no inkling about what was going on so and how we could react better to it so all I could do when X was coming back from the course was ask: 'How was it? Was it good? Was it helpful?'... I personally thought that X should go along with me and that we should go and practice at home.*

This breakdown in communication was despite PLWD being perceived by group facilitators to be motivated to share with their caregivers, therefore pointing to issues of recall and retention as potential barriers to wider implementation and change.

*Facilitator 4: They were finding what we were covering in sessions was really opening their awareness to a new way of looking at things and they wanted to share that awareness with the carers.*

## 4.2. Trial Processes

### 4.2.1. Trial Framework

#### Operational Setup and Delivery

Several NHS staff reported challenges in setting up the groups, citing timing pressures and uncertainty over what was required. Some NHS staff experienced the trial setup as stressful (3/7), potentially indicating logistical challenges during setup.

*Senior Management Clinician: It was just so frustrating at the beginning because we had so much to do, and I was constantly, it seemed, being called to do things... we did go in as kind of virgins, really. None of us knew anything, and you're kind of very naive that we'll be running the group, not realizing that there's so much work to do beforehand with all the assessments.*

Caregivers from the control group expressed understanding and acceptance of group allocation, although 2/3 would have preferred allocation to the CFT group.

*Caregiver 8: We were hoping that she was going to be in the other group, that she would have got some (CFT), but she wasn't. Because it was randomly done, we got that it was random.*

There were mixed opinions about how intervention and control caregivers reported PLWD experiences of assessments; some stated that PLWD found them “frightening” (Caregiver 1) or “*taxing*” (Caregiver 6), while others believed that PLWD did not mind (4/10), or even enjoyed it (1/10).

### Training and Preparedness

Group facilitators felt that the CFT training served as a good CFT refresher, improved their confidence and provided useful tools for session delivery (4/6), but did not focus enough on applying CFT to dementia (2/6) leading to uncertainty over how to tailor delivery.

*Facilitator 6: it felt like we were quite involved. We were kind of actually practising it, putting it into place rather than just kind of being given didactic content... but there's the uncertainty I experienced of adapting it – to what extent do I adapt to make sure it's still adhering to the model enough.*

While some found supervision helpful and reflective, others did not feel it was frequent enough (2/6) and that they would have benefited from it being offered earlier on in the trial (3/6). More time during trial setup was suggested as a way to ensure supervision was focused on.

#### 4.2.2. Cognitive Difficulties

As well as impacting engagement with the intervention, cognitive difficulties were also cited by intervention and control caregivers and NHS staff as a perceived barrier to PLWD access and engagement with the trial itself (7/17). Caregivers from both groups outlined that they felt PLWD struggled to understand the assessment process (4/10) and potentially had difficulty understanding what the trial was about (6/10).

*Caregiver 6: Her understanding of the questions wasn't complete, so we actually had to explain those questions to her.*

Several intervention and control caregivers also reported their own comprehension and recall difficulties when asked about their experiences of trial access and assessment processes (5/10), which highlighted challenges of being asked to recall events that happened months previously.

*Caregiver 10: I didn't really, you know, understand some of it (the assessment)...*

*Interviewer: Do you remember much about how the conversation went?*

*Caregiver 10: Not at all.*

#### 4.2.3. Psychological Influences and Outcomes

##### Motivation for Trial Involvement

NHS staff unanimously (7/7) described their motivation to participate in the trial being due to interest in dementia research or buying into the CFT model compared to other

approaches such as CBT or CST. More senior staff (2/7) also added that they wished to develop the service they were operating in, showing how having a passionate workforce improved access to trials such as the present one.

*Facilitator 2: It's less, sort of, in your mind and more letting people feel something, which I think is really meaningful... it has a nice way of validating people's experience in a humanising way.*

Caregivers in both groups typically spoke about motivation to engage in the trial in the context of their own personal motivation and what they believed to motivate the PLWD they cared for. In contrast to NHS staff, caregivers cited as a combination of willingness to give anything a go (3/10) and potentially for them and the PLWD they care for to learn a bit about dementia (2/10). However, this was tempered by caregiver scepticism about the CFT approach and how they believed PLWD might receive the intervention (5/10), highlighting both facilitators and barriers to engagement.

*Caregiver 1: It scares me actually to get her to buy into the compassion because she's just not been built like that.*

*Caregiver 5: What made me interested? Because it was helping him. He wanted to get his head around what's happening.*

### Caregiver Burden

There was a noteworthy difference between the intervention and control caregiver reports of burden, highlighting the ethical dilemma of people not receiving an intervention.

*Caregiver 3 (intervention group): It has made my life a lot easier because she's having more good days ... she's fully functional more often, which does take a little bit of pressure off us.*

*Caregiver 9 (control group): It feels like I've got a fourth child... I have to make sure she takes her meds, make sure she's eating... It's just like I've got a patient in my house. I'm a single mum of three and I've got my mum that's got dementia. And I've got my demanding job as well so it's quite a lot.*

#### 4.2.4. Systemic Integration

##### Support Structures

Nearly all caregivers in both groups (9/10) identified professionals who suggested they participate in the trial, which indicates that trial access may be reliant on professional signposting. In addition to trial engagement, other formal and informal support structures were cited by caregivers as being helpful for them and PLWD. In the absence of receiving the CFT intervention, control group caregivers emphasised the importance of informal support more than those in the CFT group. Lack of ongoing engagement with formal support services was highlighted by two out of three control group caregivers (Caregiver 9, Caregiver 10) both of whom highlighted increased caregiver burden compared to other caregivers. This contrasted to those receiving the

CFT group, who according to group facilitators were given access to signposting suggestions from facilitators. Participants unanimously shared that they would be willing to participate in similar projects, though for caregivers this was felt to be mitigated by their proximity to local organisations and other commitments such as caring for family members.

*Caregiver 10: I sort of half expected more support... we didn't feel abandoned, but not really within the system... It would just be useful to hear about more things... at the moment it's just people around us: I've been offered assistance by the vicar and that sort of thing... Friends are good, church is very good.*

*Caregiver 9: Because I don't get any support... I'm just struggling with everything because I have no choice.*

*Facilitator 3: We have to signpost anyway because they're in our service, so we have been able to do that.*

Similarly for NHS staff, various systemic factors were cited as being helpful for their trial involvement, including close connections to Research and Development departments, proximity to training, and flexible work patterns (6/7). However, systemic barriers to access and engagement were identified such as staffing issues impacting capacity for NHS staff involvement.

### Communication and awareness

In addition to the possible communication issues between group members and caregivers reported in section 4.1.5., NHS staff reported difficulties in communication between research and clinical departments during trial setup (2/7). All group facilitators reported challenges in using the fidelity checklist, either through not knowing it existed (2/6), or due to forgetting to use it (4/6). Suggestions were that reminders should be written into the manual.

There were mixed opinions on communication between researchers and caregivers. It was generally spoken about positively, with both intervention and control caregivers attributing their understanding of trial processes to this communication (5/10), however one reported not being aware of the caregiver's workshop (Caregiver 6), and another outlined uncertainty around group allocation (Caregiver 7).

*Caregiver 4: You've been communicative all the way through. Most people aren't. You've been kind and caring - some of the groups aren't. You've been informative of everything that's been going on, asking consent and it has been about the actual person.*

*Caregiver 7: Yes I think they sort of vaguely said he might not get on... they ask a lot of questions don't they.*

## 5. Discussion

### 5.1. *Summary*

This study set out to explore caregiver, group facilitator and senior management clinician perspectives of a trial of CFT for low mood and anxiety in dementia. This included their ideas about how PLWD experienced the CFT intervention and the trial as a whole, as well as their own experiences. Group facilitators and caregivers of PLWD in the intervention group were asked about their perspectives on feasibility and acceptability of the CFT intervention, specifically: barriers and facilitators to PLWD engagement and participation with the intervention, the mechanisms of change and outcomes for PLWD, and future recommendations for delivering group-based CFT to PLWD. Group facilitators, senior management clinicians and caregivers of PLWD in both the intervention and TAU groups were asked about their perspectives on feasibility and acceptability of the trial itself, specifically: barriers and facilitators to recruitment, access and engagement with the trial itself, outcomes from trial involvement and future recommendations for trial design. Five themes were extracted relevant to Intervention Processes: Benefits and Challenges of Group Format, Intervention Delivery, Knowledge and Understanding, Psychological Impact, and Systemic Integration. Four themes were extracted relevant to Trial Processes: Trial Setup, Cognitive Difficulties, Psychological Influences and Outcomes, and Systemic Integration. All of these themes can be situated within the original research questions.

Overall, the CFT intervention was perceived to have a positive outcome on PLWD mood, understanding and relationships, though there was discrepancy in the degree

to which improvements were reported between interview participants. Potential differences between intervention and control caregiver reports of caregiver burden and support structures were identified. The group setting was viewed to be an important factor influencing PLWD access, engagement and outcomes, while comparatively CFT components were spoken about as helpful but less important. PLWD cognitive abilities were perceived to impact session engagement, interpersonal dynamics as well as recall between sessions, and some caregivers reported that their own memory was at times limited during the interview process. Moreover, communication difficulties across the trial were perceived by interviewees to impact caregiver awareness of session content and researcher awareness of trial processes during setup. Despite being seen as useful to have, session resources were viewed as complicated, lengthy and not tailored to PLWD enough. Access to the trial was suggested to be facilitated by professional signposting for caregivers, and flexibility in clinical roles for facilitators. Timings were also reported as a universal difficulty during setup and session delivery.

## *5.2. Suggestions and Implications*

The 'Benefits and Challenges of Group Format' theme mirrors findings from qualitative evaluations of group-based Cognitive Stimulation Therapy (CST) whereby interviewees believed that PLWD liked the group setting and found it helpful sharing experiences and listening to others (Spector et al., 2011). Despite social interaction being suggested to be beneficial for PLWD (Knecht & Rodriguez, 2025) the present study also corroborates findings that there are potentially initial challenges opening up in a group for some PLWD (Orfanos et al., 2021). However, as suggested by Orfanos et al. (2021), it is arguable that this challenge may have played a facilitatory role in overall group experience, as those PLWD who struggled to share in the group initially

were perceived to have undergone a transformation across the sessions and overcome their fears. Moreover, the interviewee perspectives in the present study support findings that PLWD may speak more openly about dementia in their daily lives as a result of group sessions (Spector et al., 2011), highlighting the role of socialisation and sharing in facilitating discussion with others.

Importantly, no interviewees perceived that CFT group to have detrimental impacts on PLWD, and most believed there to be a degree of improvement in PLWD mood and understanding, which aligns with existing reviews of therapeutic groups for PLWD (Gibbor et al., 2021). NHS staff in particular also highlighted potential PLWD improvements in CFT-specific areas such as compassion, acceptance and self-care which aligns with qualitative findings of previous CFT for dementia trials (Craig et al., 2018), and cited a variety of exercises as helpful tools. However, caregivers perceived less substantial PLWD improvements than NHS staff and almost exclusively only cited breathing exercises in their recounts of specific exercises they felt might have been helpful for PLWD, which differs from studies of CFT for older adults without dementia who report a wider variety of useful CFT tools (Altavilla & Strudwick, 2022b). This discrepancy may suggest that while socialisation and sharing continued beyond the sessions, improvements in understanding and mood were less effectively generalised. One explanation is that there was limited PLWD communication of session content and home tasks with caregivers (Spector et al., 2011), possibly due to memory deficits (Cohen-Mansfield, 2018). Closer involvements of caregivers assists in promoting PLWD engagement with support and implementation of skills (Campbell et al., 2024), and yet caregivers of PLWD frequently report to be unsure of their responsibilities within clinical trials (Miranda et al., 2023). This may have been the case in the present

trial given that caregivers were not provided with detailed descriptions of CFT exercises or frameworks. Therefore, where PLWD communication of session content and home tasks may be limited, researchers should endeavour to bolster caregiver understanding through clearer oral or written communication directly with individuals or via caregiver clinical trials groups (Miranda et al., 2023).

Communication difficulties may also have been present between researchers and caregivers in relation to trial processes. Researchers were unable to arrange interviews with ten caregivers. This may have been due to caregiver burden making it difficult for them to engage in interviews, particularly if little value was seen in the process. This may have been the case with caregivers of PLWD in the control group as they had minimal contact with researchers and often reported a lack of awareness of trial processes. The attrition rates may also indicate that relying on phone calls was an insufficient recruitment strategy, particularly if those involved had varying caregiving responsibilities. In addition to caregivers' schedules, restricted interviewer schedules may have impeded opportunities to conduct interviews. These issues may have led to an underrepresentation of caregiver voices who were the most burdened or disengaged from the trial. Recommendations would be to involve caregivers more consistently throughout the trial by providing them with updates and reminders, and to pre-establish alternative communication methods with caregivers in instances where phone calls are unsuccessful. Also, additional interviewers could be recruited to reduce the chances of caregivers missing out on interviews due to scheduling issues.

The 'Intervention Delivery' and 'Trial Setup' themes outlined several potential issues with the session materials and trial setup. Session resources were identified as a substantial barrier to engagement by all interviewees, with the manual and CFT exercises being perceived by group facilitators to be complicated, lengthy and not always applicable to the group. This supports previous reports of PLWD experience in research (Clement et al., 2019) and may have contributed to PLWD's limited sharing of session content with caregivers. While the manual was developed to be deployed flexibly in accordance with findings from other manualised interventions for PLWD (Anderson-Ingstrup & Ridder, 2020), the emerging themes aligned with suggestions that facilitators are often confused due to a lack of detail in how to apply manual content, compounded by feelings that training does not adequately prepare them for how to do so (Berry et al., 2021; Renouf et al., 2023). Adaptations should be considered whereby worksheets and exercises are made more accessible following co-production with PPI teams (Durose et al., 2017). Moreover, the manual and session resources could be organised more effectively, and supervision could be organised more frequently to assist facilitators in applying CFT knowledge within the group.

Timings are often reported as a barrier to engagement and effectiveness in psychosocial research, particularly during trial setup and in session delivery (Cohen-Mansfield & Jensen, 2022). Group facilitators in the present study reported needing more time in sessions to consolidate learning, supporting suggestions of PLWD engagement being facilitated by additional practise time (Walton et al., 2020). A recommendation from multiple interviewees was to allocate extra time at the beginning of sessions or during a coffee break for session orientation and socialising, which could serve to promote important social connection and sharing (Aroogh &

Shahboulaghi, 2020; Suragarn et al., 2021) while protecting the hour for CFT. Timing issues were also highlighted in the interview process as caregivers reported difficulties recalling trial experiences, particularly in control group caregivers who were less able to recall experiences of early trial access and assessments. Timely interviews are imperative and adaptations could be made to facilitate accurate recall by conducting interviews at various timepoints throughout the trial rather than solely at the end.

Support structures within participant systems were identified by interviewees as potential facilitators to PLWD access and engagement in the trial, with professional signposting being cited as the primary way people accessed the trial. Crucially for caregivers, this highlights the necessity of support structures and implies that those better integrated with formal support are more likely to gain access to trials (Nocivelli et al., 2023). Extending from this, a lack of formal or informal support is thought to negatively impact caregiver burden (Shiba et al., 2016), which was echoed by some caregivers in the present study, particularly those in the control group. Moreover, control group participants did not receive ongoing signposting recommendations or resources from group facilitators, highlighting disparities in support availability for trial participants. These findings outline the important role of equitable resource provision within trials whereby all caregivers can benefit regardless of their existing support networks (Frank et al., 2021). Future intervention design should embed signposting into all trial arms and provide participants with resources for local support groups (Dunkin & Anderson-Hanley, 1998).

### 5.3. *Strengths and Limitations*

This study provides insight into the mechanisms and outcome of a novel CFT approach for dementia, as well as insight into the trial itself. The use of a critical realist framework was appropriate and beneficial; interviewee experiences as well as structural and contextual factors were considered in the evaluation of feasibility and acceptability. This enabled a multifaceted understanding of what worked and did not work as well in the intervention and trial as a whole. This aligns with existing literature on the value of critical realism in clinical research (Fletcher, 2017; Pawson & Tilley, 1997). From this position, several important recommendations have been identified that can be used to inform full-scale RCT design and delivery. These recommendations also have wider implications for group delivery of psychosocial interventions for PLWD that align with the evidence base (Gibbor et al., 2021; Orfanos et al., 2021; Spector et al., 2011). Moreover, data saturation was reached during the analysis process, with no new themes emerging beyond the point of approximately 15 – 17 interviews. Saturation was assessed both inductively through the coding process, and deductively based on the research questions and theoretical framework. This supports the adequacy of the sample size within the context of this feasibility study (Fusch & Ness, 2015; Saunders et al., 2018).

There were some noteworthy limitations. The sample was predominantly White British, which limits the transferability of findings to more ethnically diverse populations. This may reflect broader issues in access to psychological services and research for minority ethnic groups. Moreover, it may present a systemic issue that intersects with various socioeconomic and cultural issues relating to healthcare access such as a mistrust in professionals (Brijnath et al., 2022). Addressing such limitations requires

future research to deploy culturally sensitive recruitment strategies that are perhaps more community based rather than reliant on professional signposting. Translation of recruitment adverts should also be implemented (Waheed et al., 2020), as well as culturally validated psychometric tools (Brijnath et al., 2022). Additionally, the interpretive nature of the analysis introduces potential for researcher bias. While efforts were made to promote reflexivity and reduce bias by seeking input from the PPI group, the influence of the researcher's positionality cannot be disregarded. This is particularly relevant in the critical realist approach taken in the present study where researcher assumptions guided the exploration of the research questions (Braun & Clarke, 2021; Fletcher, 2017). There is also debate in the use of quantification in qualitative research. Stating participant numbers (X/Y) is argued to potentially misrepresent data and care must be taken to not generalise findings inappropriately (Neale et al., 2014).

## 6. Conclusion

Overall, the CFT intervention showed potential as a promising and acceptable intervention for PLWD, particularly due to its relational and group-based elements. Some key issues were identified with trial processes. It is suggested that future RCTs should aim to enhance caregiver involvement, simplify materials, and address structural barriers to improve implementation and engagement.

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## Part 3: Critical Appraisal

## *1. Introduction*

This appraisal details key reflections on my experience of conducting research into the older adult population. I will attend primarily to my empirical paper that explored Compassion Focused Therapy (CFT) for People Living With Dementia (PLWD) and offer my thoughts on my initial interest in the project, the epistemological stance and analytical technique adopted as well as practical and systemic challenges encountered throughout the process. I will conclude with my thoughts about the personal impact of completing this research.

## *2. Initial interest in the project*

I was drawn to the project on two fronts primarily: working with PLWD, and being able to further my interest in CFT. I had never worked with older adults prior to my involvement with this project, and when I first saw it listed as a thesis option I began my reflective process as to why. Aside from not having been placed in an older adult setting at that point, I noticed I initially had no desire to be. When I considered the reasons for this, it brought to mind my own grandparents and how ageing had impacted them. As a child, going to see my grandparents was special, however as I myself grew up I found it hard to see the people I'd known as being so sturdy and infallible deteriorating mentally and physically. As care homes became involved and dementia took hold in two of them, I found myself feeling frustrated and angry at a society which so readily views older adults as a burden and does relatively little to support people in this demographic (Warnes, 1993). When I saw this project listed, I saw it as an opportunity to work in an under-researched domain and to be part of something that could help people live with dignity and happiness rather than shame, anxiety and depression.

In addition to my connection with older adults and dementia, I was drawn to the idea of being involved in a study trialling CFT. I had begun incorporating CFT into my clinical practice and had bought into the model entirely. I felt adept at formulating within a CFT framework and delivering techniques, but lacked knowledge in how to promote compassionate mindsets or helping people to develop understandings of their multiple selves (Gilbert, 2010). Having seen the impact of dementia first hand, I recognised the potential place CFT had in overcoming the shame of the diagnosis (Aminzadeh et al., 2007b), managing shame around the symptoms such as forgetting names or the deterioration of skills (Kłosińska & Leszko, 2024) and working within a stigmatised community (Nguyen & Li, 2020b; Urbańska et al., 2015). I was aware of the lack of psychological support that is generally offered to PLWD and therefore the intersection of personal interest within societal and academic requirement for development in the research field catalysed my involvement.

### *3. My position within qualitative research and framework analysis*

It is noteworthy that my initial involvement in the trial was to conduct quantitative analysis by comparing participants' scores on quantitative outcome measures pre and post intervention. However, due to limitations imposed by the trials unit, I was not able to request the data necessary to conduct this analysis. Instead, I joined my project partner in conducting a qualitative analysis of participant interviews. This presented as an opportunity to conduct a thorough exploration of participant experiences, with two researchers providing capacity to analyse a larger sample size and give more participants the chance to shape future trial design. Moreover, from a personal perspective it enabled me to enhance my reflexivity skills.

There were some practical difficulties with this transition. With the switch happening in November 2024 and the thesis submission deadline in June 2025 there was limited time for me to embed myself into qualitative literature. Given the intensity and time-consuming nature of qualitative research (Ferguson & Gordon, 2019), I came to the analysis feeling slightly underprepared and unclear about processes. Aligning with suggestions from the literature, I reflected on how challenging I found the language used within the field at times, and how it made me want to disengage from the learning (Carrera-Fernández et al., 2014; Clark & Sousa, 2018). Interestingly, this issue also seems to mirror participants' experiences of the CFT materials within the groups, highlighting some potential parallel processes within the trial itself.

In addition to time constraints, the transition from quantitative to qualitative presented personal reflexive challenges. I had rarely considered my position in research before, which is something that takes time to develop an understanding of. In reflecting now, I recognise that my limited exposure to qualitative research led to an underestimation of how my own background and beliefs shape data interpretation. In focusing on reflexivity I recognised that my role as a group facilitator on the trial was shaping the way I viewed the data during the familiarisation phase of framework analysis. I wanted the CFT group to be feasible and acceptable, and was keen to draw out positive outcomes. Additionally, I was aware of my own experiences within the trial, and certain comments from participants resonated with me more than others as I shared their perspectives (I will discuss these in more detail later in this appraisal). Acknowledging this aided my ability to mitigate bias within my interpretations during the coding and indexing phases.

Moreover, my academic roots were grounded in quantitative rather than qualitative approaches. I came to research with heightened expectations of objectivity and measurement, and I felt more comfortable seeking clear-cut answers that fitted pre-established frameworks. It therefore it took time to acclimatise to the subjective researcher position that comes with qualitative research. This was particularly evident in the early stages of framework analysis whereby I experienced some discomfort working inductively with emerging data, particularly where data did not fit neatly into prescribed categories. I was trying to combat this discomfort by seeking patterns too quickly and was mentally grouping codes into themes earlier than necessary. However, I was able to notice this and change the way I approached the data. I felt contained within the analytical framework and enhanced the reflexive process through regular consultation with my research partner. As an adept qualitative researcher, she supported me in challenging my assumptions, and as a result I noticed my analytical confidence growing. Moreover, consultation with the Public and Patient Involvement (PPI) group regarding my initial codes helped me not to overlook subtleties in participant interviews. The group members were able to spotlight examples of where I had interpreted something differently to them, and this facilitated my ability to a step back from the data and consider nuance in what was being conveyed.

#### *4. Reflections on CFT intervention processes*

Facilitating one of the CFT groups offered me a valuable opportunity to occupy the dual role of practitioner-researcher and gain deeper insight into the feasibility and acceptability of the intervention. Mirroring the experiences described by several facilitators I interviewed, I found the hour-long intervention format challenging in

practice. Delivering the full breadth of CFT content within the allocated time was often difficult, compounded by the reality that group members often displayed cognitive limitations that impacted their ability to stay focused on the session material. This occasionally led to conversations veering off-topic, which had knock-on effects for group cohesion and content delivery. I sometimes noticed other group members expressing subtle signs of frustration when space in the group became dominated by more tangential contributions. My cofacilitator and I sought to manage this sensitively by adopting a firmer approach to facilitation, creating group agreements that enabled us to gently steer discussions back to the session focus when necessary. However, this was often ineffective, requiring more direct interrupting and reorientation with group material. I experienced a degree of discomfort during this process; I hoped that all group members would find the space useful and recognised that we needed to steer the conversation at times, however it felt uncomfortable to interrupt somebody who felt they were expressing relevant information. I reflected on this discomfort in supervision as I found it hard to interrupt, particularly in a group centred around compassion. Balancing the needs of the group with a compassionate response to individual communication styles became a core part of the reflexive process during this phase of the research.

Another factor that contributed to the challenge of covering the CFT material within the designated session time was the need for frequent repetition. The group manual was designed to include brief recaps of key concepts to accommodate for memory deficits in PLWD, however in practice these often extended beyond a quick summary. For many group members, the content being revisited did not appear as familiar, and sessions often had the quality of introducing material for the first time rather than

building upon previous knowledge. This was particularly evident with more foundational topics that were essential to the intervention such as the three circles model. With larger topics such as this, we found ourselves allocating significant portions of multiple sessions to re-introducing the framework before being able to move forward. I was aware of the necessity of doing so to support comprehension and engagement, yet this naturally placed limitations on how much new material could be introduced in a single session. I found this difficult at times, as the pressure to balance thorough explanation with understanding with fidelity to the manual often left me feeling stretched.

Memory difficulties also appeared to impact participants' ability to implement the CFT practices outside of the group setting. Despite engagement during sessions, several group members struggled to recall the exercises between meetings, and few reported using them independently at home. This mirrors findings from my empirical paper, in which staff and caregiver accounts similarly suggested limited carryover of therapeutic techniques outside of the group context. While the group manual included strategies to support generalisation such as home practice prompts and handouts, these were often insufficient without more consistent reminders or support. Some participants would express enthusiasm about exercises such as soothing rhythm breathing or compassionate imagery during the session, but by the following week had little or no memory of having done them. At the time this felt somewhat frustrating, as I was aware of the important role of implementation beyond the group sessions, and yet something was getting in the way. In supervision, this raised important questions for me about how to promote ongoing engagement in the absence of strong memory traces. One factor that seemed to contribute was the limited communication between participants

and their caregivers about group content. As reflected in the qualitative data, there was often minimal dialogue about what had taken place in the sessions, meaning that caregivers were not always in a position to offer prompts or encouragement between meetings. On reflection, we may have put too much onus on the group members to remember to speak to caregivers and to feedback what had been covered in the group. We could have done more to support PLWD with this process, opening up discourse in assessment sessions around how PLWD-caregiver dyads would like to have group material communicated to them.

Being a visibly younger facilitator in a group of older adults raised important reflections for me around perceived authority, expertise, and relational dynamics. Although I was positioned as a mental health professional within the group, my status as a trainee meant I often felt conflicted in adopting the role of 'expert'. At times, I wondered how my age may have shaped participants' expectations of me. I was curious as to whether it gave the impression of competence and up-to-date knowledge, or conversely suggested a lack of lived experience and therefore a limited capacity to truly understand the challenges they faced. This was particularly relevant given the generational gap between myself and group members, which seemed to influence how mental health was conceptualised and spoken about. Conversations around shame, self-criticism, and compassion often felt unfamiliar to participants, and I was aware that for some these themes may have clashed with more traditional views of stoicism or simply coping. This was particularly apparent within those who were mothers and grandmothers who reported that they had spent their lives caring for others and that they initially perceived the idea of self-compassion as being selfish.

On several occasions, male participants made remarks that reflected potential generational expectations for men to suppress emotion and avoid the portrayal of vulnerability. Identifying with some of the discourse around men's mental health, I felt a sense of pride in being part of a process that gently challenged these norms by creating space for men to express thoughts and feelings they may not have shared openly before. Facilitating these shifts felt meaningful and highlighted to me the value of CFT in challenging stigma.

##### *5. Reflections on the interview process*

It is important to acknowledge the duality of insider and outsider positionality I held within the semi-structured interviews (Dwyer & Buckle, 2009). When interviewing caregivers of PLWD I predominantly held an outsider position; I was not a caregiver of a PLWD, I was younger, and I was coming to the interviews from an academic background. This may have influenced how open caregivers felt they could be with me. Some may have been more reserved in discussing their experience due to uncertainty over whether I could empathise. Alternatively, something I often noticed was that some of the more basic aspects of caregiving were focused on rather than delving into the more personal experiences of trial participation. This may have been due to a lack of understanding of the purpose of the interviews. I attempted to mitigate this by adopting a more informal interview style to reduce power imbalances and promote open sharing. Despite this, it could be that the proposed differences between caregiver and NHS staff reports of outcomes in PLWD are explained by interview bias rather than true differences.

Contrastingly, during interviews with NHS staff I adopted much more of an insider role, which brings a host of benefits and challenges to qualitative research (Buys et al., 2022). On the one hand my visible role as a researcher may have helped staff to open up under the assumption that I would understand and be able to empathise with their position. Participants were unaware of my role as a CFT group facilitator, and without knowledge of my insider status in this area they may have felt less concerned about being judged or compared with. Contrastingly to caregivers who sometimes offered surface-level information, NHS staff may have felt more able to provide detailed descriptions of their experiences due to an enhanced understanding of what was required from the research. That being said, it is worth considering that my insider position during these interviews may have led to analytical bias through over-identification in assuming the experiences of these participants. This may have been exacerbated by my role as a CFT facilitator as I had my own interpretations of barriers and facilitators to access and engagement, mechanisms of change, outcomes and implications for future RCTs.

One issue that came to light within the interviews was caregivers' the lack of clarity in their memory of trial experiences. A key part of the interview schedule was focusing on issues of access and initial engagement with the trial, and yet participant interviews were taking place several months after initially accessing the trial. This meant that caregivers were often unable to give comprehensive answers about their experiences of this early part of the trial, and there was somewhat a lack of detail here during analysis. This was particularly the case for those in the control group who had minimal interaction with researchers between baseline and follow-up assessments; two of these participants had almost completely forgotten they were part of a trial. This may

be compounded by recall difficulties in older adult participants (Rhodes et al., 2019). Therefore, in future trials it may be beneficial to conduct interviews closer to key trial milestones and to maintain researcher contact with participants to improve the qualitative interview process.

## *6. Ethical reflections*

Conducting research with PLWD inevitably raised numerous ethical considerations, particularly around vulnerability, consent, and the management of emotional risk. As is always the case with dementia research, it is essential to track and manage potential changes in capacity (Hegde & Ellajosyula, 2016). It required me to be sensitive to any signs that a participant's understanding, engagement, or comfort with the research process might have shifted. However, this felt hard to do while delivering the group as there were lots of interpersonal factors that needed to be attended to. Moreover, I was conscious that changes in presentation did not necessarily reflect impaired capacity (Sherratt et al., 2007). As a newcomer to the field of dementia research, navigating this balance was a particular challenge, and one that future group facilitators and researchers may wish to discuss more in supervision spaces.

During interviews, some caregivers became visibly emotional when speaking about their experiences of supporting a loved one with dementia or reflecting on the impact of the daily difficulties. In one interview a participant became dejected when talking about the lack of formal and informal support, and I found myself questioning whether continuing the interview was helpful or potentially detrimental as it illuminated their current isolation as a caregiver. In those moments, it was challenging to balance the need for rich, meaningful data with my duty of care to participants. While the interview

schedule encouraged open discussion, it became clear that certain questions could elicit strong emotional responses, and I had to remain attuned to how far to probe. These decisions were not always straightforward and required a degree of intuition and reflexivity that I feel developed over time.

Power dynamics also came into focus during these encounters; as a trainee psychologist positioned within a structured research project, I was aware that participants may have viewed me as an 'expert' or form of authority figure and therefore might have felt unable to disagree or challenge the direction of the conversation. In considering this I aimed to promote a sensitive approach that prioritised participant wellbeing alongside research aims rather than just the latter.

## *7. Conclusion*

I am proud to have been a part of this project. It has been a constant source of learning, not only through the research process but also through the wisdom and narratives shared by the people I've interviewed and facilitated in the group. I was drawn to working with PLWD despite possessing limited experience of doing so and therefore have experienced a steep learning curve in both a clinical and research capacity. I feel that I have been exposed to some of the challenges of dementia research while being able to add to people's lives, even if just in a small way. Overall, this project has enhanced my confidence in navigating research complexity and bolstered my commitment to ethical, compassionate, and person-centred clinical practice.

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## Appendices

### Appendix 1: PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
<b>TITLE</b>			
Title	1	Identify the report as a systematic review.	
<b>ABSTRACT</b>			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
<b>METHODS</b>			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	3.1; Table 1
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	3.2; Table 2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	3.3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	3.3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	3.3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	3.3
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	3.4

Section and Topic	Item #	Checklist item	Location where item is reported
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	3.5
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	3.5
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	3.5 ; 3.6
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	3.6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	3.6
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	3.6
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	3.6
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	3.4
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	3.7
<b>RESULTS</b>			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	4; Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	4
Study characteristics	17	Cite each included study and present its characteristics.	Table 3
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	4.1; Figure 2
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Figures 3, 6 and 8
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	4.2 – 4.5
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	4.2 – 4.5
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	4.2 – 4.5
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	4.2 – 4.5
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	4.1; Figure 2

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	4.6
<b>DISCUSSION</b>			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	5.1
	23b	Discuss any limitations of the evidence included in the review.	5.1; 5.2
	23c	Discuss any limitations of the review processes used.	5.2
	23d	Discuss implications of the results for practice, policy, and future research.	5.3; 5.4
<b>OTHER INFORMATION</b>			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	3
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	3
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	3.1
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

## Appendix 2: Database search strategy

05/07/2024

APA PsycInfo (via Ovid) <1806 to June Week 4 2024>

- 1 exp Mindfulness/ or exp Cognitive Therapy/ or exp Dialectical Behavior Therapy/ or exp "Acceptance and Commitment Therapy"/ 31187
- 2 exp Anxiety/ or exp Major Depression/ or exp Mental Health/ or exp Well Being/ 390644
- 3 exp Older Adulthood/ or exp Geriatrics/ or exp Aging/ or exp Geriatric Patients/ 131823
- 4 ((third adj wave) or CFT or (compassion adj focused) or mindful\* or MBCT or "mindfulness based cognitive therapy" or ACT or "acceptance and commitment therapy" or MCT or "metacognitive therapy" or DBT or "dialectical behavior?r therapy" or "schema therapy").mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word] 121149
- 5 (anx\* or depress\* or dysph\* or wellbeing or "quality of life" or self compassion).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word]723926
- 6 ((older adj adult) or elder\* or (old adj age) or (late\* adj life) or ag?ing or geriatric or (older adj people) or over 65).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word] 227820
- 7 1 or 4 133855
- 8 2 or 5 823823
- 9 3 or 6 245666
- 10 7 and 8 and 9 **1530**

05/07/2024

Ovid MEDLINE(R) ALL <1946 to July 03, 2024>

- 1 ((older adj adult) or elder\* or (old adj age) or (late\* adj life) or ag?ing or geriatric or (older adj people) or over 65).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word] 864806
- 2 (anx\* or depress\* or dysph\* or wellbeing or quality of life or self compassion).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word] 1361001
- 3 ((third adj wave) or CFT or (compassion adj focused) or mindful\* or MBCT or "mindfulness based cognitive therapy" or ACT or "acceptance and commitment therapy" or MCT or "metacognitive therapy" or DBT or "dialectical behavior?r therapy" or "schema therapy").mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary

concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]392692

4 1 and 2 and 3 **1059**

**05/07/2024**

**Scopus**

1. TITLE-ABS-  
KEY ( ( old\* AND adult ) OR elder\* OR ( old AND age ) OR ( late\* AND life ) OR ag?ing OR geriatric OR ( old\* AND people ) OR over 65 ) 219849
2. TITLE-ABS-  
KEY ( anx\* OR depress\* OR dysph\* OR wellbeing OR ( well AND being ) OR ( quality AND of AND life ) OR ( self AND compassion ) ) [12,841,046](#)
3. TITLE-ABS-  
KEY ( ( third AND wave ) OR cft OR ( compassion AND focused ) OR mindful\* OR mbct OR ( mindfulness AND based AND cognitive AND therapy ) OR act OR ( acceptance AND commitment AND therapy ) OR mct OR ( metacognitive AND therapy ) OR dbt OR ( dialectical AND behavior AND therapy ) OR ( schema AND therapy ) ) [1,327,171](#)
4. 1 AND 2 AND 3 **866**

**10/07/2024**

**Proquest psychology database**

Set#: S1

Searched for: summary((third wave) OR (CFT) OR (compassion focused therapy) OR mindful\* OR MBCT OR (mindfulness based cognitive therapy) OR ACT OR (acceptance AND commitment therapy) OR MCT OR (metacognitive therapy) OR DBT OR dialectical behavior\* therapy OR (schema therapy))

Results: 55143

Set#: S2

Searched for: summary(anx\* or depress\* or dysph\* or wellbeing or "well being" or "quality of life" or "self compassion")

Results: 243212

Set#: S3

Searched for: summary(old\* adult OR elder\* OR old\* age OR late\* life OR ageing OR geriatric\* OR old\* people OR over 65)

Results: 152110

Set#: S4

Searched for: [S1] AND [S2] AND [S3]

**Results: 821**

**10/07/2024**

## **Cochrane (CENTRAL) database**

ID Search Hits

#1 third wave therapy or third wave intervention or CFT or "compassion focused therapy" or mindful\* or MBCT or "mindfulness based cognitive therapy" or ACT or "acceptance and commitment therapy" or MCT or "metacognitive therapy" or DBT or dialectical behavi\* therapy or "schema therapy" 31118

#2 anx\* or depress\* or dysph\* or wellbeing or "well being" or "quality of life" or "self compassion" 327989

#3 old\* adult OR elder\* OR old\* age OR late\* life OR ageing OR geriatric OR old\* people OR "over 65" 196863

#4 #1 and #2 and #3

**1618**

## Appendix 3: RoB 2 Tool

# Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne  
on behalf of the RoB2 Development Group  
**Version of 22 August 2019**

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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**Study details**

<b>Reference</b>	
<b>Study design</b>	
<input checked="" type="checkbox"/> Individually-randomized parallel-group trial <input type="checkbox"/> Cluster-randomized parallel-group trial <input type="checkbox"/> Individually randomized cross-over (or other matched) trial	
<b>For the purposes of this assessment, the interventions being compared are defined as</b>	
Experimental: <input style="width: 150px;" type="text"/> Comparator: <input style="width: 150px;" type="text"/>	
<b>Specify which outcome is being assessed for risk of bias</b>	<input style="width: 100%;" type="text"/>
<b>Specify the numerical result being assessed.</b> In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	<input style="width: 100%; height: 80px;" type="text"/>
<b>Is the review team's aim for this result...?</b>	
<input type="checkbox"/> to assess the effect of <i>assignment to intervention</i> (the 'intention-to-treat' effect) <input type="checkbox"/> to assess the effect of <i>adhering to intervention</i> (the 'per-protocol' effect)	
<b>If the aim is to assess the effect of <i>adhering to intervention</i>, select the deviations from intended intervention that should be addressed (at least one must be checked):</b>	
<input type="checkbox"/> occurrence of non-protocol interventions <input type="checkbox"/> failures in implementing the intervention that could have affected the outcome <input type="checkbox"/> non-adherence to their assigned intervention by trial participants	
<b>Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)</b>	

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- “Grey literature” (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

## Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

### Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		<b>Y</b> / <b>PY</b> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN</u> / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN</u> / N / NI
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / <u>PN</u> / N / NI
2.4 <u>If Y/PY to 2.3:</u> Were these deviations likely to have affected the outcome?		NA / Y / PY / <u>PN</u> / N / NI
2.5. <u>If Y/PY/NI to 2.4:</u> Were these deviations from intended intervention balanced between groups?		NA / <u>Y</u> / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		<u>Y</u> / PY / PN / N / NI
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / <u>PN</u> / N / NI
Risk-of-bias judgement		Low / High / Some concerns

Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable
--	--	--

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN</u> / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN</u> / N / NI
2.3. [If applicable:] <u>If Y/PY/NI to 2.1 or 2.2:</u> Were important non-protocol interventions balanced across intervention groups?		NA / <u>Y</u> / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / <u>PN</u> / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / <u>PN</u> / N / NI
2.6. <u>If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5:</u> Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / <u>Y</u> / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

### Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.2 <b>If <u>N/PN/NI</u> to 3.1:</b> Is there evidence that the result was not biased by missing outcome data?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u>
3.3 <b>If <u>N/PN</u> to 3.2:</b> Could missingness in the outcome depend on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.4 <b>If <u>Y/PY/NI</u> to 3.3:</b> Is it likely that missingness in the outcome depended on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / <u>PN</u> / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / <u>PN</u> / N / NI
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / <u>PN</u> / N / NI
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / <u>PN</u> / N / NI
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / <u>PN</u> / N / NI
<b>Risk-of-bias judgement</b>		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
<b>5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?</b>		<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
<b>Is the numerical result being assessed likely to have been selected, on the basis of the results, from...</b>		
<b>5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?</b>		<b>Y</b> / <b>PY</b> / <u>PN</u> / <u>N</u> / NI
<b>5.3 ... multiple eligible analyses of the data?</b>		<b>Y</b> / <b>PY</b> / <u>PN</u> / <u>N</u> / NI
<b>Risk-of-bias judgement</b>		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Overall risk of bias

<b>Risk-of-bias judgement</b>		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



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## Appendix 4: Full R Script

```
# Load R libraries

library(dmetar)

library(tidyverse)

library(meta)

library(readxl)

library(metafor)

library(ggplot2)

library(dplyr)

library(esc)

# Load DepressionDataSheet.csv containing pre-calculated data for depression analysis

DepressionDataSheet <- read_excel("Documents/Doctorate/Research project/Systematic
review/Meta analysis/R /DepressionDataSheet.xlsx")

View(DepressionDataSheet)

# Calculate Hedges' g and the adjusted SE, storing each in a new column, to correct for small
sample bias

DepressionDataSheet <- DepressionDataSheet %>%
  mutate(
    CombinedSampleSize = C_EndpointSample + E_EndpointSample,
    J = 1 - (3 / (4 * (CombinedSampleSize - 2) - 1)),
    Adjusted_SMD = SMDB_Endpoint * J,
    SE_Adjusted_SMD = J * SESMDBetween)
```

```

# Run meta-analysis for depression

depression_meta <- metagen(TE = Adjusted_SMD,
                          seTE = SE_Adjusted_SMD,
                          studlab = Study,
                          data = DepressionDataSheet,
                          sm = "SMD",
                          common = FALSE,
                          random = TRUE,
                          method.tau = "REML",
                          method.random.ci = "HK",
                          title = "Depression Meta-Analysis")

# Create forest plot of depression data

# Save filtered forest plot to PDF with adjusted dimensions
pdf(file = "Depression_Forest.pdf", width = 10, height = 12)

# Create a forest plot
forest(depression_meta,
       label.left = "Favours Control",
       label.right = "Favours Treatment",
       prediction = TRUE,
       print.tau2 = TRUE,
       leftcols = c("studlab", "TE", "seTE"),
       leftlabs = c("Study", "SMD", "SE"))

```

```

# Close the PDF file

dev.off()

# Find outliers and filter them out from depression data

# Display summary of the depression_meta object

summary(depression_meta)

# Find and print outliers in the depression_meta object

outliers_depression <- find.outliers(depression_meta)

print(outliers_depression)

# Filter out Giulietti et al 2023 and Ng et al 2022

DepressionFilteredData <- DepressionDataSheet %>%

  filter(!(Study %in% c("Giulietti et al 2023", "Ng et al 2022", "Quintana et al 2023b",

"Quintana et al 2023c"))))

# Run meta-analysis using filtered data for depression

filtered_depression_meta <- metagen(TE = Adjusted_SMD,

  seTE = SE_Adjusted_SMD,

  studlab = Study,

  data = DepressionFilteredData,

  sm = "SMD",

  common = FALSE,

  random = TRUE,

  method.tau = "REML",

  method.random.ci = "HK",

```

```

title = "Filtered Depression Meta-Analysis")

# Create forest plot of filtered depression data

# Save filtered forest plot to PDF with adjusted dimensions
pdf(file = "Filtered_Depression_Forest.pdf", width = 10, height = 12)

# Create a forest plot
forest(filtered_depression_meta, label.left = "Favours Control", label.right = "Favours
Treatment")

# Close the PDF file
dev.off()

# Conduct meta-analysis to compare depression effect sizes in studies using MBSR and MBIs
# Filter data
depression_intervention_filtered_data <- subset(DepressionDataSheet, Intervention_Type
%in% c("MBI", "MBSR"))

# Run meta-analysis for depression grouped by intervention type
intervention_depression_meta <- metagen(TE = Adjusted_SMD,
seTE = SE_Adjusted_SMD,
studlab = Study,
data = depression_intervention_filtered_data,
sm = "SMD",
common = FALSE,
random = TRUE,
method.tau = "REML",
method.random.ci = "HK",

```

```

        subgroup = Intervention_Type,
        title = "Intervention_Depression Meta-Analysis")

# Create forest plot of depression data grouped by intervention type
# Save filtered forest plot to PDF with adjusted dimensions
pdf(file = "Intervention_Depression_Forest.pdf", width = 10, height = 12)

# Create a forest plot
forest(intervention_depression_meta,
       prediction = TRUE,
       print.tau2 = TRUE,
       leftcols = c("studlab", "TE", "seTE"),
       leftlabs = c("Study", "SMD", "SE"))

# Close the PDF file
dev.off()

# Conduct meta-analysis to compare depression effect sizes in studies using MBSR and MBIs
using the filtered data

# Filter data
filtered_depression_intervention_filtered_data <- subset(DepressionFilteredData,
Intervention_Type %in% c("MBI", "MBSR"))

# Run meta-analysis for depression grouped by intervention type
filtered_intervention_depression_meta <- metagen(TE = Adjusted_SMD,
        seTE = SE_Adjusted_SMD,
        studlab = Study,
        data = filtered_depression_intervention_filtered_data,

```

```

sm = "SMD",

common = FALSE,

random = TRUE,

method.tau = "REML",

method.random.ci = "HK",

subgroup = Intervention_Type,

title = "Filtered Intervention_Depression Meta-Analysis")

# Create forest plot of filtered depression data grouped by intervention type

# Save filtered forest plot to PDF with adjusted dimensions

pdf(file = "Filtered_Intervention_Depression_Forest.pdf", width = 10, height = 12)

# Create a forest plot

forest(filtered_intervention_depression_meta,

       prediction = TRUE,

       print.tau2 = TRUE,

       leftcols = c("studlab", "TE", "seTE"),

       leftlabs = c("Study", "SMD", "SE"))

# Close the PDF file

dev.off()

# Load QoLDataSheet.csv containing pre-calculated data for QoL analysis

QoLDataSheet <- read_excel("Documents/Doctorate/Research project/Systematic

review/Meta analysis/R /QoLDataSheet.xlsx")

View(QoLDataSheet)

```

```
# Calculate Hedges' g and the adjusted SE, storing each in a new column, to correct for small
sample bias
```

```
QoLDataSheet <- QoLDataSheet %>%
  mutate(
    CombinedSampleSize = C_EndpointSample + E_EndpointSample,
    J = 1 - (3 / (4 * (CombinedSampleSize - 2) - 1)),
    Adjusted_SMD = SMDB_Endpoint * J,
    SE_Adjusted_SMD = J * SESMDBetween)
```

```
# Run meta-analysis for QoL
```

```
QoL_meta <- metagen(TE = Adjusted_SMD,
  seTE = SE_Adjusted_SMD,
  studlab = Study,
  data = QoLDataSheet,
  sm = "SMD",
  common = FALSE,
  random = TRUE,
  method.tau = "REML",
  method.random.ci = "HK",
  title = "QoL Meta-Analysis")
```

```
# Create forest plot of QoL data
```

```
# Save filtered forest plot to PDF with adjusted dimensions
```

```
pdf(file = "QoL_Forest.pdf", width = 10, height = 12)
```

```

# Create a forest plot
forest(QoL_meta,
      label.left = "Favours Control",
      label.right = "Favours Treatment",
      prediction = TRUE,
      print.tau2 = TRUE,
      leftcols = c("studlab", "TE", "seTE"),
      leftlabs = c("Study", "SMD", "SE"))

# Close the PDF file
dev.off()

# Find outliers and filter them out from QoL data
# Display summary of the QoL_meta object
summary(QoL_meta)

# Find and print outliers in the QoL_meta object
outliers_QoL <- find.outliers(QoL_meta)
print(outliers_QoL)

# Filter out Giulietti et al 2023
QoLFilteredData <- QoLDataSheet %>%
  filter(!(Study %in% c("Giulietti et al 2023")))

# Run meta-analysis using filtered data for QoL
filtered_QoL_meta <- metagen(TE = Adjusted_SMD,
                             seTE = SE_Adjusted_SMD,

```

```

studlab = Study,

data = QoLFilteredData,

sm = "SMD",

common = FALSE,

random = TRUE,

method.tau = "REML",

method.random.ci = "HK",

title = "Filtered QoL Meta-Analysis")

# Create forest plot of filtered QoL data

# Save filtered forest plot to PDF with adjusted dimensions

pdf(file = "Filtered_QoL_Forest.pdf", width = 10, height = 12)

# Create a forest plot

forest(filtered_QoL_meta, label.left = "Favours Control", label.right = "Favours
Treatment")

# Close the PDF file

dev.off()

# Conduct meta-analysis to compare QoL effect sizes in studies using MBSR, MBCT, ACT
and MBIs

# Filter data

QoL_intervention_filtered_data <- subset(QoLDataSheet, Intervention_Type %in% c("MBI",
"MBSR", "ACT", "MBCT"))

# Run meta-analysis for depression grouped by intervention type

intervention_QoL_meta <- metagen(TE = Adjusted_SMD,

```

```

seTE = SE_Adjusted_SMD,

studlab = Study,

data = QoL_intervention_filtered_data,

sm = "SMD",

common = FALSE,

random = TRUE,

method.tau = "REML",

method.random.ci = "HK",

subgroup = Intervention_Type,

title = "Intervention_QoL Meta-Analysis")

# Create forest plot of QoL data grouped by intervention type

# Save filtered forest plot to PDF with adjusted dimensions

pdf(file = "Intervention_QoL_Forest.pdf", width = 10, height = 12)

# Create a forest plot

forest(intervention_QoL_meta,

       prediction = TRUE,

       print.tau2 = TRUE,

       leftcols = c("studlab", "TE", "seTE"),

       leftlabs = c("Study", "SMD", "SE"))

# Close the PDF file

dev.off()

# Conduct meta-analysis to compare QoL effect sizes in studies using MBSR, ACT, MBCT
and MBIs using the filtered data

```

```

# Filter data
filtered_QoL_intervention_filtered_data <- subset(QoLFilteredData, Intervention_Type
%in% c("MBI", "MBSR", "ACT", "MBCT"))

# Run meta-analysis for QoL grouped by intervention type
filtered_intervention_QoL_meta <- metagen(TE = Adjusted_SMD,
      seTE = SE_Adjusted_SMD,
      studlab = Study,
      data = filtered_QoL_intervention_filtered_data,
      sm = "SMD",
      common = FALSE,
      random = TRUE,
      method.tau = "REML",
      method.random.ci = "HK",
      subgroup = Intervention_Type,
      title = "Filtered Intervention_QoL Meta-Analysis")

# Create forest plot of filtered QoL data grouped by intervention type
# Save filtered forest plot to PDF with adjusted dimensions
pdf(file = "Filtered_Intervention_QoL_Forest.pdf", width = 10, height = 12)

# Create a forest plot
forest(filtered_intervention_QoL_meta,
      prediction = TRUE,
      print.tau2 = TRUE,
      leftcols = c("studlab", "TE", "seTE"),
      leftlabs = c("Study", "SMD", "SE"))

```

```

# Close the PDF file

dev.off()

# Load AnxietyDataSheet.csv containing pre-calculated data for Anxiety analysis
AnxietyDataSheet <- read_excel("Documents/Doctorate/Research project/Systematic
review/Meta analysis/R / AnxietyDataSheet.xlsx")

View(AnxietyDataSheet)

# Calculate Hedges' g and the adjusted SE, storing each in a new column, to correct for small
sample bias

AnxietyDataSheet <- AnxietyDataSheet %>%
  mutate(
    CombinedSampleSize = C_EndpointSample + E_EndpointSample,
    J = 1 - (3 / (4 * (CombinedSampleSize - 2) - 1)),
    Adjusted_SMD = SMDB_Endpoint * J,
    SE_Adjusted_SMD = J * SESMDBetween)

# Run meta-analysis for Anxiety

Anxiety_meta <- metagen(TE = Adjusted_SMD,
  seTE = SE_Adjusted_SMD,
  studlab = Study,
  data = AnxietyDataSheet,
  sm = "SMD",
  common = FALSE,

```

```

        random = TRUE,

        method.tau = "REML",

        method.random.ci = "HK",

        title = "Anxiety Meta-Analysis")

# Create forest plot of Anxiety data

# Save filtered forest plot to PDF with adjusted dimensions
pdf(file = "Anxiety_Forest.pdf", width = 10, height = 12)

# Create a forest plot
forest(Anxiety_meta,

       label.left = "Favours Control",

       label.right = "Favours Treatment",

       prediction = TRUE,

       print.tau2 = TRUE,

       leftcols = c("studlab", "TE", "seTE"),

       leftlabs = c("Study", "SMD", "SE"))

# Close the PDF file

dev.off()

# Find outliers and filter them out from Anxiety data

# Display summary of the Anxiety_meta object
summary(Anxiety_meta)

# Find and print outliers in the Anxiety_meta object
outliers_Anxiety <- find.outliers(Anxiety_meta)

```

```

print(outliers_Anxiety)

# Run meta-regression with the rma() function for control group type for the depression
outcome

# Ensure Control_Category is treated as a factor
DepressionFilteredData$Control_Category <-
as.factor(DepressionFilteredData$Control_Category)

# Change the reference category to "No treatment"
DepressionFilteredData$Control_Category <-
relevel(DepressionFilteredData$Control_Category, ref = "No treatment")

# Run the meta-regression using Control_Category as a moderator
control_category_regression <- rma(yi = Adjusted_SMD,
      sei = SE_Adjusted_SMD,
      mods = ~ Control_Category,
      data = DepressionFilteredData,
      method = "REML",
      test = "knha")

# Display results
summary(control_category_regression)

# Run meta-regression with the rma() function for outcome measure

# Ensure Outcome_Measure is treated as a factor
DepressionFilteredData$Outcome_Measure <-
as.factor(DepressionFilteredData$Outcome_Measure)

# Run the meta-regression using Outcome_Measure as a moderator

```

```

outcome_measure_regression <- rma(yi = Adjusted_SMD,
                                  sei = SE_Adjusted_SMD,
                                  mods = ~ Outcome_Measure,
                                  data = DepressionFilteredData,
                                  method = "REML",
                                  test = "knha")

# Display results
summary(outcome_measure_regression)

# Create a factor variable with corresponding ITT labels
DepressionFilteredData$ITT <- factor(
  DepressionFilteredData$ITT,
  levels = c(0, 1),
  labels = c("no", "yes"))

# Run meta-regression with the rma() function for intention to treat analysis
ITT_regression <- rma(yi = Adjusted_SMD,
                     sei = SE_Adjusted_SMD,
                     mods = ~ ITT,
                     data = DepressionFilteredData,
                     method = "REML",
                     test = "knha")

# Display results
summary(ITT_regression)

# Create a factor variable with corresponding risk of bias labels

```

```

DepressionFilteredData$RoB <- factor(
  DepressionFilteredData$RoB,
  levels = c(1, 2, 3),
  labels = c("low", "medium", "high"))
# Run meta-regression with the rma() function for risk of bias
RoB_regression <- rma(yi = Adjusted_SMD,
  sei = SE_Adjusted_SMD,
  mods = ~ RoB,
  data = DepressionFilteredData,
  method = "REML",
  test = "knha")
# Display results
summary(RoB_regression)

# Run meta-regression with the rma() function for attrition
# Combine the columns C_Attrition and E_Attrition into a new column Combined_Attrition
DepressionFilteredData$Combined_Attrition <- DepressionFilteredData$C_Attrition +
FilteredData$E_Attrition
# Ensure Combined_Attrition is treated as a factor
DepressionFilteredData$Combined_Attrition <-
as.numeric(DepressionFilteredData$Combined_Attrition)
# Run the meta-regression using Combined_Attrition as a moderator
attrition_regression <- rma(yi = Adjusted_SMD,
  sei = SE_Adjusted_SMD,

```

```

    mods = ~ Combined_Attrition,
    data = DepressionFilteredData,
    method = "REML",
    slab = DepressionFilteredData$Study,
    test = "knha")

# Display results
summary(attrition_regression)

# Run meta-regression with the rma() function for intervention length
# Ensure TotalHours is numeric
DepressionFilteredData$TotalHours <- as.numeric(DepressionFilteredData$TotalHours)
# Run the meta-regression with TotalHours as a moderator
InterventionLength_regression <- rma(yi = Adjusted_SMD,
    sei = SE_Adjusted_SMD,
    mods = ~ TotalHours,
    data = DepressionFilteredData,
    method = "REML",
    slab = DepressionFilteredData$Study,
    test = "knha")

# Display the results
summary(InterventionLength_regression)

```

```

# Run meta-regression with the rma() function for age

# Ensure MeanAge is numeric

DepressionFilteredData$MeanAge <- as.numeric(DepressionFilteredData$MeanAge)

# Run the meta-regression with MeanAge as a moderator

Age_regression <- rma(yi = Adjusted_SMD,
                     sei = SE_Adjusted_SMD,
                     mods = ~ MeanAge,
                     data = DepressionFilteredData,
                     method = "REML",
                     slab = FilteredData$Study,
                     test = "knha")

# Display the results

summary(Age_regression)

# Create a factor variable with corresponding community labels

DepressionFilteredData$Community <- factor(
  DepressionFilteredData$Community,
  levels = c(0, 1),
  labels = c("no", "yes"))

# Run meta-regression with the rma() function for community

community_regression <- rma(yi = Adjusted_SMD,
                             sei = SE_Adjusted_SMD,
                             mods = ~ Community,
                             data = DepressionFilteredData,

```

```

        method = "REML",
        slab = DepressionFilteredData$Study,
        test = "knha")

# Display the results

summary(community_regression)

# Create a factor variable with corresponding Dementia labels
DepressionFilteredData$Dementia <- factor(
  DepressionFilteredData$Dementia,
  levels = c(0, 1),
  labels = c("no", "yes"))

# Run meta-regression with the rma() function for dementia
dementia_regression <- rma(yi = Adjusted_SMD,
  sei = SE_Adjusted_SMD,
  mods = ~ Dementia,
  data = DepressionFilteredData,
  method = "REML",
  slab = DepressionFilteredData$Study,
  test = "knha")

# Display the results

summary(dementia_regression)

```

```
# Run the meta-regression using Control_Category, Intervention_Type, and MeanAge as
moderators in multiple regression
```

```
relevant_factors_regression <- rma(yi = Adjusted_SMD,
    sei = SE_Adjusted_SMD,
    mods = ~ Control_Category + Intervention_Type + MeanAge,
    data = DepressionFilteredData,
    method = "REML",
    test = "knha")
```

```
# Display results
```

```
summary(relevant_factors_regression)
```

## Appendix 5: Ethics application



Professor Aimee Spector  
UCL Department of Clinical and Health Psychology  
1-19 Torrington Place  
London  
WC1E 7HBN/A

Email: [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)  
[HCRW.approvals@wales.nhs.uk](mailto:HCRW.approvals@wales.nhs.uk)

11 August 2023

Dear Professor Spector

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

**Study title:** Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused Therapy (CFT) to improve depression and anxiety in Dementia

**IRAS project ID:** 327086

**REC reference:** 23/LO/0535

**Sponsor** North East London NHS Foundation Trust

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

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

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

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

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

**What are my notification responsibilities during the study?**

The standard conditions document "[After Ethical Review – guidance for sponsors and investigators](#)", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **327086**. Please quote this on all correspondence.

Yours sincerely,  
Barbara Cuddon

Approvals Specialist

Email: [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)

Copy to: *Miss Fiona Horton*,

## List of Documents

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

Document	Version	Date
Copies of materials calling attention of potential participants to the research [Brief Project Outline V2.0 09.08.23]	V2.0	09 August 2023
Copies of materials calling attention of potential participants to the research [CFT Poster V2.0 09.08.23]	V2.0	09 August 2023
Covering letter on headed paper [Cover_letter_CFT_24.05.23]	V1.0	24 May 2023
GP/consultant information sheets or letters [GP Information Sheet CFT Study V2.0 09.08.23]	V2.0	09 August 2023
IRAS Application Form [IRAS_Form_25052023]		25 May 2023
Letter from funder [Outcome Feedback]		05 April 2022
Letter from funder [Confirmation of Dates]		21 June 2023
Letter from sponsor [Being kind to ourselves NELFT letter of sponsorship and indemnity 24.05.23]	V1.0	24 May 2023
Non-validated questionnaire [Client Service Receipt Inventory V2.0 09.08.23]	V2.0	09 August 2023
Organisation Information Document [Organisation Information Document NonCommercial v2-6 CFT IRAS 327086 V2.0]	V2.0	09 August 2023
Other [Response to Ethics ]	V1.0	09 August 2023
Other [Demographics ]	V1.0	09 August 2023
Other [Collection of Measures Built onto REDCap]	V1.0	09 August 2023
Participant consent form [Professionals Qualitative Consent Form V2.0 09.08.23]	V2.0	09 August 2023
Participant consent form [Carer or Supporter Consent Form CFT Study V2.0 09.08.23]	V2.0	09 August 2023
Participant consent form [Carer or Supporter Qualitative Interview Consent Form V2.0 09.08.23]	V2.0	09 August 2023
Participant consent form [Participant Consent Form CFT Study V2.0 09.08.23]	V2.0	09 August 2023
Participant consent form [Participant Qualitative Consent Form V2.0 09.08.23]	V2.0	09 August 2023
Participant information sheet (PIS) [Participant Information Sheet CFT Study V2_09.08.23]	V2.0	09 August 2023
Participant information sheet (PIS) [Participant Information Sheet Qualitative Interview V2.0 09.08.23]	V2.0	09 August 2023
Participant information sheet (PIS) [Carer or Supporter Information Sheet for Qualitative Interview V2.0 09.08.23]	V2.0	09 August 2023
Participant information sheet (PIS) [Carer or Supporter Information Sheet CFT Study V2.0 09.08.23]	V2.0	09 August 2023
Participant information sheet (PIS) [Professionals Information Sheet Qualitative Interview V2.0 09.08.23]	V2.0	09 August 2023
Research protocol or project proposal [CFT_Protocol_V2.0_09.08.23]	V2.0	09 August 2023
Schedule of Events or SoECAT [SoECAT CFT Aimee Spector 190523]	V1.0	24 May 2023
Summary CV for Chief Investigator (CI) [CV_Chief_Investigator]	V1.0	24 May 2023
Summary CV for student [Ben Loe CV_CFT]	V1.0	24 May 2023
Summary CV for student [Shoshanna Freedman CV_CFT]	V1.0	24 May 2023
Summary CV for supervisor (student research) [Josh Stott CV]	V1.0	24 May 2023

Summary CV for supervisor (student research) [Aimee Spector medium CV]	V1.0	24 May 2023
Validated questionnaire [HADS_for_screening]	V1.0	24 May 2023
Validated questionnaire [Cornell Scale for Depression in Dementia]	V1.0	24 May 2023
Validated questionnaire [ Rating Anxiety in Dementia]	V1.0	24 May 2023
Validated questionnaire [Quality of Caregiver patient relationship PWD]	V1.0	24 May 2023
Validated questionnaire [Quality of the Caregiver patient relationship_carer]	V1.0	24 May 2023
Validated questionnaire [ Clinical Dementia Rating]	V1.0	24 May 2023
Validated questionnaire [Self-Compassion_ Scale]	V1.0	24 May 2023
Validated questionnaire [EQ_5D_5L]	V1.0	24 May 2023
Validated questionnaire [MOCA-Test]	V1.0	24 May 2023
Validated questionnaire [demqol-questionnaire]	V1.0	24 May 2023
Validated questionnaire [Zarit-Caregiver-Burden-Assessment]	V1.0	24 May 2023

IRAS project ID	327086
-----------------	--------

### Information to support study set up

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

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other agreement to be used with participating NHS organisations of this type.	Study funding arrangements are detailed in the Organisation Information Document.	A Principal Investigator should be appointed at participating NHS organisations.	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance. These should confirm standard DBS checks.

### Other information to aid study set-up and delivery

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

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

## Appendix 6: Summary of intervention phases

Phase	Topic	Content
Phase 1 (sessions 1-4)	Setting up: Introducing compassion focused therapy and engagement	<ul style="list-style-type: none"> <li>- Psychoeducation</li> <li>- Experiencing/developing mindful awareness</li> <li>- Collaborative formulation and goal setting</li> <li>- Developing self-soothing (soothing rhythm breathing)</li> <li>- Starting to experience compassion (flow)</li> </ul>
Phase 2 (sessions 5-8)	Developing compassion for the self	<ul style="list-style-type: none"> <li>- Choice of content/practices:</li> <li>- Loving-kindness for the self</li> <li>- Fears and blocks to compassion</li> <li>- Imagery: safe-place, compassionate self</li> <li>- Compassion in everyday life</li> <li>- Compassionate letter/postcard</li> <li>- Choice of content/practices:</li> </ul>
Phase 3 (sessions 9-12)	Managing difficult feelings  Consolidating and ending	<ul style="list-style-type: none"> <li>- Threat-based emotions</li> <li>- Soften, soothe, allow</li> <li>- Returning to key concepts/reflection on practices</li> <li>- Reviewing the therapy and compassionate future</li> </ul>

## Appendix 7: Caregiver information sheet for qualitative interview

### INFORMATION SHEET FOR CARER/ SUPPORTER – QUALITATIVE INTERVIEW

**Study Title: Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused Therapy (CFT) to improve depression and anxiety in Dementia.**

#### Introduction

We are grateful that you have chosen to take part in our feasibility study investigating the use of group Compassion Focused Therapy to enhance mood in dementia. To help us plan a future study we would like your opinion on how you found the research process and your experience of helping the person you support to take part in the study.

#### What will happen if I agree to the interview?

If you agree, you will be invited to take part in an interview which will take about 30-60 minutes and can take place face to face, over video call or on the telephone. We will audiotape and transcribe the interview. The information you provide will help us determine if running a large study evaluating the effects of group Compassion Focused Therapy is feasible.

#### What will I have to do?

You will be asked to sign a consent form to take part in the interview then attend the interview when requested.

#### What are the possible advantages and disadvantages of taking part?

There are no direct advantages for you in taking part, although you may enjoy the experience of talking about the impact of the Compassion Focused Therapy groups. By taking part, you will help to potentially shape an intervention, which will then be used as part of a trial and could be of benefit for future patients. It is very unlikely that any harm should come to you in this study.

#### How will we use information about you?

We will need to use information from you for this research project. This information will include your name, ethnicity, gender and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. At the end of the trial, all essential documentation will be archived securely by the study Sponsor for a minimum of 5 years from the declaration of end of trial.

#### **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

#### **Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- At [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- Our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- By asking one of the research team ([melissa.melville@nelft.nhs.uk](mailto:melissa.melville@nelft.nhs.uk)), 07745737574
- You can request further information from Dr. Lindsay Royan, the Principal Investigator at NELFT ([Lindsay.royan@nelft.nhs.uk](mailto:Lindsay.royan@nelft.nhs.uk)), 07958699871
- By sending an email to NELFT Data Protection Officer, Robert Paley, [Robert.Paley@nelft.nhs.uk](mailto:Robert.Paley@nelft.nhs.uk).
- By ringing us on 0300 300 1748.

#### **What will happen to the results of the research?**

The study will be registered on a public web-based database where the study design and results can be viewed. The results of the trial will also be published in a scientific journal and presented at conferences, but you will not be identified. Any quotations used from the interview will be anonymised in the final report or any publications. Once the study has ended, you and your carer / supporter can meet with a researcher to find out about the results; a written summary of the findings can also be requested.

**Thanks for considering taking part in an interview with us.**

## Appendix 8: NHS staff information sheet for qualitative interview

### INFORMATION SHEET FOR PROFESSIONALS– QUALITATIVE INTERVIEW

**Study Title: Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused Therapy (CFT) to improve depression and anxiety in Dementia.**

#### **Introduction**

We are grateful for your professional contribution to our feasibility study investigating the use of group Compassion Focused Therapy to enhance mood in dementia. To help us plan a future study we would like to hear your professional opinion on your experience of being part of this feasibility study.

#### **What will happen if I agree to the interview?**

If you agree, you will be invited to take part in an interview which will take about 30-60 minutes and can take place face to face, over video call or on the telephone. We will audiotape and transcribe the interview. The information you provide will help us determine if running a large study evaluating the effects of group Compassion Focused Therapy is feasible.

#### **What will I have to do?**

You will be asked to sign a consent form to take part in the interview then attend the interview when requested.

#### **What are the possible advantages and disadvantages of taking part?**

There are no direct advantages for you in taking part, although you may enjoy the experience of talking about your experience of contributing to this study. By taking part, you will help to potentially shape an intervention, which will then be used as part of a trial and could be of benefit for future patients. It is very unlikely that any harm should come to you in this study.

#### **How will we use information about you?**

We will need to use information from you for this research project. This information will include your name, ethnicity, gender and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

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Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. At the end of the trial, all essential documentation will be archived securely by the study Sponsor for a minimum of 5 years from the declaration of end of trial.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- At [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- Our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- By asking one of the research team, [melissa.melville@nelft.nhs.uk](mailto:melissa.melville@nelft.nhs.uk), 07745737574
- By sending an email to NELFT Data Protection Officer, Robert Paley, [Robert.Paley@nelft.nhs.uk](mailto:Robert.Paley@nelft.nhs.uk).
- By ringing us on 0300 300 1748.
- By contacting Dr. Lindsay Royan, the Principal Investigator at NELFT ([Lindsay.royan@nelft.nhs.uk](mailto:Lindsay.royan@nelft.nhs.uk)), 07958699871

**What will happen to the results of the research?**

The study will be registered on a public web-based database where the study design and results can be viewed. The results of the trial will also be published in a scientific journal and presented at conferences, but you will not be identified. Once the study has ended, you can meet with a researcher to find out about the results, a written summary of the findings can also be requested.

**Thanks for considering taking part in an interview with us.**

## Appendix 9: Example consent form

### CONSENT FORM FOR CARER / SUPPORTER (QUALITATIVE INTERVIEW)

**Study Title:** Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused Therapy (CFT) to improve depression and anxiety in Dementia.

**Centre Number:**

**Please Initial Boxes:  
(researcher initials if verbal consent)**

I have been asked to participate in an interview about my experience of the Compassion Focused Therapy research study. I have had the opportunity to ask questions about the study and have read the information sheet [date 04.10.2023, version 3.0) and understand what is involved.	
I understand that the session will be audio recorded for the purpose of research.	
I understand that I can request to withdrawn from the study at any time, without giving any reason.	
I understand that any quotations used from the recording will be anonymised to ensure that I cannot be identified.	
I consent to taking part in the interview section of this research study.	

\_\_\_\_\_  
**Name of participant  
(carer / supporter)**

\_\_\_\_\_  
**Date  
(DD/MMM/YYYY)**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Signature of researcher  
(verbal consent)**

\_\_\_\_\_  
**Name of researcher**

\_\_\_\_\_  
**Date  
(DD/MMM/YYYY)**

\_\_\_\_\_  
**Signature of researcher**

1 copy for participant, 1 stored in research file, 1 stored in medical records.

## Appendix 10: Interview schedule for caregivers in the intervention group

<p style="text-align: center;"><b>CFT for mood in dementia feasibility study</b> <b>Interview schedule for carers/supporters (treatment)</b></p>
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Please follow this guide flexibly. The questions do not need to be asked in the exact order they are written below – the interviewer should respond to the interviewee and be guided by them. The questions in bold are the questions we will aim to ask. The bullet points that are below each question in italics are prompts. The prompts are not essential and do not need to be asked - they are here to steer the interviewer if helpful.

For this interview, we give carers/supporters the choice to answer questions about their perspective only, the perspective of the PWLD they support only, or both. We have included questions covering all options but please for their preference in the introduction and only ask questions/prompts in line with their preference.

### Introduction:

Hi [*insert name*] many thanks for taking the time to help with this interview today. Just to introduce myself [*insert name and role*].

This interview is being carried out to gather information about the experiences and opinions of participants in the CFT for mood in dementia project. We can ask you questions about your experiences as a carer/supporter, your perspective on the experiences of the person you support or both – do you have a preference? [proceed in line with interviewee preference].

If at any time you want to stop the interview, have a break, or if you don't want to answer a question please let me know. There are no right or wrong answers to our questions – we are keen to hear about your views and experience, both positive and negative.

Can I ask you to confirm that you are happy to continue?

### [Background]

**1. I'm going to start by asking some demographic questions if that's OK with you? We're aware these questions can be sensitive and you do not need to answer questions you don't feel comfortable answering:**

- **What is your age?**
- **What was your registered sex at birth?**
- **What is your ethnic group? Could you choose one option that you feel best describes your ethnic background from this list? [researcher shows list of categories at end of interview guide]\***

**2. Just to start, could you tell me a bit about your role as a [carer/supportive other, supporter, carer]?**

- **What's your relationship to the person living with dementia who you are involved in this project with?**
- *How long have you supported someone living with dementia?*

- *In what ways do you support them? What type of caring duties do you have?*

### **[Acceptability and feasibility: trial procedures]**

#### **[Recruitment]**

**3. Could you tell me a bit about how you and the person you support heard about this project?**

- *Who first discussed the study with you both?*
  - *What did you think about this discussion?*
  - *What did the person you support think about this discussion?*

**4A. What were your first impressions of the study when you were contacted about it?**

- *What made you interested in joining the study?*
- *Was there anything that was off-putting or made you hesitate about joining the study?*
- *Were you aware it was possible that the person you support might be allocated to a group receiving CFT and that they might be allocated to a group not receiving the CFT sessions?*
  - *What were your thoughts on this?*

**4B. What were the first impressions of the person you support when they were contacted about it?**

- *Repeat prompts from above*

#### **[Baseline and follow-up assessments]**

*You may remember at the start of the project that the person you support met with a researcher to answer a range of questions and that you may have also met with a researcher to answer some questions about your relationship with the person you support and the impact this relationship has on you.*

**5A. If you met with a researcher to answer some questions yourself, could you tell me a bit about your experience of these meetings?**

- *How comfortable did you feel in these meetings?*
  - *Were there any questions or sets of questions that you did not feel comfortable answering?*
- *Did you feel you were able to answer the questions accurately?*
- *How did you find the length of the meeting?*
- *Did you attend this meeting virtually or face to face?*
  - *Did this affect your experience?*

**5B. Could you tell me a bit about what the experience of participating in these assessments (the baseline and follow-up assessments) was like for the person you support?**

- *How comfortable do you think they felt in these meetings?*
  - *Were there any questions or sets of questions that they did not feel comfortable answering?*
- *Do you think they were able to answer the questions accurately?*
- *How did they find the length of the meeting?*

- *Did they attend this meeting virtually or face to face?*
  - *Did this affect their experience?*

### **[Acceptability and feasibility: workshop]**

*I'm now going to ask you some questions about the carers'/supporters' workshop*

#### **6. Did you attend the carers'/supporters' workshop?**

##### **6A) If didn't attend the workshop:**

- *What were your first impressions when you heard about the workshop?*
  - *Did attending appeal to you?*
- *Did you feel you understood what the workshop would entail?*
- *What got in the way of attending?*
  - *Motivation/appeal?*
  - *Practical difficulties e.g. available time, when workshops were scheduled?*

##### **6B) If did attend the workshop**

- **How did attending the workshop [insert online or face to face] affect your experience of the workshop?**
  - *Do you think there were any difficulties related to attending [insert online or face to face]*
    - *E.g. online: technology difficulties, connection with other participants?*
    - *E.g. face to face: was the setting suitable?*
- **What did you think about the content of the workshop? (Just a reminder, the workshop introduced the principles of CFT; gave a brief outline of what would be covered in the group sessions; and gave tips for what you could do at home to encourage and support the person you support who is attending the CFT sessions)**
  - *Was there anything you particularly liked or disliked?*
  - *Was it easy/hard to understand?*
  - *Did it feel appropriate to you?*
- **What did you think of the length of the workshop?**
- **Did the workshop lead to any changes for you?**
  - *If yes*
    - *What were these changes?*
    - *What led you to make these changes?*
    - *Were some changes easier to make than others?*
  - *If not*
    - *why not?*
    - *Did anything get in the way?*

### **[Acceptability and feasibility: CFT group sessions]**

*If it's OK with you, I'll now ask you some questions about the group CFT sessions (nb structure is questions about content, dose, virtual versus face to face, group)*

## **7. Did the person you support attend these sessions in person or virtually?**

**7i. If attended in person: A) What was this experience like for you as a carer/supporter? B) What was this experience like for the person you support?**

- *Was this your preference?*
  - *If so, why?*
  
- *Was this the preference of the person you support?*
  - *If so, why?*
  
- *Was the person you support able to travel to and from the sessions OK?*
  - *Able to secure transport?*
  - *Able to afford transport*
  - *Able to set aside the time?*
  - *Any help needed e.g. did you accompany them to the sessions or drop them off?*
  
- *What were your thoughts about the space where the sessions were held?*
  - *Did you see the space?*
  - *Based on what was shared with you by the person you support and what you may have seen, did you feel it was fit for purpose?*
    - *Did it meet the needs of the person you support?*
    - *Do you think the person you support felt comfortable in this space?*
    - *Do you think they were able to engage with the CFT activities in this space?*

**7ii: If attended virtually? a) What was this experience like for you as a carer/supporter? b) What was this experience like for the person you support?**

- *Was this your preference?*
  - *If so, why?*
  
- *Was this the preference of the person you support?*
  - *If so, why?*
  
- *Was the person you support able to access and participate in the sessions virtually?*
  - *Did they have appropriate resources, such as a computer, tablet or smartphone?*
  - *Did they have access to an internet connection?*
  - *Did they have an appropriate (private) space at home to access the sessions?*
  - *Did they have the digital skills to log on and participate?*
    - *Did you or anyone else need to help them?*
  
- *Do you think it was appropriate to deliver the CFT sessions virtually?*
  - *Did you think the person you were caring for felt comfortable engaging virtually?*

*Do you think the activities were suited to being delivered virtually (based on what was shared with you about these)?*

**8A. What are your thoughts about CFT being delivered in a group (as opposed to one on one)?**

**8B. What are your thoughts of the person you support about CFT being delivered in a group (as opposed to one to one)?**

**9A. The CFT sessions took place weekly over a period of twelve weeks. What did you think about the number of sessions?**

- *Did you think it was the right amount?*
- *Did the person you are caring for attend the whole twelve weeks?*
  - *Did anything get in the way?*

**9B. What did the person you support think about the number of sessions?**

- *Repeat prompts*

**10A. What did you think about the sessions being weekly?**

**10B. What did the person you support think about the sessions being weekly?**

**11A. Each session was one hour. What did you think about the length of the sessions?**

**11B. Each session was one hour. What did you think about the length of the sessions?**

**12A. Based on what has been shared with you, what do you think about the kinds of topics and activities that were covered in the Compassion Focused Therapy sessions?**

- *Was there anything you particularly liked? (such as a particular set of sessions, particular session, concepts or techniques)*
- *Anything you disliked? (such as a particular set of sessions, particular session or technique)*
- *Do you think the topics and activities seemed relevant to the person you support?*
- *Do you think the person you support was able to engage?*

**12B. What did the person you support think about the kinds of topics and activities that were covered in the Compassion Focused Therapy sessions?**

- *Repeat prompts*

**13A. At the end of each session, the facilitators suggested a task for participants to practise at home, what were your thoughts on the home practice tasks?**

- *How did the person you support manage with practising these tasks at home?*
  - *Did you help the person you were caring for practise these tasks at home?*
  - *Were some tasks easier or harder than others to provide support with?*

**14B. At the end of each session, the facilitators suggested a task for participants to practise at home, what were the thoughts of the person you support regarding these tasks?**

- *Do you think the person you support understood what they were being asked to do?*
- *Do you think that they found some tasks easier than others*

## **[Perceived impact of the intervention and potential mechanisms of change]**

**15A. Do you think any changes, positive or negative, have come about as a result of the CFT sessions?**

- *Do you think changes have come about in your life as a result of the CFT sessions?*
  - *Has your mood changed?*
  - *Has your life been made any easier?*
  - *Have aspects of your life been made harder?*

**15B. Have you noticed any changes that have come about in the life of the person you support as a result of the CFT sessions?**

- *E.g. changes in their mood, such as feeling low or anxious?*
  - *Changes in their behaviour?*
  - *Changes in how they feel about themselves and how they treat themselves?*
    - *How do they feel about their symptoms?*
    - *How do they respond to their symptoms?*
  - *Changes in how the person you support interacts with others?*
- 
- *How does this compare to the impact of the support they were receiving already?*
    - *Does CFT provide anything different?*

**16. Have you noticed any changes in your relationship with the person you support?**

- *Changes in how they respond to you?*
- *Changes in how you respond to them?*

**17. If you have noticed any changes that have come about as a result of CFT, what do you think has led to these changes?**

- *E.g. any particular techniques that were covered in the CFT sessions or the CFT workshop?*

**17A. Is there anything you were hoping that would change that hasn't?**

**17B. Is there anything the person you support was hoping that would change that hasn't?**

**18. If you have noticed any benefits come about as a result of the CFT sessions, do you think these will be sustained long-term?**

**18A. Overall, do you think this experience could be improved in any way?**

- *Could it be made more dementia-friendly?*

**18B. Do you think the person you support thinks this experience could be improved in any way?**

**To end:** I have asked you all the questions I wanted to ask you, is there anything you would like to say or any other issue I haven't mentioned that you would like to discuss?

**Thank you very much for your help.**

## Appendix 11: Interview schedule for caregivers in the control group

### CFT for mood in dementia feasibility study Interview schedule for carers/supporters (control)

Please follow this guide flexibly. The questions do not need to be asked in the exact order they are written below – the interviewer should respond to the interviewee and be guided by them. The questions in bold are the questions we will aim to ask. The bullet points that are below each question in italics are prompts. The prompts are not essential and do not need to be asked - they are here to steer the interviewer if helpful.

For this interview, we give carers/supporters to answer questions about their perspective only, the perspective of the PWLD they support only, or both. We have included questions covering all options but please for their preference in the introduction and only ask questions/prompts in line with their preference.

#### Introduction:

Hi [*insert name*] many thanks for taking the time to help with this interview today. Just to introduce myself [*insert name and role*].

This interview is being carried out to gather information about the experiences and opinions of participants in the CFT for mood in dementia project. We can ask you questions about your experiences as a carer/supporter, your perspective on the experiences of the person you support or both – do you have a preference? [proceed in line with interviewee preference].

If at any time you want to stop the interview, have a break, or if you don't want to answer a question please let me know. There are no right or wrong answers to our questions – we are keen to hear about your views and experience, both positive and negative.

Can I ask you to confirm that you are happy to continue?

#### [Background]

**1. I'm going to start by asking some demographic questions if that's OK with you? We're aware these questions can be sensitive and you do not need to answer questions you don't feel comfortable answering:**

- **What is your age?**
- **What was your registered sex at birth?**
- **What is your ethnic group? Could you choose one option that you feel best describes your ethnic background from this list? [researcher shows list of categories at end of interview guide]\***

**2. Just to start, could you tell me a bit about your role as a [carer/supportive other, supporter, carer]?**

- **What's your relationship to the person living with dementia who you are involved in this project with?**
- *How long have you supported someone living with dementia?*
- *In what ways do you support them? What type of caring duties do you have?*

#### [Acceptability and feasibility: trial procedures]

#### [Recruitment]

**3. Could you tell me a bit about how you and the person you support heard about this project?**

- *Who first discussed the study with you both?*
  - *What did you think about this discussion?*
  - *What did the person you support think about this discussion?*

**4A. What were your first impressions of the study when you were contacted about it?**

- *What made you interested in joining the study?*
- *Was there anything that was off-putting or made you hesitate about joining the study?*

**4B. What were the first impressions of the person you support when they were contacted about it?**

- *Repeat prompts from above*

**5A. What were your thoughts when you learnt that you might be allocated to the intervention group where the person you support would attend Compassion Focused Therapy sessions and you would attend a carer/supporter's workshop and that you might be allocated to a control group not receiving the intervention?**

- *How did you feel about this?*
  - *Did this affect your desire to take part?*

**5B. What were the thoughts of the person you support when they learnt that you might be allocated to the intervention group where they would attend Compassion Focused Therapy sessions and you would attend a carer/supporters' workshop and that you might be allocated to a control group not receiving the intervention?**

- *Repeat prompts*

**6A. How did you respond when you were learnt that you were allocated to the group who would not be receiving the Compassion Focused Therapy sessions and the carers/supporters' workshop?**

- *How did you feel about this?*
- *What are your thoughts on how this was communicated to you?*
  - *Could this have been explained more clearly?*
  - *Could this have been explained more sensitively?*

**6B. How did the person you support respond when they were learnt that you were allocated to the group who would not be receiving the Compassion Focused Therapy sessions and the carers/supporters' workshop?**

- *Repeat prompts*

**[Baseline and follow-up assessments]**

*You may remember at the start of the project that the person you support met with a researcher to answer a range of questions and that you may have also met with a researcher to answer some questions about your relationship with the person you support and the impact this relationship has on you.*

**7A. If you met with a researcher to ask some questions yourself, could you tell me a bit about your experience of these meetings?**

- *How comfortable did you feel in these meetings?*
  - *Were there any questions or sets of questions that you did not feel comfortable answering?*

- *Did you feel you were able to answer the questions accurately?*
- *How did you find the length of the meeting?*
- *Did you attend this meeting virtually or face to face?*
  - *Did this affect your experience?*

**7B. Could you tell me a bit about what the experience of participating in these assessments (the baseline and follow-up assessments) was like for the person you support?**

- *Repeat prompts from above*
- *How comfortable do you think they felt in these meetings?*
  - *Were there any questions or sets of questions that they did not feel comfortable answering?*
- *Do you think they were able to answer the questions accurately?*
- *How did they find the length of the meeting?*
- *Did they attend this meeting virtually or face to face?*
  - *Did this affect their experience?*
- 

**[Acceptability of and perceived impact of Treatment as Usual (TAU)]**

*We're interested in hearing more generally about your experience of being in the control group and a bit more about how the person you support manages living with dementia and with anxiety and depression – for example, if they receive any formal support from services.*

**8A. How have you found being in the control group and not receiving the Compassion Focused Therapy sessions?**

- *Is this something you have thought about the last few weeks?*
- *Do you think it has affected you in any way?*

**8B. How has the person you support found being in the control group and not receiving the Compassion Focused Therapy sessions?**

- *Repeat prompts*

**9A. Do you think you would be willing to take part in this type of project again?**

- *If yes, why?*
- *If no, why not?*

**9B. Do you think the person you support would be willing to take part in this type of project again?**

- *Repeat prompts*

**10. Do you access or receive any support to help you in your caring/supporting role?**

- *Formal support from services?*

- *Informal support from friends and family?*

**11. Does the person you support access any other support to help them manage living with dementia (other than the support they receive from you?)**

- *Do they receive any formal support from services?*
  - *Are they prescribed medication?*
  - *Do they receive regular support from professionals?*
    - *Social care professionals?*
    - *Health care professionals?*
  - *Do they attend any day groups?*
- *What about informal support from other sources, such as support from friends or family?*

**12. Does the person you support access or receive any support to help them manage or cope with their symptoms of anxiety or low mood?**

- *Do they receive any formal support from services?*
  - *Are they prescribed medication?*
  - *Do they receive regular support from professionals?*
    - *Social care professionals?*
    - *Health care professionals?*
  - *Do they attend any day groups?*
- *What about informal support, such as support from friends or family?*

**13. How do you feel about the current support that is on offer to you to help you as a carer/supporter of someone living with dementia who has anxiety and depression?**

- *Do you think it meets your needs?*
- *Is there anything you feel that is missing from what is on offer at the moment?*
- *Is there anything that gets in the way of you accessing support?*

**14A. How do you feel about the current support that is available to the person you support to help them manage living dementia and to help them manage their mood?**

- *Do you think it meets their needs?*
- *Is there anything you feel that is missing from what is on offer at the moment?*
- *Is there anything that gets in the way of them accessing support?*

**14B. How do you think the person you support feels about the current support that is on offer to them?**

- *Repeat prompts*

**To end:** I have asked you all the questions I wanted to ask you, is there anything you would like to say or any other issue I haven't mentioned that you would like to discuss?

**Thank you very much for your help.**

## Appendix 12: Interview schedule for CFT group facilitators

<p style="text-align: center;"><b>CFT for mood in dementia feasibility study</b> <b>Interview schedule for CFT facilitators</b></p>
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Please follow this guide flexibly. The questions do not need to be asked in the exact order they are written below – the interviewer should respond to the interviewee and be guided by them. The questions in bold are the questions we will aim to ask. The bullet points that are below each question in italics are prompts. The prompts are not essential and do not need to be asked - they are here to steer the interviewer if helpful.

### **Introduction:**

Hi [*insert name*] many thanks for taking the time to help with this interview today. Just to introduce myself [*insert name and role*].

As a reminder, this interview is being carried out to gather information about the experiences and opinions of the CFT facilitators in the Compassion Focused Therapy for mood in dementia project. There are no right or wrong answers in this interview and we're here to hear about your experience and your views, both positive and negative.

If at any time you want to stop the interview, have a break, or if you don't want to answer a question please let me know.

Can I ask you to confirm that you are happy to continue?

### **[Background]**

**1. I'm going to start by asking some demographic questions if that's OK with you? We're aware these questions can be sensitive and you do not need to answer questions you don't feel comfortable answering:**

- **What is your job title?**
- **How long have you worked as a [*insert job title*]?**
- **How long have you worked in this service?**
- **What is your age?**
- **What was your registered sex at birth?**
- **What is your ethnic group? Could you choose one option that you feel best describes your ethnic background from this list? [*researcher shows list of categories at end of interview guide*]\***

**2. Could you tell me a bit about what your job involves normally i.e. separate from facilitating the CFT sessions?**

- *What is your job title?*
- *In an average day or week, what does your role entail?*

**3. What was your role in facilitating the CFT sessions?**

- *Did you deliver the CFT intervention itself?*

- *Were you in a supportive role? (i.e. did you provide technical support to the facilitator and technical and emotional support to participants?)*

### **[Acceptability and feasibility: pre-intervention]**

#### **[Initial involvement/impressions]**

#### **4. Could you tell me a bit about how you first heard about this project?**

- *What were your first impressions when you heard about the idea of trialling group CFT in your service?*
  - *Did the idea appeal to you?*
    - *If yes, why?*
    - *If not, why?*
  - *Did you think it was feasible?*
    - *Did any barriers spring to mind?*
- *How was the idea of trialling group CFT received in your service more generally?*
  - *Did the idea appeal to the service as a whole/your colleagues?*
  - *Were there any barriers? (motivational, practical)*

#### **5. How did you end up becoming involved as a facilitator?**

- *What, if anything, appealed to you about becoming involved?*
- *Were there any barriers to you becoming a facilitator?*
  - *Anything that you found off-putting or made you hesitate?*
  - *Any practical barriers (e.g. how it fit in with your existing role and workload, space to host the sessions if f2f, time to attending training)*

#### **[Training in CFT delivery]**

(nb this might not be relevant to facilitators who were in a supportive role/not delivering CFT)

#### **6. Did you have any experience or understanding of CFT before you became involved in this project?**

- *Did you have any understanding or knowledge of the key concepts?*
- *Before this training, had you received any prior training on CFT?*

#### **7. Did you attend the two-day CFT training with balanced minds?**

##### **7A. If attended the CFT training:**

##### **What were your initial thoughts on attending this training?**

- *Did the idea of attending this training appeal to you?*
  - *If yes, what appealed to you about attending this training? (i.e. incentive of paid training)*
- *Were there any barriers that got in the way or made it hard for you to attend this training?*
  - *E.g. time?*

##### **How did you find the training itself?**

- *Do you feel you gained any new knowledge or skills?*
- *Did your understanding of CFT change following the sessions?*
  - *For example, did your view of its potential value/benefits of the group sessions change?*
- *Did it prepare you adequately to deliver the CFT sessions?*
- *Are there any ways in which you think the training could be improved?*

**8. Did you receive regular clinical supervision while you were delivering the intervention?**

- *If yes, what are your thoughts on this experience?*

**[Acceptability and feasibility: intervention implementation and delivery]**

*If it's OK with you, I'll now ask you some questions about your experience of delivering the group CFT sessions (nb structure is questions about content, dose, virtual versus face to face, group)*

**[Materials - manual and adherence checklist and resources]**

**9. Starting with a broad question, how did you find using the CFT manual to deliver the sessions?**

- *How beneficial was it having a manual to follow?*
- *Was there anything you disliked about having a manual to follow?*

**10. How closely did you stick to the manual when delivering your sessions?**

- *Did you deviate from the manual at all?*
  - *If yes, why?*
  - *Did anything get in the way of sticking to the manual?*
    - *Personal preference?*
    - *Availability of resources?*
    - *Limitations of physical space?*
    - *Limitations of virtual?*
    - *Limitations of your skill-set?*
    - *Anything to do with the participants?*
- *Did you make any adaptations to the manual?*
  - *If so, what were they?*
  - *What were your reasons for making these adaptations?*

**11. Do you have any feedback on the equipment and resources you used to deliver the sessions?**

- *Were the recommended equipment and resources sufficient to deliver the sessions?*
- *Was it possible to source these?*
- *Do you think additional or alternative resources were necessary?*

## 12. What was your experience of using the adherence checklist?

- *Did you complete it after each phase?*
- *Did anything get in the way of completing it?*
- *Did it have an impact on how you delivered the sessions?*

### [Content of the sessions]

## 13. Overall, what were your thoughts on the content of the CFT sessions? By this, I mean the concepts, activities and techniques that you covered?

- *Did the content of the sessions feel appropriate to you?*
  - *Was there anything you particularly liked or disliked?*
- *Did the sessions feel feasible to deliver?*
  - *Did anything get in the way?*
    - *Confidence in your own skills?*
    - *Practical limitations?*
    - *Participant-specific barriers?*
- *Do you feel that participants were able to engage in the CFT sessions?*
  - *For example, did you feel they were able to understand the ideas that were covered?*
  - *Were participants able to complete the tasks set in the session (e.g. goal-setting) or practise the techniques (e.g. techniques for self-compassion)*
    - *If not, what got in the way?*

*Each session had a CFT practice, such as practising slowing and deepening the breath. How did you find these practices at the start of the session?*

- *Did you feel able to lead/assist with these practices?*
  - *If not, what got in the way?*
- *Do you think participants were able to engage?*
  - *If not, what got in the way?*

*At the end of each session, there were suggested tasks for you to set the participants to practise at home, what were your thoughts on the home practice tasks?*

- *Did you always ask participants to practise tasks at home?*
- *Did you feel able to explain and set these tasks at the end of the session?*
- *Based on what you observed, do you think participants engaged with the home practice tasks?*

### [Dose]

## 14. The CFT sessions took place weekly over a period of twelve weeks. What did you think about the number of sessions?

- *Do you think delivering sessions regularly over this length of time works within the context of your service?*

**15. Each session was one hour. What did you think about the length of the sessions?**

**[Medium]**

**16. Did you deliver these sessions in person or virtually?**

**16A. If delivered face to face:**

- *Do you think this was an appropriate way to deliver CFT?*
  - *If yes, why?*
  - *If not, why not?*
- *Were participants able to travel to the sessions OK?*
  - *Able to secure transport?*
  - *Able to afford transport*
  - *Able to set aside the time?*
  - *Any help needed from e.g. friend or family member to travel to sessions?*
- *What were your thoughts about the space where you hosted the sessions?*
  - *Did you feel it was fit for purpose?*
    - *Were you able to deliver the sessions as you intended in this space?*
- *How easy was it to secure a space to host the sessions?*
  - *Did hosting the sessions in this space have an impact or affect on any parts of your service?*

**16B: If delivered virtually:**

- *Do you think this was an appropriate way to deliver CFT?*
  - *If yes, why?*
  - *If not, why not?*
- *Were you able to deliver the sessions as you intended virtually?*
  - *Did you have access to adequate resources?*
  - *Did you feel confident in your digital skills?*
- *Were participants able to access and participate in the sessions virtually?*
  - *Did they have appropriate resources, such as a computer, tablet or smartphone?*
  - *Access to an internet connection?*
  - *Did they have an appropriate (private) space at home to access the sessions?*
  - *Did they have the digital skills to log on and participate?*
    - *Did anyone help you?*

**[Participants/reach and group]**

**17. What are your thoughts about CFT being delivered in a group (as opposed to one on one)?**

- *Did this feel like an appropriate way for CFT to be delivered?*
- *Did you feel like participants were able to engage with the activities in a group setting?*
- *What were your thoughts on the group size?*

**18. Do you think the participants who were enrolled in your group were a good fit for CFT?**

- *What did you think about the inclusion criteria used to recruit for the project i.e. mild to moderate dementia diagnosis?*
- *Do you think this project was able to involve/reach those who would most benefit from participating in CFT?*
  - *If not, why not?*

**[Perceived impact of the intervention and potential mechanisms of change]**

**19. Do you think any changes, positive or negative, came about as a result of the CFT sessions?**

- *If yes, what were these?*
  - *E.g. changes in their mood, such as feeling low or anxious?*
  - *Changes in their behaviour?*
  - *Changes in how they feel about themselves and how they treat themselves?*
    - *How do they feel about their symptoms?*
    - *How do they respond to their symptoms?*
  - *Changes in how the person you care for interacts with others?*
  - *Changes in the person living with dementia's relationship with their carer?*
- *What would you say was the main benefit of the CFT sessions for participants?*
- *What about any changes in the service?*

**20. Do you think CFT sessions offer any unique benefits that set it apart from the work that you or your colleagues normally deliver?**

**21. Would you consider delivering CFT sessions in your service in the future?**

- *Would you like to deliver these sessions again?*
- *Do you think it would be feasible to set these up in your service as a permanent/regular offering?*

**To end:** I have asked you all the questions I wanted to ask you, is there anything you would like to say or any other issue I haven't mentioned that you would like to discuss?

**Thank you very much for your help.**

## Appendix 13: Interview schedule for senior management clinicians

### CFT for mood in dementia feasibility study Interview schedule for Service Leads

Please follow this guide flexibly. The questions do not need to be asked in the exact order they are written below – the interviewer should respond to the interviewee and be guided by them. The questions in bold are the questions we will aim to ask. The bullet points that are below each question in italics are prompts. The prompts are not essential and do not need to be asked - they are here to steer the interviewer if helpful.

#### Introduction:

Hi [*insert name*] many thanks for taking the time to help with this interview today. Just to introduce myself [*insert name and role*].

As a reminder, this interview is being carried out to gather information about the experiences and opinions of service managers involved in the Compassion Focused Therapy for mood in dementia project. There are no right or wrong answers in this interview and we're here to hear about your experience and your views, both positive and negative.

If at any time you want to stop the interview, have a break, or if you don't want to answer a question please let me know.

Can I ask you to confirm that you are happy to continue?

#### [Background]

**1. I'm going to start by asking some demographic questions if that's OK with you? We're aware these questions can be sensitive and you do not need to answer questions you don't feel comfortable answering:**

- **What is your job title?**
- **How long have you been the service manager for [*insert name of service*]?**
- **What was your registered sex at birth?**
- **What is your age?**
- **What is your ethnic group? Could you choose one option that you feel best describes your ethnic background from this list? [*researcher shows list of categories at end of interview guide*]\***

**2. Could you tell me a bit about what your job as a service manager involves?**

- *In an average day or week, what does your role entail?*

**3. Could you tell me a bit about the service you manage?**

- *Who accesses your service?*
  - *People above a certain age or who have certain needs?*
- *What services do you offer?*
  - *E.g. 1:1 therapy, group therapy, memory services?*
- *What professions work in your service?*

#### [Acceptability and feasibility: initial project set-up]

**[Initial involvement/impressions]**

**4. Could you tell me a bit about how you first heard about this project?**

- *Do you remember a researcher contacting you with information about the project?*

**5. What were your first impressions when you heard that your service would be involved in the CFT for dementia project?**

- *Did the idea appeal to you?*
  - *If yes, why?*
  - *If not, why?*
- *Did you think it was feasible?*
  - *Did any barriers spring to mind?*

**6. How involved were you with the setting up the project at your site?**

- *What roles did you take on, if any?*
  - *Insert examples of roles*
    - *E.g. help with finding therapists?*
    - *E.g. raising awareness through posters?*
    - *E.g. sharing the study with clinicians at your site?*
    - *E.g. aiding recruitment, such as encouraging clinicians to refer participants to the project?*
    - *E.g. arranging for researchers to present the project at your weekly clinical team meetings?*
    - *E.g. helping with practicalities such as finding a room in which the the therapy could be run*

**[If interview participant engaged in any way with the project set-up in their service, ask 7A and 7B]**

**7A. What was your experience of fulfilling [insert] role/carrying out [insert] task?**

- *Did anything get in the way of you doing X task?*
- *Would you want to do X task again?*
  - *If not, why not?*

**7B. What motivated you to help with setting up the project in your service?**

- *Interest in research?*
- *Perceived benefits to your service?*

**8. What, if anything, got in the way of you becoming involved with setting up the project at your site?**

- *Anything about the project that you found off-putting or made you hesitate?*
- *Anything specific about your service context (e.g. staff capacity)?*
- *Understanding about how to engage?*
- *Understanding about what the project might entail?*
- *Any practical barriers (e.g. time, workload)?*

## **[Perceived impact of the intervention and potential mechanisms of change]**

**9. Overall, how do you think your service has been impacted by being involved in this project?**

- **Impact on you?**
- **Impact on your staff?**
- **Any impact on patients?**

**10. Do you think CFT sessions offer any unique benefits that sets it apart from the work that you or your colleagues normally deliver?**

## **[Future considerations]**

**11. We're hoping to use insights from this project and interviews like this to inform how we carry out future research. Based on your experience being involved in this project, do you have recommendations for our work with service managers in future projects?**

- **Is there anything we could do differently to increase engagement amongst service managers?**
  - *In the project set-up?*
  - *At the intervention stage?*

**12. Would you consider offering CFT sessions in your service in the future?**

- *Do you think it would be feasible to set these up in your service as a permanent/regular offering?*
  - *If no, what might get in the way?*

**To end:** I have asked you all the questions I wanted to ask you, is there anything you would like to say or any other issue I haven't mentioned that you would like to discuss?

**Thank you very much for your help.**

## Appendix 14: Coding tree

Code name*	Number of participants	Number of times
<b>Intervention Processes</b>		
<u><i>Benefits and Challenges of Group Format</i></u>	17	59
Interpersonal difficulties	6	10
Group vs individual	7	9
Benefit of group	4	4
Challenge of group	3	3
Social comparison	1	1
Demonstrating skills	2	3
Facilitator dynamics	3	4
Opening up	4	5
Peer support	10	13
Sharing and being open	4	5
Emotional vulnerability	2	3
Self-consciousness	1	1
Safe space	2	3
Socialising	3	6
Continued connection	1	1
Engaging with others	2	2
<u><i>Intervention Delivery</i></u>	17	112
Online benefits	2	2
Online negatives	10	13
CFT complications	4	5
Negatives of long practices	2	2
Homework challenges	1	2
CFT exercise positives	9	15
CFT exercise negatives	2	2
CFT benefits	6	8
CFT challenges	1	1
Discussion and reflection	3	5
Pacing	1	1
Repetition	4	4
Facilitator/ researcher assistance	4	6
Adapting delivery	6	9
Frequency	3	3
Session timings	6	7
Assessment logistics	1	1
Technical difficulties	2	2
Timings	6	8
Spaces	3	3
Date effects	1	1

Transport	5	6
Location	1	1
More time	4	5
Intervention length	9	9
<b><u>Knowledge and Understanding</u></b>	11	39
Difficulty consolidating ideas	2	2
Gatekeeping	1	1
Cognitive engagement	4	4
Recall and retention	1	1
Space orientation	1	1
Comprehension	1	1
Benefit of short practices	1	1
Increased understanding of compassion	4	4
Increased understanding of dementia	5	8
No change in understanding	3	3
Implementation	4	5
Limited implementation	1	1
Supervision outcome	1	1
Workshop learning	5	5
Workshop suggestions	1	1
<b><u>Psychological Impact</u></b>	15	61
Small changes	6	6
Improvement in mood	9	14
No change in mood	1	1
Negative impact on mood	1	1
Anxiety improvements	3	3
No change in anxiety	1	2
No change in frustration	2	3
Improvements in frustration	2	2
Increased compassion	8	11
Increased acceptance	2	5
Reclaiming life	6	10
Increased self-care	3	3
<b><u>Systemic Integration</u></b>	11	37
Caregiver involvement	3	3
Awareness of processes	11	11
Clarity	6	6
Sharing learning with caregiver	4	6
Reminders	2	2
Relational outcomes	8	9
<b>Trial Processes</b>		
<b><u>Trial Framework</u></b>	17	58

Unsuitable inclusion	6	7
Assessment experience	7	9
Trial structure	3	4
Initial interest	1	2
Adapting resources	9	12
Adapting setup	2	2
Trial structure	6	8
CFT training issues	1	2
Supervision frequency	2	2
CFT training positives	4	10
<u><i>Cognitive Difficulties</i></u>	10	14
Trial understanding	3	3
Assessment difficulties	4	7
Cognitive engagement	4	4
<u><i>Psychological Influences and Outcomes</i></u>	17	59
Drive for involvement	2	2
Model buy-in	3	4
Previous experience	7	9
Trial interest	11	15
Learning opportunities	4	4
Scepticism	5	6
Trial disengagement	1	1
Service benefit	2	2
Team excitement	2	2
Group engagement	5	7
Future groups	4	4
Caregiver burden	3	3
<u><i>Systemic Integration</i></u>	12	58
Other commitments	1	1
Setup assistance	1	1
Research opportunities	7	9
Plug gaps	3	3
Professional involvement	9	9
Supervision content	1	1
Formal support	6	9
Informal support	2	2
Respite	3	4
Supervision	4	5
Caregiver assistance	6	7
Caregiver involvement	3	3
Additional support	3	3
Work patterns	5	7
Awareness of processes	6	8

Clarity of communication

6

6

\***Meta-themes** are highlighted in bold, *themes* are written in italics and underscored

## Appendix 15: Excerpt of the thematic framework

Ppt	Intervention Processes					Trial Processes			
	Benefits and Challenges of Group Format	Intervention Delivery	Knowledge and Understanding	Psychological Impact	Systemic Integration	Trial Framework	Cognitive Difficulties	Psychological Influences and Outcomes	Systemic Integration
C3	-	-	-	-	-	Caregiver was quite happy about group allocation due to not wanting to drive. Both PLWD and caregiver uncertainty of what the trial entailed. felt PLWD didn't mind the assessment process and would be open to future involvement.	Caregiver also didn't understand some of the assessment questions and was unable to recall much about the trial process	PLWD was ambivalent about the process, but caregiver wanted to learn about how to help and seek support.	Memory service provided leaflets advertising the study. Expected more support in general following diagnosis; Alzheimer's UK offer something but it's infrequent and both carer/PLWD feel out of the system, made worse by support groups making contact who weren't from the local area and not knowing what was available nearby. Informal support has been offered but

									not really utilised. Clear communication
T6	Suggested a combination of group and 1:1 to aid with any social anxieties at the start of the group. F2F was good for engagement as other studies that offered online were undesirable to PLWD.	Attendance hampered by transport issues due to living further away. Soothing rhythm breathing was a particularly good exercise for aiding relaxation.	-	Minimal changes arising from group 'steady state' other than being unwell for a bit which may have impacted her mood	Suggested more reminders to PLWD to do homework. Caregiver role was emphasised in promoting the group.	PLWD found the assessment process taxing. Understanding of potential to be in control group. Also suggested that more time was spent at the beginning orienting people to the group due to social anxiety – potential 1:1, therefore a combination of group and 1:1	PLWD had some difficulties understanding assessment questions	Initial interest due to wanting to try anything, but caregiver sceptical of talking therapies.	Access = advert in local publication and proximity to a dementia fare. Unaware of carer's workshop but otherwise found communication clear.
F1	Some group dynamic difficulties such as people not identifying with other, leading to less sharing, or individuals dominating the group, causing group frustration. Benefits of shared experience compared to 1:1 with	CFT is great for validating. Adapted manual: language, length and adapted the way homework was reviewed as it felt like a parent asking to review. Manual had too many copies of each exercise and was too broad which led to uncertainty of what was needed for each session. Also, session summaries often didn't match what had been covered in session	Outcomes hindered in places by memory difficulties and not being able to recall things from previous sessions. Also some difficulties with PLWD comprehension of therapy/resources	Subtle changes made	-	-	Identified challenges where PLWD in group are at different cognitive stages.	Interest in CFT/dementia and previous use, as well as research connections. Scepticism around ability of PLWD to take on board CFT content. and provides staff in the service with an opportunity to do more clinical work compared to usual work	Clinical service connections to research and across older adults / dementia. CFT trial plugs some gaps rather than people just getting a diagnosis and being discharged, patterns. Highlighted supervision as being important for facilitators and that it wasn't

	someone who doesn't have dementia. Power of sharing when it did occur and hope for continued connection between group	due to not covering things. Long exercises were the hardest. Other big barriers were fitting into time							frequent enough, particularly at the start
F4	Group discussions helped people overcome avoidance of dementia due to a sense of safety. Social interaction bolstered by people coming in early and talking with each other, which helped engagement with group material as well as opened awareness.	Adaptations to resources e.g. wording of scripts due to PLWD reactions/feedback, but felt manual was absolutely necessary. Difficulty understanding old brain/new brain and some exercises were really unhelpful and caused upset.	People didn't really understand compassion but did in small ways e.g. it's ok to not be ok.	-	-	Wants longer sessions – 1.5hrs with time at beginning and end to check in/out, and resources to be less verbose. Fidelity not used. Additional CFT training improved confidence, but on the whole felt very confident in delivering due to previous group facilitation, but spoke about other staff perhaps not feeling as confident	-	Finding time in work plan to be a facilitator. Involvement requirement close examination of commitments and moving things around, particularly in services where there's minimal psychology and the onus to be involved falls on a few individuals.	Group members wanted to share things with caregivers e.g. talking about threat system, which improved relationships.
SM	Feels people would benefit from virtual if needed	Adaptations: language, organisation into binders. Mindfulness exercises and recordings were	Felt that an increase in people's understanding of compassion played a part in the improvements but	Lightening of people's faces, increased acceptance and acknowledged the impact on	Better communication with caregivers to make the process smoother	Setup challenges: admin side of things e.g. redcap and documentation, room setup,	Found it difficult understanding trial procedures e.g. blinding,	Access for PLWD was impacted by having to support other family members	Access helped by training being run in service and existing work with dementia.

		good. Future suggestions: manual to be given out at the start along with recordings, and documents to be organised more effectively to help facilitators and PLWD	that some cognitive and emotional factors got in the way such as fear of being away from caregiver.	mood of those working with dementia/being part of the trial, as well as their therapeutic skills. Reclaiming life noted as an outcome e.g. volunteering and getting involved in things; one of them feels like a new man.		parking, timings feeling really rushed in setting up. Novelty of the trial and having to learn on the job Changing start time so that people could chat	who to email - more support needed in setup to orient people to research	and not having time for group.	
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## **Appendix 16: Overview of trainee contribution in a joint thesis project**

As specified in the Thesis Overview on page 3, this thesis was completed jointly with Shoshanna Freedman (trainee clinical psychologist) and Melissa Melville (PhD student).

Ben Loe (BL), Shoshanna Freedman (SF) and Melissa Melville (MM) had individual input to this project. Melissa Melville was coordinating the full trial, also under the supervision of Aimee Spector and therefore the trial was already running. Initially, the plan was for BL and MM to analyse different quantitative outcomes while SF conducted a qualitative analysis. However, issues arose whereby it was not possible to release data subsets for BL's clinical psychology doctorate research due to the potential impact on power for the planned full-scale RCT. Therefore, BL joined SF in completing qualitative analysis. Both had individual responsibility for their own empirical paper, with SF focusing on analysing interviews with people living with dementia, while BL analysed interviews with their caregivers, group facilitators and senior management clinicians affiliated with the trial. Two university undergraduate students assisting with the main trial also completed some transcriptions. The table below highlights who was responsible for which aspects of the project.

Task	Contributor
Literature Review Search, Analysis and Write Up	BL
Ethics Application	MM
Design of Intervention	MM

Recruitment	MM & BL
Delivery of CFT group	BL & SF
Baseline and Follow-Up Quantitative Assessments	BL (6), MM (ongoing)
Design of Interview Guide	SF & MM
Interviews for the Present Study	SF (8), BL (5) & MM (4)
Transcription of Interviews for the Present Study	BL (13), Undergraduates (4)
Analysis for Present Study	BL
Write Up of Present Study	BL