Feasibility study protocol

Full title of trial	Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused therapy (CFT) to improve depression and anxiety in Dementia
Short title	CFT- for mood in dementia
Version and date of protocol	Version 2.0 (09/08/2023)
Sponsor:	North East London NHS Foundation Trust
Sponsor protocol number	
Funder (s):	NIHR-RfPB
ISRCTN / Clinicaltrials.gov no:	To be obtained once study is registered as a NIHR portfolio study
Intervention:	Group Compassion Focused Therapy
Single site/multi-site:	Multi-site

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Protocol Version History

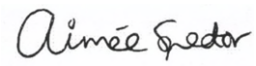
Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update
Version 0.1	04/05/2023	Mel Melville	First draft
Versions 0.2	18/05/2023	Aimee Spector	Updated after review with the NELFT management team
Version 1.0	24/05/2023	Mel Melville	Updated after second review with the NEFLT management team
Version 2.0	09/08/2023	Mel Melville	Updated after provisional opinion received from the REC.

Signatures

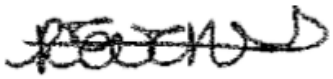
The Chief Investigator and NELFT have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, the UK Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the current Research Governance Framework, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator(s)

Aimee Spector		**09.08.23**
	Signature (s)	Date

Statistician

		**09.08.23**
Rachel Evans	Signature (s) Signature	Date Date

Sponsor

		**09.08.23**
NELFT	Signature	Date

Contents

List of abbreviations

AE	Adverse Event
CI	Chief Investigator
CBT	Cognitive Behavioural Therapy
CRF	Case Report Form
CSDD	Cornell Scale for Depression in Dementia
CSRI	Client Service Receipt Inventory (resource use questionnaire)
CFT	Compassion Focused Therapy
CST	Cognitive Stimulation Therapy
DEMQOL	Dementia Quality of Life
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Forth Edition
EQ-5D-5L	EuroQol 5-dimension 5-level quality of life questionnaire
GCP	Good Clinical Practice
HADS	Hospital and Anxiety Depression Scale
HRA	Health Research Authority
ISRCTN	International Standard Randomised Controlled Trial Number
MCA	Montreal Cognitive Assessment
NELFT	North-East London NHS Foundation Trust
NHS R&D	National Health Service Research & Development
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health and Care Research
NWORTH	North Wales Organisation for Randomised Trials in Health and Social Care
PI	Principal Investigator
PPI	Personal and Public Involvement
RAID	Rating Anxiety in Dementia
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
SCC-SF	Short-Self-Compassion Scale
TAU	Treatment as Usual
TMG	Trial Management Group
QOL	Quality of Life
QALYs	Quality-Adjusted Life Years
ZBI	Zarit Burden Interview

1. Trial personnel

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2. Summary

Objectives:	1. To undertake a feasibility Randomised Controlled Trial (RCT) to assess critical elements of a full RCT of Compassion Focused Therapy (CFT) in dementia. These include eligibility rates, recruitment and attrition rates, data collection and intervention delivery; 2. To establish acceptability of CFT as an online or face-to-face intervention for people with dementia; 3. To assess intervention fidelity; 4. To establish preliminary intervention efficacy; 5. To establish suitability of study outcome measures including cost-effectiveness measures; 6. To gather data to inform the decision of the primary outcome for a full RCT, and obtain estimates of parameters to inform the calculation of the required sample size for a full RCT; 7. To use qualitative and quantitative findings to modify the treatment manual (if required).
Type of trial:	Multi-site randomised feasibility trial of group CFT compared to "Treatment as usual" (TAU) in participants with dementia and depression or anxiety.
Trial design and methods:	A CFT intervention, developed by the team, will be adapted for delivery in a group format (to include a fidelity checklist) at a consensus meeting involving stakeholders (PPI and CFT clinicians). 50 people with mild to moderate dementia and anxiety and/or depression will be recruited to a two-armed RCT (CFT plus TAU vs TAU). Primary carers / supporters, if available, will be invited to a brief workshop focussing on principles of CFT and supporting the person at home. Blind assessments will be conducted at baseline, 16 weeks and 6 months follow up, to collect data on depression, anxiety, quality of life, cognition, self-compassion and carer stress. Qualitative interviews will be used to gather participant, carer/ supporter and clinician perspectives on the value, acceptability and feasibility of the intervention.
Estimated total trial duration:	30 months
Planned trial sites:	North-East London NHS Foundation Trust, Mersey Care NHS Foundation Trust, Oxford Health NHS Foundation Trust.
Total number of participants planned:	50
	Main inclusion criteria:

Main inclusion/exclusion criteria:	1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type (American Psychiatric Association, 1994) 2. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR (Morris, 1997)); 3. Experience symptoms of depression and/or anxiety (8≥) as measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983); 4. Have capacity to consent to take part in research; 5. Can communicate in English; 6. Have access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group; 7. Are not participating in another interventional research programme concurrently; 8. Aged 18 and over; 9. People can be included whether or not they have a caregiver. No age, care situation or access to teleconferencing devices exclusion criteria will be applied.
Statistical methodology and analysis:	A full analysis plan will be written and agreed before data collection is complete. Primary analysis will be based around the feasibility outcomes defined. For the proposed clinical outcomes, we will conduct exploratory statistical analyses using 'intention to treat' principles.

3. Background and Rationale

Depression and anxiety are common in dementia and have a devastating impact. However, there are currently no pharmacological or psychological therapies with established efficacy for these individuals, presenting a critical gap in both treatment and care. Around 850,000 people live with dementia in the UK (Prince et al., 2014) of which 20-37% have diagnosable depression and many more experience depressive symptoms (Kuring et al., 2020). Depression significantly reduces quality of life, accelerates cognitive decline, increases behavioural symptoms and is associated with higher mortality (Orgeta et al., 2015). 38-72% of people with dementia experience anxiety (Kwak et al., 2017) leading to cognitive deterioration and withdrawal from daily activities. 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 (Gibbons et al., 2002). 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); and is a common trigger for depression and anxiety.

Our meta-analysis (Noone et al., 2019) suggested that psychosocial treatments for both depression and anxiety in people with dementia are limited, but they provide an important avenue of likely benefit. A Cochrane review (Dudas et al., 2018) including ten, high-quality randomised controlled trials (RCTs) showed that antidepressants in dementia are ineffective. The 2018 NICE guidelines for dementia (NICE, 2018) 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. Anxiolytic or antidepressant medication is sometimes prescribed for anxiety, despite evidence suggesting it is ineffective and causes adverse events such as increased risk of falls (Allain et al., 2000). In extreme cases, anxiety can be treated with antipsychotic medication which has limited efficacy and serious side-effects including sedation, stroke and cognitive deterioration.

CFT (Gilbert, 2009) is a 'third wave Cognitive Behavioral Therapy (CBT)'; an emerging group of approaches which extend from traditional CBT and for which the evidence base is developing. CFT integrates techniques from evolutionary, social and developmental psychology. It aims to build compassion for the self and others and reduce self-criticism and shame. The theoretical stance lends itself well to those with mild-to-moderate dementia, for whom stigma can result in shame, embarrassment and self-criticism (Cheston, 2005). This can translate to people withdrawing socially and no longer engaging in cognitively stimulating activity, ultimately resulting in a spiral of disability and emotional distress. CFT specifically addresses how people with dementia respond to their cognitive deterioration, e.g. encouraging them to notice that they are struggling to find the words, to acknowledge that this is part of the dementia experience, not their fault and that they are not alone in their experience. Developing such acceptance is likely to facilitate adjustment and be emotionally protective, ultimately reducing clinical depression and anxiety, and improving wellbeing.

We systematically reviewed the effectiveness of CFT in clinical populations including depression, psychosis and borderline personality disorder(Craig et al., 2020). Including 15 studies (4 RCTs), significant improvements in symptomatology and self-compassion were found. CFT was acceptable and feasible to deliver in clinical settings, especially when delivered in a group format over at least 12 hours. The review concluded that CFT shows promise for a range of conditions, with RCT evidence urgently needed. An uncontrolled study run in routine NHS practice evaluated six, weekly sessions of CFT for 28 people with dementia and their caregivers (Collins et al., 2018). Whilst the study reported benefits to quality of life, anxiety and depression; there were significant limitations, e.g. self-completion of measures (with only 17 people completing the QoL-AD), reliance on people having a caregiver willing to participate; and the intervention not being manualised, limiting replication. Of note, attrition was only 6%, indicating high acceptability. Our team (Craig et al., 2018) developed and led a ten session manualised CFT intervention for dementia, through evaluating the relevant literature and consultation with people with dementia, carers / supporters and psychologists. A multiple case-series (n=7) assessed feasibility and preliminary effects. Following the intervention, improvements in depression, anxiety and self-compassion were seen. Six participants had definite or probable depression at baseline compared to only two at follow up. All seven had clinical anxiety at baseline compared to only four at follow-up. Interviews suggested that CFT was well-liked and that individuals were able to acquire self-compassion skills. The study suggested that CFT can be delivered to people with dementia, with a feasibility RCT now needed.

Our systematic review (Craig et al., 2020) found the majority of the studies in group format, with insufficient studies of individual CFT to draw conclusions on its impact. Whilst our pilot study (Craig et al., 2018) focused on individual CFT sessions, there are strong economic and theoretical arguments for group delivery. Groups present huge cost savings, with one therapist able to treat up to five people at once. As an example of implementation, group CST has been routinely delivered for people with dementia across the NHS since 2006. Several authors have discussed how group processes act as therapeutic mechanisms of change, with benefits including installation of hope, normalisation and altruism (Marmarosh et al., 2005). A recent synthesis of systematic reviews (McDermott et al., 2019) covering a broad range of psychosocial interventions in dementia, included 22 reviews incorporating 197 unique studies. A common theme and key conclusion was the potential importance of group activities to improve social integration. There is growing evidence of the ability to assemble groups, as well as the benefits of group interventions in other anxious clinical populations, for example Cognitive Behavioural Groups for anxiety in adults (Wolgensinger, 2015).

3.1 Assessment and Management of Risk

There will be no invasive tests or procedures that will be included above standard care. All the assessments will be based on standardised questionnaires. The intervention is not invasive.

The table below summarise the risks and mitigations of all tests above standard care that are being performed in a table:

Stage	Potential risk	Risk Management
Administration of group Compassion Focused Therapy	Distress to participants	Whilst risks are perceived as low, we will take all measures to ensure that appropriate environmental safety provisions are fulfilled and that study procedures are not unduly taxing or stressful for participants. If, at any point, a participant becomes distressed or expresses a desire to terminate their participation, this will be respected.
Administration of group Compassion Focused Therapy	New strain of Covid-19 resulting in further social distancing	With recruitment not due to commence until late 2023, we hope that this will not continue to be a problem. However, a contingency plan would be for the study to take place entirely online, as per the stage 1 proposal.

Administration of group Compassion Focused Therapy	Access to technology or ability to travel to face-to face groups	We anticipate that some participants will lack the technology or WiFi required to access virtual groups, whilst others may lack transport provision or have co-morbid health problems preventing attendance to face-to-face groups. Our contingency plan is to offer people the choice of virtual or face-to- face attendance.
Administration of group Compassion Focused Therapy	Attrition (in intervention groups)	The direct assessment (along with consent procedures) at baseline will enable us to gauge the motivation of participants and explain the nature and purpose of the intervention. This will hopefully enable exclusion of people who are unlikely to attend sessions. We will aim to exclude people with serious health problems, which might reduce the likelihood of attrition.
Recruitment	Problems with recruitment	For our CBT for anxiety in dementia trial, we recruited 50 people within 14 months, primarily through NELFT but extending to one other trust to increase numbers. This proposed trial will be more inclusive in that family carers / supporters are not essential, and we will also include those with depression, hence we anticipate that larger numbers will meet inclusion criteria. Our contingency plan is expanding to two further trusts and online recruitment through the 'Join Dementia Research' network.
Project management	Overrun of budget or time	We will regularly review the budget and timetable at steering committee and management meetings, ensuring that targets are met.

4.Objectives

We propose a feasibility RCT where participants will be randomly allocated to one of two groups: Twelve sessions of virtual or face-to-face group CFT plus treatment as usual (TAU) or TAU. There will be nested qualitative interviews, with the aims/objectives being to establish:

1. Feasibility of conducting an RCT: In terms of recruitment, eligibility rates, participants' willingness to be randomised, access to technology, ability to collect outcome data and participant retention in the trial and intervention.
2. Acceptability: whether CFT as an online intervention is acceptable to people with dementia and assess patient preference between virtual or face-to-face.
3. Fidelity: whether the intervention is delivered and adhered to as intended.
4. Estimates of the potential efficacy of the intervention.
5. Suitability of study outcome measures for participants, including cost-effectiveness measures.
6. The most appropriate primary outcome measure and parameters of quantitative measures to inform the sample size calculation for a full definitive RCT (if appropriate).
7. To modify the treatment manual (if required) according to qualitative and quantitative findings.

5. Trial design

The initial phase will involve the adaptation of the intervention and development of the group CFT manual, as well as the adaptation of the CSRI resource use questionnaire for the purposes of the trial.

5.1 Preparation of trial materials

The team of applicants and collaborators, including service users ('the PPI advisory group') will review the CFT manual developed for the initial study. We will then hold a half-day consensus meeting for the PPI advisory group, addressing the following:

a) Any adjustments required to the manual, to make it accessible in both an online and group format (which will mainly require rewording and minor edits). As our literature review suggested that a dose of 12 hours or more is preferable, we will increase sessions from ten (used in the initial study) to twelve, one-hour sessions. We will factor in time for social interaction before and after the session, either over a video conference platform or face-to-face.

b) The adherence checklist, devised by the team prior to this meeting, building on previous examples used for CST. It will include a framework of CFT components consisting of more general principles (such as beginning with a compassion practice, visual and audio resources, session summaries) and specific session tasks (such as soothing breathing and psychoeducation on emotion-regulation). The draft checklist, to include a Likert rating scale, will be discussed with the advisory group and amendments will be made based on feedback

c) The Client Services Receipt Inventory (CSRI). A version of the questionnaire that was adapted for use with dementia participants (Spector et al., 2015) will be used. This will be presented to the trial team and to the PPI panel, to check that relevant resource use items, unpaid care time and other out-of-pocket expenses are covered, and also that the wording is appropriate. It will be amended in light of the feedback prior to use in the feasibility trial.

5.2 Training of facilitators in CFT delivery

Professionals in the participating trusts will attend the two-day CFT training. Support around reasonable adjustments to the materials in order for them to be delivered to the ability level of the participants would also be provided to potential group facilitators.

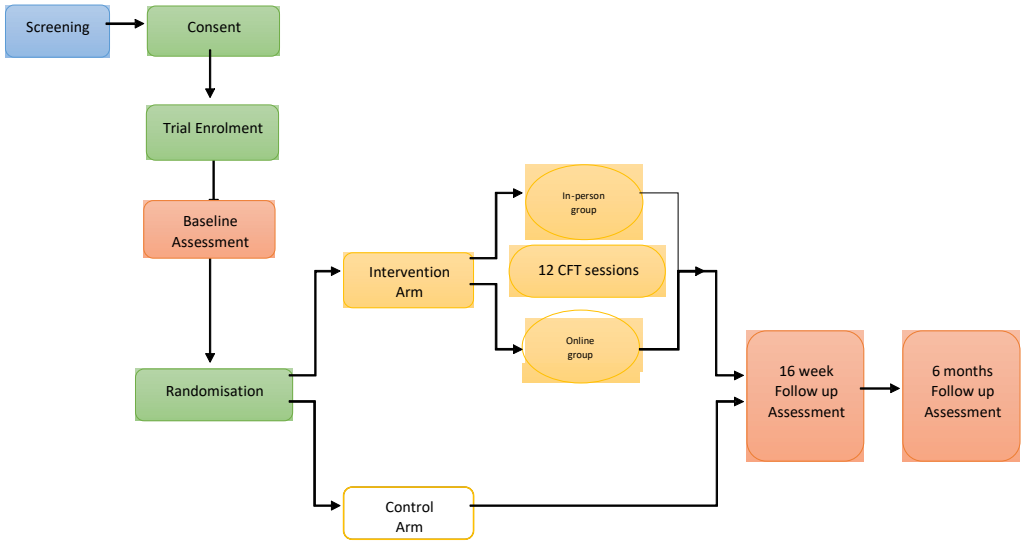
5.3 Feasibility Randomised Controlled Trial

This will be a single blind, feasibility randomised controlled trial of group CFT plus TAU versus TAU. Fifty participants will be randomised to either the intervention group (CFT plus TAU) or control group (TAU). Randomisation will occur after baseline assessments are completed. Each arm will have approximately 25 participants and they will be allocated to one CFT group with up to seven participants in each group.

The duration of the intervention will be 15 weeks, consisting of 12 CFT therapy sessions. Given that it can prove difficult to always fit the 12 sessions into 12 consecutive weeks (due to factors such as weather issues / therapist annual leave, strikes, illness), the additional 3 weeks provides a buffer and may increase the likelihood that participants could receive all 12 sessions. There will be assessments at baseline during the week prior to randomisation, and at the end of the intervention at 16 weeks and at 6 months follow-up.

Please refer to figure 1 which shows the overall trial design.

Figure 1
Trial schematic diagram



6. Selection of Participants

6.1 Inclusion criteria

1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type (American Psychiatric Association, 1994);
2. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR (Morris, 1997);
3. Experience symptoms of depression and/or anxiety (8 ≥) as measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983);
4. Have capacity to consent to take part in research;
5. Can communicate in English,
6. Have access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group;
7. Are not participating in another interventional research programme concurrently.
8. Aged 18 and over
9. People can be included whether or not they have a caregiver.

6.2 Exclusion criteria

People will be excluded if they do not meet the inclusion criteria outlined in section 6.1

6.3 Recruitment

Recruitment will primarily be through NorthEast London NHS Foundation Trust (NELFT), Mersey Care NHS Foundation Trust and Oxford Health NHS Foundation Trust. Recruitment will be conducted in adherence with local Trust privacy notice permissions and consent to contact arrangements. The study will be promoted through relevant services and routes specific to the local Trust including non-NHS pathways such as third sector organisations, supported living accommodation and care-homes. We will recruit through 'Join Dementia Research', an online recruitment platform. 'Join Dementia Research' recruitment can only be from within the locality of the Trusts involved.

6.4 Informed consent

NHS ethical approval will be obtained. Due to participants being in the mild-to-moderate stages of dementia, they will be expected to be able to provide informed consent in accordance with the guidance in the Mental Capacity Act (2005). Consent will be treated as an ongoing process and re-affirmation will be sought at each study visit. Participants will have the right to withdraw their consent at any stage, should they wish to. All procedures will be GDPR compliant, with participants explicitly informed of who has access to their data, how their data will be used and plans for anonymised data sharing. Any complaints or adverse incidents will be referred to the ethics committee for independent review and appropriate action. In line with HRA guidance, we will detail our plans for informing study participants of

the research outcome in the information sheets, so that they are informed of these plans from inception.

Participants lacking capacity

The intervention will be taking place with participants who are able to provide informed consent at the time of consenting. However, this might change through the duration of the study and therefore consent will be sought throughout the study period. In the unlikely but possible event that a participant's level of impairment increases during the time they are involved in the study, such that they are no longer able to provide informed consent, they will be withdrawn from the study and no further data will be collected, however data collected up until that point will be retained for use in the study.

This intervention is aimed at helping people with mild to moderate dementia that have sufficient cognitive ability to participate in group sessions. The participant will also need sufficient cognitive ability to complete a series of questionnaires to determine their quality of life, mood, cognitive function, and self-compassion. Should any participant experience significant cognitive decline such that they no longer have capacity to consent, they are unlikely to remain cognitively able to participate in the groups or provide meaningful results for the outcome measures.

7. Intervention

7.1 Group CFT intervention

Twelve, 60-minute virtual or face-to-face group CFT sessions including three phases. Phase 1 involves 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. Sessions will begin with a core CFT practice, for example 'soothing rhythm breathing' which involves slowing and deepening the breath. Each session will introduce a new concept, such as the qualities of compassion, mindful awareness and understanding the function of self-criticism. There will be time to reflect on the emotional experience of living with dementia, e.g. how the diagnosis can be experienced as a 'threat' to the self and future, triggering fear, anxiety and disconnection. Sessions will end with suggesting home practices, with participants given session summaries. CFT will be adapted to compensate for cognitive changes, including frequent repetition and use of visual and verbal information. Building on the experience of running CST groups (Spector et al., 2003), groups will consist of approximately five people. We will factor in time for social interaction before and after the session, either over a video conference platform or face-to-face.

Additional carer/ supporter workshop: we will run a brief workshop (flexibility for online or face-to-face) for primary carers / supporters (if available) towards the beginning of the CFT program. This will educate carers / supporters on the principles of CFT, providing an outline of what we intend to do in the sessions and giving people tips on what can be done at home

to encourage and support the therapy (for example, reminding the person to do breathing or relaxation exercises).

The intervention group will continue to have access to treatment as usual (see description below). As both groups will have access to TAU, this study will look at the *additional* impact of CFT.

For those who do not own a tablet and wish to complete the online intervention, ten tablets will be purchased and lent to those participants, aiming to maximise inclusivity.

Control group (TAU)

Defined as standard treatment available to people with dementia and depression and/or anxiety, which might include medication, other therapies, day care, input from health and social care professionals such as psychiatrists, psychologists and social workers or no treatment. We will collect information on all health and care services used by people with dementia (which we can compare with ongoing observational studies such as IDEAL (Henderson et al., 2019) to describe what TAU involves for each participant; this can be taken into account in a future, fully powered trial.

7.2 Concomitant medication

The participants will be permitted to take any medication that they usually take, including medication that may enhance cognition (e.g. acetyl cholinesterase inhibitors). These will be recorded carefully at baseline and follow up.

Concomitant medications will be recorded in the trial's electronic CRF.

8. Trial procedures

8.1 Recruitment

The participants will have been diagnosed with mild to moderate dementia as measured by the Clinical Dementia Rating (CDR) (Morris, 1997) Scale. The CDR Scale is used to measure cognition and to provide a global rating of dementia severity as part of the general background information. The participants will experience symptoms of depression and/or anxiety (8 ≥) as measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). HADS is a brief, clinically useful measure of anxiety and depressive symptoms found to have good reliability and validity. It takes 2-5 minutes to administer. The HADS questionnaire has seven items each for depression and anxiety subscales. The scale has been developed to reduce the impact of physical illness on the total score. A score of 8 or more indicate cases.

The research team will conduct recruitment in adherence with local Trust privacy notice permissions and consent to contact arrangements. Participants will be approached by the recruiting team to discuss the study with the participant and their carer / supporter (where

available and willing). If they are interested in taking part, both the participant and their carer / supporter (if applicable) will be provided with a relevant information sheet. If interested, the research team will arrange a meeting to answer questions and assess eligibility. If the participant and carer / supporter (if applicable) agree to taking part, then written informed consent will be received from the participant and the carer / supporter. Participants without carers / supporters are eligible to take part in the study. Carers / supporters are defined as being the main source of practical or emotional support for the person with dementia.

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed via green light correspondence from the Sponsor (or its delegated representative), and

2. Has received REC Favourable opinion and HRA Approval

Recruitment will take place over approximately 12 months. Taking up or declining the study will not affect the usual support and treatment that people receive.

Face -to-face groups will be held within (as opposed to across) sites. Online groups can consist of participants across sites and include participants from the 'Join Dementia Research' online platform. We will endeavour to ensure that waiting times do not exceed 6 months. If they do, we aim to address this by: a) giving people the option of the group with the shorter waiting time (e.g. lending tablets to people who prefer face to face, exploring transport options for people who prefer online), b) randomising in smaller blocks. See section 8.3 for randomisation details.

8.2 Baseline assessments

The following measures, all with good to excellent psychometric properties, will be collected by a researcher (blind to group allocation), at week zero (baseline). Assessments will be delivered virtually or face-to-face, depending on participant preference. Demographics and general information will be collected including age, gender, ethnic group, use of medication (including antidepressants, anxiolytics and cholinesterase inhibitors), treatment preference, participation in other activities and presence / absence of a carer / supporter. The baseline assessment will take approximately 1.5 hours for the participant with dementia and 25 minutes for the carer / supporter. Where appropriate we will ask the carer to complete the Client Service Receipt Inventory (CSRI). We will pilot the assessment battery and if it is perceived as too arduous, we will revisit the assessments. We will ensure that we offer breaks during the assessment and hold more than one assessment session if required. There were no problems conducting a similar battery assessment in our initial study (Craig et al., 2018).

Measures to be completed by the Participant

Type of measure	Name of measure	Description	Time taken to complete the measure
Symptoms of depression	CSDD (Alexopoulos et al., 1988)	Rates depression in 5 categories including mood related signs, behavioural disturbance and ideational disturbance, using information from interviews with staff and participants. Good reliability and validity have been demonstrated.	~ 15 minutes
Symptoms of anxiety	The RAID (Shanker et al., 1999)	Rates signs and symptoms of anxiety using interviews with carers / supporters and people with dementia. There are 18 questions in 4 categories: worry, apprehension, vigilance, motor tension and autonomic hypersensitivity. A score of 11 or above indicates significant clinical anxiety. It has good inter-rater and test-retest reliability and is sensitive to change.	~ 15 minutes
Quality of life	The DEMQOL (Smith et al., 2005)	The DEMQOL is included because quality of life has been linked to mood in dementia. It measures five domains of quality of life; health and well-being, cognitive functioning, social relationships and self-concept. The scale uses self-rated reports of quality of life from the person with dementia and will be administered to a carer / supporter (where available) to provide the DEMQOL-proxy. It has high internal consistency (0.87) and acceptable inter-rater reliability (ICC 0.84).	~ 10 minutes

Quality of Life	The EQ-5D-5L (Herdman et al., 2011)	The EQ-5D-5L is included because quality of life has been linked to mood in dementia. It measures 5 domains of the participant's health-related quality of life (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The scale uses self-rated reports of quality of life from the person with dementia. It has good internal consistency and inter-rater and test-retest reliability. The EQ-5D-5L proxy will be used to calculate quality-adjusted life years (QALYs) in line with NICE guidance (Herdman et al., 2011).	~ 10 minutes
Cognitive function	The Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 2005)	The MoCA will enable us to explore whether mood is a predictor of cognitive change. It is a 30-point test consisting of 13 tasks covering eight domains: visuospatial/executive functions, naming, verbal memory registration and learning, attention, abstraction, delayed verbal memory, and orientation. It has demonstrated high sensitivity and specificity.	~ 10 minutes
Self-compassion	The Short-Self-Compassion Scale (SCS-SF) (Raes et al., 2011)	The Short-Self-Compassion Scale (SCS-SF) measures self-kindness, self-judgement, common humanity, isolation, mindfulness, and over-identification. It has good internal consistency ($\alpha \geq 0.86$), factorial validity and convergent validity. It has not been specifically validated for use in dementia populations although was completed successfully in our pilot study (Craig et al., 2018). We will look at the validation data within our analysis	~ 10 minutes
Relationship with caregiver:	The Quality of Caregiver and Patient	The Quality of Caregiver and Patient Relationship scale is a 14-	~ 15 minutes

	Relationship scale (Spruytte et al., 2002)	item scale measuring relationship quality. For those who have a caregiver, it will be rated by both the person and their caregiver hence enabling both perspectives to be examined.	
Resource use	The Client Service Receipt Inventory (CSRI) (Chisholm et al., 2000)	The Client Service Receipt Inventory (CSRI) is used extensively in economic studies of dementia: it gathers data on accommodation, medication, use of public, private and voluntary sector services, and inputs from carers / supporters.	~ 20 minutes

Measures to be completed by the Carer/ Supporter (if applicable)

Type of Measure	Name of Measure	Description	Time taken to complete the measure
Relationship with caregiver:	The Quality of Caregiver and Patient Relationship scale (Spruytte et al., 2002)	The Quality of Caregiver and Patient Relationship scale is a 14-item scale measuring relationship quality. For those who have a caregiver, it will be rated by both the person and their caregiver hence enabling both perspectives to be examined.	~ 15 minutes
Caregiver Burden	Zarit Burden Interview (ZBI) (Zarit et al., 1985)	The revised Zarit Burden Interview (ZBI-22) consists of 22 items rated on a 5-point Likert scale that ranges from 0 (never) to 4 (nearly always) with the sum of scores ranging between 0–88. Higher scores indicate greater burden. The ZBI is used extensively to assess caregiving burden in clinical and research settings.	~ 10 minutes

8.3 Randomisation Procedures

Participant randomisation will be undertaken remotely via a secure online system using a dynamic adaptive randomisation algorithm provided and maintained by NWORTH, University of Bangor (Russell et al., 2011). Participants will have indicated whether they are only able to attend face to face or online sessions (in addition to their preference), when they provide consent, from this the researcher will construct "randomisation blocks" based on their ability to attend either format. Once the recruiting site reaches approximately 10 recruits to a ''randomisation block'' (i.e. online or face to face), the randomisation procedure described below will be carried out. If there are too few participants at one site that can only attend online, then the online groups may be combined with other sites including participants from 'Join Dementia Research' to form one online group. As we are aiming for ~5 participants per group, we require approximately 10 participants per "randomisation block." However, if required, smaller groups may be randomised and constructed (i.e. groups of 6 or 8). A minimum number in each group is 3 participants, therefore a minimum of 6 participants will need to be recruited to a "randomisation block" before being randomised. A maximum number in each group is 7 participants, therefore a maximum of 14 participants will be recruited to a ''randomisation block'' before being randomised.

Once the desired recruitment number has been reached for a block at that site, the study researcher will arrange to collect the participants baseline data. Following this, eligible participants will be randomised using a partial list system (via NWORTH CTU). A list of participants will be entered into the system and allocated on a 1:1 ratio to the intervention or the control group. Participants will have been allocated a unique participant identification number. The researcher will enter the participant identification number into the online system along with participant information such as date of birth and stratification data (Site and Delivery format (Site 1 – face to face; Site 2 - face to face; Site 3 face to face; Online (can be a combination of sites)). Within the algorithm, the likelihood of the participant being allocated to each treatment group is recalculated based on the participants already recruited and allocated (Russell et al., 2011). This recalculation is done at the overall allocation level, within stratification variables and within stratum level (the relevant combination of stratification levels). The results of the randomisation will be presented to the researcher and relayed to the participants, arrangements can then be made to begin the intervention or for treatment as usual. The intervention should begin within a week of randomisation.

Due to the nature of the intervention, it is not possible to blind participants, however, researchers collecting outcome data will be blinded. As participants are unblinded they may accidentally unblind researchers during follow-up assessments, we will collect data on the occasions where this happens in the feasibility study and where possible a different researcher will conduct future assessments. The trial statistician will remain blind throughout the duration of the study, until the blinded analysis detailed in the statistical analysis plan has been conducted and reported to the study team.

Participants are considered to be enrolled into the trial following: consent, confirmation of eligibility and allocation of the participant trial number.

8.4 Intervention procedures

See section 7.1 for intervention description. Below are practical considerations for the intervention delivery.

CFT sessions will be led by professionals with (or receiving) recognised clinical training such as Clinical or Counselling Psychologists or trainees and 'Increasing Access to Psychological Therapies' (IAPT) high intensity therapists, ideally with clinical experience with people with dementia. All clinical professionals will be required to attend a two-day Introduction to Compassion Focused Therapy workshop delivered by Balanced Minds (https://balancedminds.com/an-introduction-to-compassion-focused-therapy-cft-2/), a similar workshop was used for training in our pilot study. As training budgets within the NHS are limited, we expect that paying for people to receive this training will be an incentive to participate as therapists. Regular clinical supervision will be offered by Dr Syd Hiskey, Consultant Clinical Psychologist and supervisor within the initial case series study.

The CFT sessions that take place online will use the Trusts preferred video conference platforms. Two professionals are required to deliver the virtual CFT sessions; one person to deliver the CFT intervention itself and one person (who is not required to be clinically trained) to provide technical support to the facilitator and technical and emotional support to participants if necessary. Face-to-face meetings will also require two facilitators. This is from a health and safety perspective and with client care in mind to accommodate possibilities such as participants becoming agitated and needing signposting. The spaces in which to hold the face-to-face CFT will vary by site and be based on both local NHS and non-NHS connections. It will be important to seek a mutually convenient location for all participants. Where a room is not freely available, the research team will seek a local affordable option. The facilitators will need to book 1.5 hours per session to allow for social interaction amongst the participants before and after the session. Tea/coffee will be provided for those participating in face-to-face CFT. Equipment required for the facilitator is minimal (printed materials and a whiteboard). For those participating online, where possible, the research team will post any relevant printed materials required to their home address.

The code of conduct for participants joining virtually is that they reside in a private space on their own and if this is not possible, to use headphones. We expect all participants online to have their cameras on, this is to ensure other participants that they are sharing within a confidential space.

Following each session, the facilitator will complete the fidelity checklist. All sessions will be audio-recorded, and an independent researcher will rate fidelity with a random 10% of the recordings. A total, mean fidelity score and percentage will be calculated for each CFT session. These scores will be compared across site and provider. We will also compare self-report (facilitator) with observer ratings (independent researcher), providing some idea about the utility of self-report in a future trial.

8.5 Follow up data collection

Follow-up assessments will take place at 16 weeks and 6 months post baseline. On both occasions, participants will be contacted two weeks in advance to arrange a time for the assessment. Assessments will be delivered virtually or face-to-face, depending on participant preference, which will take around 1.5 hours to complete. Where possible, the same researcher will complete the baseline assessments and follow ups. The local research team will be asked to book and complete subsequent assessments in the first instance, if the team does not have capacity, another researcher from the core team will be responsible. The same measures used at baseline will be used for follow up (a full description of the outcome measures is available in section 8.2. The post intervention measures at 16 weeks must be completed within 4 weeks of the end of the intervention. The post intervention measures at 6 months must be completed within 4 weeks of the 6-month mark.

8.6 Qualitative evaluation

We will conduct semi-structured, audio-recorded interviews (performed over videoconferencing software or face-to-face) with up to 20 participants with dementia (including up to 10 control group participants with dementia, in order to explore trial procedures from perspective of those who did not participate in the intervention). We will also interview up to 15 carers / supporters (including those who did not attend the workshop to better explore barriers to attendance). We will approach and plan to interview up to 10 NHS personnel (including group facilitators and service managers) for qualitative interviews to determine feasibility of implementation.

Precise sample size will be determined taking into account pragmatics (e.g., number of people participating in the trial) and using information power, which is preferred to other methods for determining qualitative sample size such as thematic saturation (Malterud et al., 2016). We will purposively sample on the basis of characteristics associated with underrepresentation in research (e.g., sex, socio-economic status, ethnicity and session attendance) to explore a range of perspectives. We will use sampling matrices to ensure sufficient representation.

Interview topic guides will be guided by process evaluation parameters described in recognised frameworks, (Moore et al., 2015) (O'Cathain et al., 2019) and draw upon theoretical models such as Normalisation Process Theory (May et al., 2007). Interview topic guides will be co-produced with people with dementia and their carers / supporters. It is, however, likely that they will broadly ask about:
a. Intervention benefits and their relative importance in order to inform decisions as to the primary outcome in a full trial.
b. How participants think key benefits came about, complementing existing work on theory of change in CFT specifically in a dementia context.
c. Limitations of the intervention and trial procedures in order to optimise intervention design and procedures for a full RCT.
d. Different domains of feasibility and acceptability by asking about factors related to the facilitators, the group context, the CFT intervention itself, the trial procedures, and the wider service context.

e. Carers'/supporters' experience of the brief workshop, the acceptability and feasibility of it, whether it led to any changes in what they did at home, and barriers and facilitators to attendance.
f. Experience of delivering the CFT sessions (group facilitators), perceptions of impact, support for facilitation required.
g. Feasibility of implementation (group facilitators and service managers) including barriers, facilitators and future considerations.

8.7 Discontinuation/withdrawal of participants

A participant may be withdrawn from the trial whenever continued participation is no longer in the participant's best interests, but the reasons for doing so should be recorded. Reasons for discontinuing the trial may include:

- disease progression whilst in trial
- chronic current illness
- patients withdrawing consent or losing capacity to consent

The decision of a participant to withdraw from treatment will be recorded in the electronic CRF and medical notes. If a participant withdraws from the intervention, they will be asked to continue to provide follow up data. Their decisions regarding withdrawal from the intervention and withdrawal from follow-up will be recorded in their medical notes and in the trial electronic CRF, along with any reasons that they have shared.

8.8 Unblinding

Participants will be aware of whether or not they are receiving the intervention, hence will not be blinded. The assessors administering the questionnaires will be blind to treatment allocation. If unblinding is disclosed, this will be reported as a protocol deviation and if possible, a different researcher will complete subsequent measures with that participant. We will monitor how many times this occurs and record whether a different researcher is able to complete subsequent measures each time. This will be considered in the analysis, and we will make any recommendations for a full trial if applicable.

8.9 Definition of End of Trial

The end of the study is defined as when the final participants enrolled in the study have completed their 6 months follow up assessments.

9. Recording and reporting of serious adverse events (SAEs) and adverse events (AEs)

In all instances the Sponsor SOP will be followed for the recording and reporting of SAEs and AEs. The Sponsor SOP will be followed for the definition and assessment of SAEs and AEs. Each event will be assessed for severity, causality, seriousness and expectedness as described and outlined in the Sponsor SOP and will therefore need to be accompanied by a detailed description of the event. The assessment of the relationship of SAEs and AEs to the

intervention will be made based on the information provided in the report. There are no known adverse effects of Compassion Focused Therapy. However, taking part may possibly cause distress/ inconvenience for some participants with dementia. It is of particular importance in this trial to capture events related to the procedure (CFT). The assessment of a possible relationship of an SAE or AE with trial procedures will be recorded and reported as part of the trial to ensure it is safe.

9.1 Research Incidents, Protocol deviations and Protocol violations

In all instances the Sponsor SOP will be followed for the recording and reporting of research incident, protocol deviations and protocol violations.

9.2 Incidents and Near Misses

Local organisation policies and SOPs will be followed for incidents and near misses.

10. Data management

The study will be managed in accordance with General Data Protection Regulations, Good Clinical Practice and relevant Sponsor and NWORTH Standard Operation procedures (SOPs). Where data are stored locally e.g. referral information, the study will adhere to local SOPs / policies All data will be stored securely on password protected NHS PCs/laptops and paper records (ICFs) stored in locked drawers or filing cabinets in NHS premises with permission based access.

10.1 Confidentiality

All data will be handled in accordance with UK legislation and the GDPR guidelines. Participants will be allocated an ID number which will be used to identify them on study documents/materials (Case Report Forms; CRF). The CRF will not contain personal identifiable data. The use of ID numbers in place of identifiable information will be clearly explained in the PIS and highlighted during the informed consent appointment.

10.2 Data collection tools and source document identification

Source data for this study is considered to be the electronic data in REDCap. All numeric outcome measures data will be entered directly onto REDCap using a laptop. REDCap is an internet cloud-based system with high security data collection and management software.

A source document list will be implemented prior to the start of the trial to identify:

- which data is to be recorded directly onto the electronic CRF;
- which data is recorded firstly into source documents, such as medical notes, and then transcribed into the electronic CRF; and
- which data is not to be recorded in the electronic CRF but only recorded in source documents, e.g. participant questionnaires.

The data will then be entered onto the REDCap electronic data capture system, that will not include the participant's name or other information that could identify them. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). All electronic databases will use a participant identification number rather than the participant's name. Hard copies of data sheets containing the participant identification number to the person's contact details will be kept securely in a locked filing cabinet in a locked office and will only be accessible to a small number of people who are involved in the study. A more detailed Data Management Plan that complies with the NWORTH's Standard Operating Procedures addresses details about the data flow and storage, system validation, data cleaning, freezing and locking, sharing, archiving and data collection tools such as electronic CRFs will be written.

10.3 Data handling

Questionnaire data (see section 8.2) will be collected from participants in accordance with the ICF, participant information sheet and section 8 of this protocol.

Data collected will be entered directly into a database hosted on REDCap by a member of the study team and may be securely downloaded by relevant personnel at NWORTH e.g. Trial Statistician for data cleaning and statistical analysis. The Sponsor will act as the data controller for the study. Data will be sent to the Health Economist for cleaning during the trial. A digital fingerprint of the file will be taken by NWORTH prior to it being sent to the recipient and a copy kept by NWORTH as a master copy. Any other data transferred to NWORTH will be encrypted, password protected and contain no identifiable information. All data sent from NWORTH will be securely encrypted. Passwords for the data will be transferred verbally so once a data set is received, the recipient should contact the sender of the data to obtain the password. A data management plan will be developed to describe procedures for data storage and cleaning.

11. Statistical Considerations

11.1 Sample size calculation

This is a feasibility study with no formal power calculation. Instead, a sufficient number of participants need to be recruited in order to determine the attrition and recruitment rates and how these are related to feasibility for a full-scale RCT. By setting our target sample size at 50 we will achieve adequate precision around our expected retention rate of 75% (95% confidence interval of 62-86%) to determine the feasibility going forward. Based on our previous study data we are anticipating we will have to screen a maximum of 70 people to reach our sample size.

11.3 Statistical analysis

11.3.1 Quantitative Analysis

A statistical analysis plan will be written, agreed, and signed off before data lock is complete detailing all quantitative analysis to be conducted by NWORTH. The Statistician will be blinded to group allocation until all blinded analysis detailed in the SAP has been conducted and reported to the team.

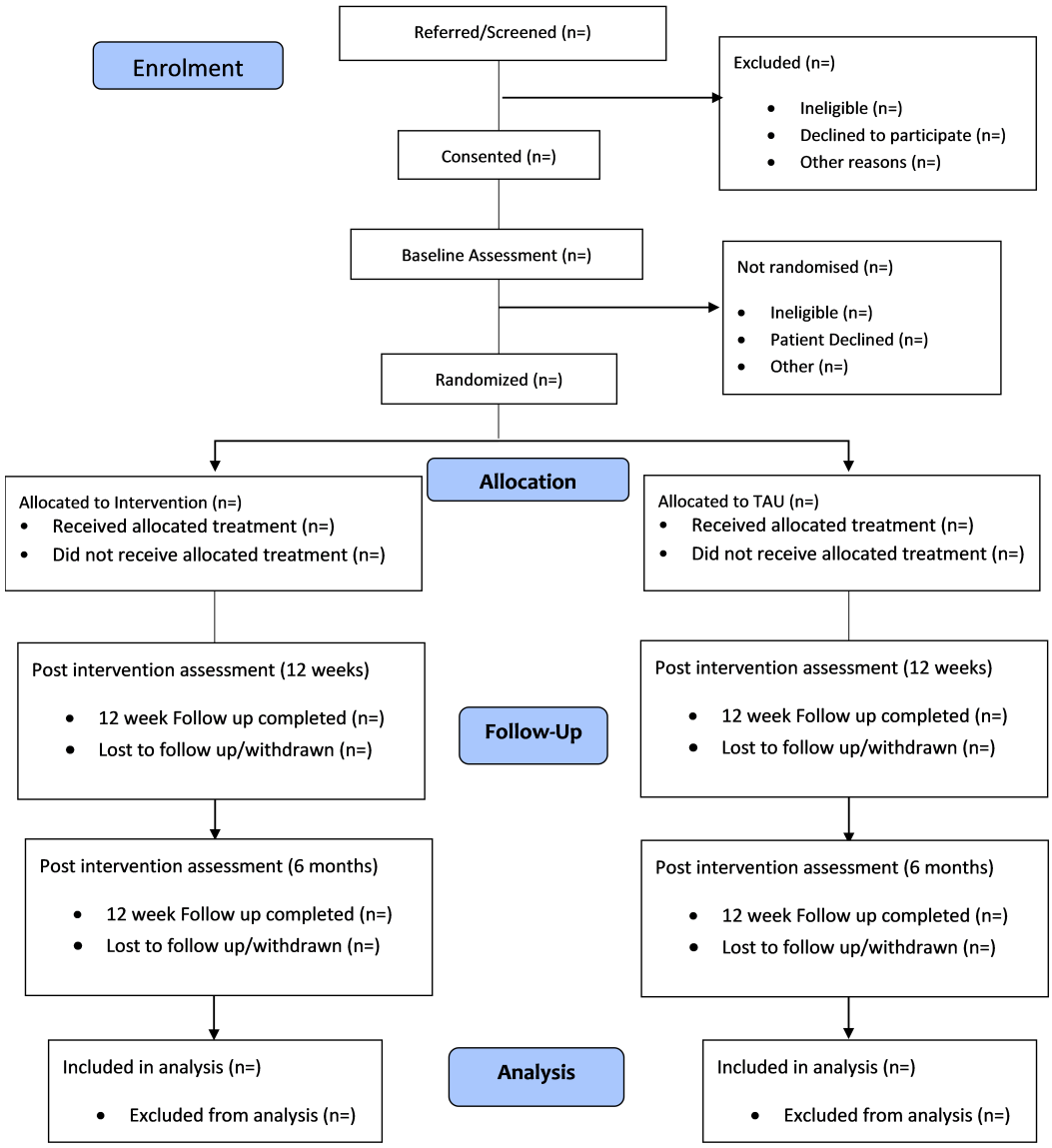
11.3.2 Feasibility outcomes

Primary analysis will be based around the feasibility outcomes defined. The CONSORT information, detailed in figure 2, will be completed. From this data some of the primary feasibility outcomes will be calculated, such as eligibility rates, willingness to be randomised (randomisation/recruitment rate) and trial retention.

Access to technology, ability to collect outcome data and retention to the intervention will be presented descriptively from data collected in the electronic CRFs. Access to technology and availability to travel will be assessed as part of the initial screening session by the local researcher. The research team will record ability to collect outcome data and retention of the intervention.

Figure 2

Consort Flow Diagram



**We would not anticipate any exclusions from analysis but any exclusions will be fully reported and justified*

Reasons for ineligibility

Inclusion criteria:

1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type (American Psychiatric Association, 1994);
2. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR (Morris, 1997);
3. Experience symptoms of depression and/or anxiety (8 ≥) as measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983);
4. Have capacity to consent to take part in research;
5. Can communicate in English,
6. Have access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group;
7. Are not participating in another interventional research programme concurrently;
8. Aged 18 and over;
9. People can be included whether or not they have a caregiver.

Reasons patient declined

- Does not want to be randomised
- Does not want to complete measures/interviews
- Does not want to participate in therapy
- Does not want to commit to multiple follow ups

11.3.3 Qualitative Analysis

Interview data will be recorded either by the videoconferencing software, or via an encrypted digital recorder and then transcribed verbatim. Transcripts will be checked for accuracy against the recordings and any corrections made. The researchers will re-read all transcripts to gain familiarity with the data which will then be coded informed by a coding framework that will be refined but will likely be focussed around intervention benefits, mechanisms of change, limitations of intervention and other feasibility and acceptability outcomes. Analysis will follow Braun and Clarke's methods of thematic analysis (Braun & Clarke, 2019) and will be done using NVivo. This analysis will reveal the experiences of CFT and its delivery, the barriers and facilitators to its uptake and continued use, and the perceived benefits for the person participating in CFT and how were these realised (mechanism of change). Results will also be considered in terms of implementation. For example, through application to aspects of the 'Context and Implementation of Complex Interventions' checklist (Pfadenhauer et al., 2017) to generate recommendations that pay particular attention to the contextual factors (e.g. personal characteristics) that may influence, or be influenced by the trial setting (e.g. group online access) and their relationship with the trial recruitment and intervention delivery, which may reflect implementation in a real world setting.

12. Health Economics

12.1 Health economic analysis

As this is a feasibility study, the focus will be on the feasibility of collecting data that would be used in a future economic evaluation alongside a larger future RCT. The aim of that future evaluation would be to assess the cost-effectiveness (value for money) of using group CFT compared to treatment as usual, over the time period of the study, from the perspective of the NHS and Personal Social Services.

12.2 Quality of life (QOL) and quality-adjusted life years (QALYs)

The EQ-5D-5L is administered to all participants at baseline and at follow-up, to allow reporting of different domains of the participant's health-related quality of life (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and to see how this has changed in each of the two randomised groups, and to allow utility weights (also called QOL scores or values) to be calculated from the responses to the EQ-5D-5L using standard algorithms. These QOL values, calculated from the EQ-5D-5L responses captured from participants at baseline and follow-up, are then used to calculate quality-adjusted life-years (QALYs) for participants over the time horizon of the study, using area under the curve methods. QALYs are calculated adjusting for baseline QOL values. QALY will also be calculated based on the dementia-specific DEMQOL-Proxy instrument.

QALYs are the health outcome preferred for use in cost-effectiveness analysis by the National Institute for Health and Care Excellence (NICE) when combined together with information on costs. The five questions covering the five domains listed above are followed

by a visual analogue score on the second page of the questionnaire, which is not used in health economic analysis but is required to be included for valid administration of the questionnaire.

The feasibility study outcomes here will assess proportions of participants who return completed EQ-5D-5L questionnaires (focusing on the 5 items on the first page and considering the VAS responses separately) at the two timepoints. DEMQOL will be evaluated by examining the proportion of items in the 31-item measure that are missing (considering separately the global QOL question that does not form part of the total score) and the proportion of missing DEMQOL total scores, having applied scoring rules.

12.3 Resource use and costs

Besides QALYs, the economic evaluation alongside the future full RCT would require information on costs to the NHS and Personal Social Services of using the group CST intervention and using treatment as usual. Costs would include cost of the intervention in that arm, costs of treatment as usual in both arms, and any other treatment pathway costs, i.e. primary and community health care, medications, routine and emergency hospital care and use of personal social services, as well as unpaid care provided by family carers / supporters and out-of-pocket costs related to participant's use of health and social care services. We include use and costs of unpaid care, as this is likely to be important in this group, although it would not be included in the base case analysis in the future cost-effectiveness analysis, as it is outside the perspective of the NHS+PSS. We will also collect baseline costs of the participant's preceding 15 weeks of resource use so that these can be adjusted for in the future analysis.

Our patient and public involvement collaborators, along with clinicians and other members of the study team, will be involved in modifying the CSRI questionnaire for use in this feasibility study, in terms of tailoring the content and language to make sure it is suitable and that we can try and collect relevant data without over-burdening participants or carers / supporters.

This will also help to assess the feasibility of collecting resource use data for generating cost information for use in a future RCT in this population and context.

Intervention costs will be calculated from data collected during the trial, including facilitators' time in training, and time spent preparing for, running and documenting groups, also venue/premises costs, materials, and supervision/management costs. Costs of travel to participants will be collected, if applicable.

Costs will be calculated using nationally applicable unit costs (Jones et al., 2022; NHS England 2023; NHS Business Services Authority, 2022). Utilities will be derived from EQ-5D (Hernández Alava et al., 2023), DEMQOL (Rowen et al., 2012 ; Smith et al., 2005) and the ZBI (Zarit et al., 1985) using population preference weights and QALYs calculated using the trapezium rule. ICCs of QALY and costs will be estimated.

The feasibility study outcomes here will assess rates of completion of the different parts of this questionnaire at the two timepoints, and what changes might need to be made to the questionnaire on the basis of the feasibility study outcomes and qualitative feedback, before using an updated and refined version of it in a future larger study.

13. Record keeping and archiving

All essential documentation will be archived securely by the Sponsor for a minimum of 5 years from the declaration of end of trial. All archiving will be conducted in line with the Sponsor SOP.

14. Oversight Committees

14.1 Trial Management Group (TMG)

The TMG will include the Chief Investigator and trial staff. The TMG will be responsible for overseeing the trial e.g. review recruitment figures, safety concerns (AEs / SAEs) and discuss potential modifications to the protocol prior to formal amendment submission. The group will meet approximately monthly and will send updates to Trust PIs.

15. Patient and Public Involvement (PPI)

Patients and the public have been involved since project inception. Our initial CFT intervention (detailed in our published case series paper), was developed jointly with PPI collaborators (four people with dementia and three family caregivers) whose views helped to inform core aspects of the intervention, including the number of sessions, involvement of family caregivers and what they felt individuals receiving the intervention could do at home outside the sessions. The current proposal was developed in collaboration with our PPI lead and PPI advisory group (three family caregivers and one person with dementia). They contributed to the lay summary and on reading it commented that they found it ‘easy to follow’, ‘clear and concise’, ‘a very positive way forward’ and that ‘caregivers opinions are included’.

Our PPI Advisory Group will meet as a group at least four times including the manual adaptation and dissemination stages. The PPI Lead will bring their lived experience to the team, attending management meetings, provide feedback on written materials (including lay summaries and information sheets) to ensure clarity for a lay audience, help to interview the research assistant and devise the qualitative interviews. Additionally, they and another service user from our advisory group will be invited to be involved in coding of interview data to enhance credibility.

Our independent steering committee will include a service user with dementia and/or family carer / supporter and representatives from charities (e.g.'Age UK'). Dementia Pathfinders and Age UK have confirmed that they will support this project e.g. by stating that they will communicate findings with their organisation at all stages of the project and feedback views and ideas to the team at steering committee meetings.

We will invite caregivers and people with dementia to participate in dissemination through co-producing plain English summaries (based on NIHR guidance) that we will send to all study participants, acknowledging their contributions. The PPI Lead will be invited to co-author publications and co-present to diverse audiences (e.g. the UK dementia congress, which has a high proportion of lay attendees). Funding for PPI and voluntary sector payment, e.g. reimbursement for carer/ supporter and user time, travel, and refreshments (at INVOLVE rates), is included. Finally, there will be optional training for PPI provided at no extra cost to the funder by UCL's doctoral school (for example on presentation skills and communication) and the research team will offer training on coding qualitative manuscripts.

16. Monitoring

The study will be conducted according to Good Clinical Practice (GCP) Guidelines. Each Trust/Organisation will be supplied with an Investigator Site File and the PI will be responsible for overseeing the maintenance of this file in accordance with the SOP provided.

Monitoring: The Sponsor accepts responsibility for monitoring the trial; (i) "Ensuring the rights and well-being of the participants are protected; (ii) checking that the reported trial data are accurate, complete, and verifiable from source documents; and (iii) that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s)" (ICH-GCP 5.18.1). The study team will work closely with the monitor to determine the monitoring requirements for each Trust/Organisation involved in the trial and set out a schedule for monitoring accordingly in line with the Sponsor Monitoring SOP.

Recruitment Monitoring: Recruitment monitoring will take place during the study via teleconference. Meetings will be chaired by Trial personnel and minutes recorded and disseminated to sites. Site PIs and their researchers are encouraged to attend and will be given the opportunity to discuss their recruitment figures, challenges and successes. Frequent recruitment monitoring will give teams the opportunity to troubleshoot queries as they arise. The degree of recruitment monitoring will be proportionate to the risks associated with the trial.

17. Finance

The study is being funded by NIHR RfPB funding ID NIHR203524. They have agreed to provide a funding of £249,975.00 subject to obtaining ethical approval.

There are no conflicts of interest to declare.

18. Insurance

NELFT holds insurance against claims from participants for injury caused by their participation in the trial. Participants may be able to claim compensation if they can prove that NELFT has been negligent. However, clinical care teams involved in the research continue to have a duty

of care to the participant of the trial. NELFT does not accept liability for any breach in the clinicians duty of care, or any negligence on the part of NHS employees.

For the duration of the trial North East London NHS Foundation Trust agrees to indemnify all staff based at the Trust employed on the study, in full against liability, loss, claim or proceeding in respect of personal injury (whether fatal or otherwise), arising from or relating to Being kind to ourselves: A feasibility randomised controlled trial of Compassion Focused therapy (CFT) to improve depression and anxiety in Dementia when adhering to this Protocol. All staff working at other Trusts or organisations should be indemnified by their own employing NHS Trust. Publication policy

We will agree a publication strategy at the outset including authorship on papers. All proposed publications will be open access in accordance with NIHR guidance.

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We will agree a publication strategy at the outset including authorship on papers. All proposed publications will be open access in accordance with NIHR guidance.

20. Intellectual property

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to NELFT.

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