Study protocol

Full title of trial	Being kind to ourselves: A 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 12.0 (21.01.2026)
Sponsor:	North East London NHS Foundation Trust
Sponsor protocol number	
Funder (s):	NIHR-RfPB
ISRCTN / Clinicaltrials.gov no:	ISRCTN20868432
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.
Version 3.0	16/01/2024	Mel Melville	Updates identified after the local site initiation meeting including the removal of a site; clarity regarding recruitment targets; clarity around the specific order of events, a sentence to reflect the plan to share audio resources of meditation exercises.
Version 4.0	20/03/2024	Mel Melville	Addition of two new sites to the protocol.
Version 5.0	16/04/2024	Mel Melville	The eligibility criteria were updated to include informant reported symptoms of anxiety and/or depression; the consent process was updated to permit remote (verbal) consent; site participation expectations were added.
Version 6.0	24/07/2024	Mel Melville	Addition of one new site to the protocol. There has been a slight tweak in the language used to describe the timing of the 16 week follow-up assessment to allow for a small amount of flexibility.

Version 7.0	27/08/2024	Mel Melville	Addition of one new site to the protocol.
Version 8.0	05/09/2024	Mel Melville	An additional site has been incorporated into the protocol, offering only online CFT sessions. As a result, the protocol has been revised to accommodate this change.
Version 9.0	29/10/2024	Mel Melville	The sponsor representative at NELFT has changed and the protocol has been updated to reflect this. The Principal Investigator at NELFT has changed.
Version 10.0	03/01/2025	Mel Melville	The trial procedures section has been updated and an appendix has been added to reflect the inclusion of a post-diagnostic survey. The protocol has also been updated to incorporate modifications to the inclusion criteria pertaining to the Clinical Dementia Rating (CDR) Scale and the Hospital Anxiety and Depression Scale (HADS).
Version 11.0	23/09/2025	Mel Melville	The sponsor representative at NELFT has changed and the protocol has been updated to reflect this. Updated the protocol throughout to reflect the transition from a feasibility study to full RCT, this includes changes to the main objectives, recruitment targets, sample size and analysis plan. The study processes remain unchanged.

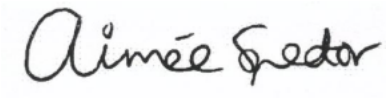
			The inclusion criteria has been revised to require participants to have sufficient hearing to engage in group discussions (with or without hearing aids).
Version 12.0	21/01/2026	Mel Melville	This amendment clarifies completed recruitment numbers from the feasibility study, including accruals of people with dementia, carers, qualitative interviews, and survey respondents. Carer recruitment estimates have been updated based on feasibility data, with corresponding updates to the overall recruitment figures.

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)

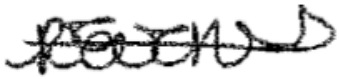


21/01/2026

Aimee Spector

Signature (s) Date

Statistician



21/01/2026

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Signature (s) Date

Sponsor

21/01/2026

NELFT
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Signature Date

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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. Evaluate the efficacy of CFT in improving depression (primary outcome, measured by the Cornell Scale for Depression in Dementia), anxiety, quality of life, cognition, self-compassion, and the caregiver-patient relationship in people with dementia, compared to TAU; at 16 weeks and 6 months. 2. Evaluate caregiver burden and caregiver perception of the caregiver-patient relationship (if caregiver is available to participate), compared to TAU, at 16 weeks and 6 months. 3. Assess the cost-effectiveness of group CFT compared to TAU at 16 weeks by estimating the incremental cost per 'Quality Adjusted Life Year' (QALY) gained. 4. Explore a) differences in outcomes between face-to-face and online groups, b) participants' preferences for delivery format and c) potential predictors of success in the intervention (such as baseline mood, cognitive impairment, engagement (or not) of a caregiver and demographic factors) as part of a secondary, exploratory analysis.
Type of trial:	Multi-site, parallel-arm, randomised controlled trial of group CFT compared to "Treatment as usual" (TAU) in participants with dementia and depression or anxiety.
Trial design and methods:	304 people with mild to moderate dementia and anxiety and/or depression will be recruited to a two-armed RCT (CFT plus TAU vs TAU). We anticipate recruiting approximately 138 carers to the study, carer participation is encouraged but not required. 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. Carers, if available, will be invited to a brief workshop focussing on principles of CFT and supporting the person at home.
Estimated total trial duration:	36 months
Planned trial sites:	North-East London NHS Foundation Trust, Black Country Healthcare NHS Foundation Trust, Oxford Health NHS Foundation Trust, Central and North West London NHS

	Foundation Trust, Lincolnshire Partnership NHS Foundation Trust. Approximately ten additional NHS Trusts will be identified to ensure adequate recruitment and geographical diversity.
Total number of participants planned:	304
Main inclusion/exclusion criteria:	Main 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. Have capacity to consent to take part in research; 3. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR) Scale, a score of 0.5, 1, or 2 (Morris, 1997). 4. Experience symptoms of depression and/or anxiety as determined by either: • A HADS score ≥ 8 on the anxiety and/or depression subscale (Zigmond & Snaith, 1983), OR • A HADS score of 5–7, accompanied by evidence of low mood as reported by a caregiver or clinician, OR • Significant psychological distress, as assessed by a clinician or researcher, regardless of the HADS score. 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. Have sufficient hearing to engage in group discussions (with or without hearing aids). 8. Are not participating in another interventional research programme concurrently; 9. Aged 18 and over; 10. 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:	**Quantitative data**: Analysis will be by linear mixed modelling, taking account of clustering by therapy group in the treatment arm, adjusting for baseline scores, allocation group and stratification factors (site and delivery format) and pre-defined

covariates. Primary analysis will be considered at the 16-week endpoint. All analyses will be done on an intent to treat basis and per-protocol will be undertaken as secondary analyses

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,.Building on this evidence, we conducted a feasibility RCT (n=73) of group CFT for people with dementia experiencing depression and/or anxiety. The findings demonstrated that the intervention was feasible and acceptable to deliver within NHS settings, with low attrition and positive feedback from participants, carers and facilitators. On this basis, we are now progressing to a full RCT, with the feasibility data serving as an internal pilot.

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	Given that this was not a problem throughout the feasibility study, we expect that this will not be a barrier to CFT administration. 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, where possible, 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	Recruitment was not a problem in the feasibility phase. We over-recruited, enrolling 73 participants against our original target of 50. This indicates strong demand for the intervention and confirms that our recruitment processes are both practical and scalable for the full RCT. Our contingency plan is expanding to include up to fifteen trusts and continue 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 an RCT where participants will be randomly allocated to one of two arms: Twelve hours of virtual or face-to-face group CFT plus treatment as usual (TAU) or TAU. The aims/objectives will be to:

1. Evaluate the efficacy of CFT in improving depression (primary outcome, measured by the Cornell Scale for Depression in Dementia, anxiety, quality of life, cognition, self-compassion, and the caregiver-patient relationship in people with dementia, compared to TAU; at 16 weeks and 6 months.
2. Evaluate caregiver burden and caregiver perception of the caregiver-patient relationship (if caregiver is available to participate), compared to TAU, at 16 weeks and 6 months.
3. Assess the cost-effectiveness of group CFT compared to TAU at 16 weeks by estimating the incremental cost per 'Quality Adjusted Life Year' (QALY) gained.
4. Explore
    a) differences in outcomes between face-to-face and online groups,
    b) participants' preferences for delivery format and
    c) potential predictors of success in the intervention (such as baseline mood, cognitive impairment, engagement (or not) of a caregiver and demographic factors) as part of a secondary, exploratory analysis.

5. Trial design

This RCT follows directly from the NIHR RfPB-funded feasibility trial (NIHR203524) of group CFT for people with dementia and depression and/or anxiety (Protocol Version 10 and earlier). All trial procedures, recruitment pathways, and intervention methods remain unchanged. The feasibility phase data (n=73) will serve as an internal pilot and will be incorporated into the final trial dataset for analysis. Protocol Version 11 onwards applies to the full trial phase; all documentation and publications relating specifically to the feasibility phase will reference Version 10 and earlier.

5.1 Preparation of trial materials

All study materials developed for the feasibility trial (Protocol Version 10 and earlier) will be used in this RCT, with only minor revisions to reflect the transition from feasibility to a fully powered trial (e.g., updated participant numbers, timelines, and objectives).

5.2 Training of facilitators in CFT delivery

Professionals in the participating trusts will attend a two-day CFT training (live online or a recording on-demand training). Professionals will also be expected to watch an interactive video focused on adapting CFT for people with dementia. Support around reasonable adjustments to the materials in order for them to be delivered to the ability level of the participants will also be provided to group facilitators.

5.3 Randomised Controlled Trial

This will be a single blind, randomised controlled trial of group CFT plus TAU versus TAU. 304 participants will be randomised to either the intervention group (CFT plus TAU) or control group (TAU). Randomisation will occur after baseline assessments are completed. The split of participants in each arm will be approximately 140:164 (TAU:INTERVENTION), with participants in the intervention arm allocated to one CFT group with up to seven participants in each group. The uneven allocation ratio is due to clustering only being present in the intervention arm.

The study adopts a dyadic design, with people living with dementia as the primary unit of randomisation and carers or supportive others invited to participate where available. Dyadic participation is encouraged to enable assessment of secondary relational and carer-related outcomes; however, carer involvement is not mandatory, and participants may be enrolled and randomised regardless of whether a carer takes part. The trial is powered on a primary outcome for people with dementia only.

<u>Trial Recruitment Targets</u>

A total randomised sample of 304 participants is required to provide adequate power for the trial (refer to Section 11.1, Sample Size Calculation, Protocol v11). Given that 73 participants have already been recruited and randomized during the feasibility phase, which serves as an internal pilot for the full RCT, an additional 231 participants are required.

Regarding carer participation, the feasibility study saw a recruitment rate of 60% (44 carers from 73 participants). Based on this rate, we conservatively anticipate recruiting approximately 94 additional carers for the RCT (46% of the total RCT sample). It should be noted that the study is not powered for carer-related outcomes; these are secondary measures, and the figure provided represents a projected recruitment rate rather than a formal target.

Combining participant and carer recruitment this requires 164 people living with dementia and 74 of their respective carers (238 in total) for the intervention arm and 140 participants with dementia and 64 of their respective carers (204 in total) for the TAU arm.

Total Recruitment Figures

During the feasibility phase, data collection included qualitative interviews with 56 participants and a supplemental survey completed by 129 participants (refer to Section 8.10). When combining these figures with the primary RCT sample (n = 304) and the carer recruitment (n = 138), we anticipate a total of 627 recruitment events across the project. Please note that this total is an estimate and may fluctuate based on the actual rate of carer enrolment.

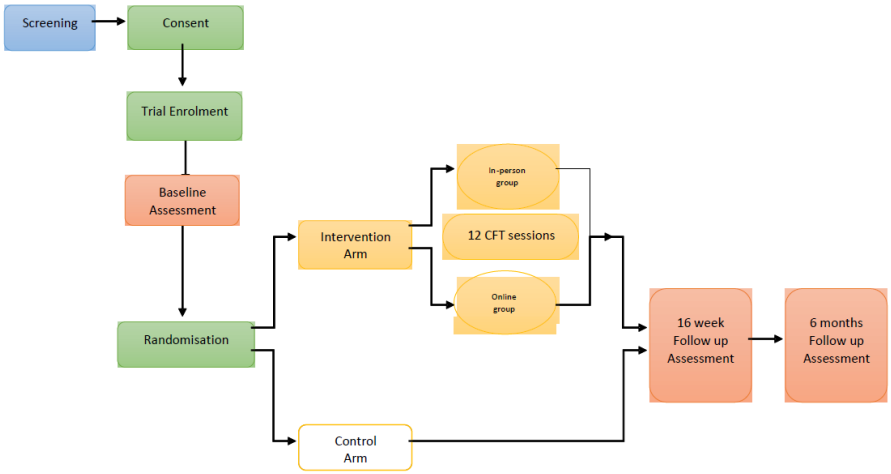
The duration of the intervention will be 15 weeks, consisting of 12 CFT therapy sessions. Given that it can prove difficult to always fit the 12 sessions into 12 consecutive weeks (due to factors such as weather issues / therapist annual leave, strikes, illness), the additional 3 weeks provides a buffer and may increase the likelihood that participants could receive all 12 sessions. There will be assessments at baseline, at the end of the intervention at approximately 16 weeks and at 6 months follow-up. The aim is for randomisation to be complete within 2 weeks of baseline data collection. This process will be reviewed as part of the analysis, to decipher whether collection can be done within this time-frame.

Participating NHS sites will each be given a recruitment target of 29. This figure comprises 20 participants with mild-to-moderate dementia and symptoms of anxiety and/or depression (to allow for 10 people in each arm of the trial) and at least 9 carers/supportive others.

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

Figure 1

Trial schematic diagram



6. Selection of Participants

6.1 Inclusion criteria

- Meet 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 following:
  - A confirmed dementia diagnosis based on DSM-IV criteria for any type of dementia, AND
  - A Clinical Dementia Rating (CDR) score of 0.5, 1, or 2 (Morris, 1997).
- Experience symptoms of depression and/or anxiety as determined by either:
  - A HADS score ≥ 8 on the anxiety and/or depression subscale (Zigmond & Snaith, 1983), OR
  - A HADS score of 5–7, accompanied by evidence of low mood as reported by a caregiver or clinician, OR
  - Significant psychological distress, as assessed by a clinician or researcher, regardless of the HADS score.
- Have capacity to consent to take part in research;
- Can communicate in English,
- Have access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group;
- Are not participating in another interventional research programme concurrently.
- Have sufficient hearing to engage in group discussions (with or without hearing aids).
- Aged 18 and over
- 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 North East London NHS Foundation Trust (NELFT), the Black Country Healthcare NHS Foundation Trust, Oxford Health NHS Foundation Trust, Central and North West London NHS Foundation Trust and Lincolnshire Partnership NHS Foundation Trust. We will open additional sites during the course of the project to support recruitment. 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 include 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. After each therapy session, the participants will receive written summaries describing the key topics covered within the hour, an audio recording of a meditation / compassion building exercise and the relevant script for that exercise. These audio recordings are based on scripts provided on the Balanced Mind website that are used across Compassion Focused Therapy classes. Some of these audio meditation / compassionate building exercises have been edited to make them more relevant for people with dementia (i.e less silences in the meditation as this has been reported to be uncomfortable for some). All recordings have been prepared and recorded by members of the research team as examples and do not contain participant identifiable information. The PPI team have reviewed all the audio recordings and suggested no changes. The audio recordings are available and will be provided to each participating site.

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 a confirmed dementia diagnosis based on DSM-IV criteria for dementia of any type, and a Clinical Dementia Rating (CDR) score of 0.5, 1, or 2 (Morris, 1997). The CDR is used to measure cognition and provide a global rating of dementia severity as part of the general background information. The CDR Scale assesses dementia severity on a scale from 0 to 3. Participants with a confirmed dementia diagnosis who score 0.5 on the CDR are included, acknowledging that some individuals may underreport symptoms or have difficulties expressing problems with cognition or activities of daily living. This ensures individuals with a clear dementia diagnosis are not excluded based solely on the CDR score, while still preventing the inclusion of those with severe dementia (CDR > 2).

The participants will also experience symptoms of depression and/or anxiety as measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The HADS consists of two subscales: depression and anxiety, each containing seven items. This scale has been designed to minimize the impact of physical illness on the total score. A score of 8 or greater on either the depression or anxiety subscale of the HADS indicates the presence of clinically significant symptoms of depression and/or anxiety. For participants with a HADS score between 5 and 7, the following questions will be asked of the caregiver:

- Have you noticed a change in mood (e.g., irritability, frustration, low motivation, anxiety, excessive worry, excessive sleeping) in the person that you support since their dementia diagnosis? YES/NO
- In your personal opinion, is this deterioration in mood having a negative impact on the person you support? YES/NO

If the caregiver answers YES to both questions and the HADS score is between 5 and 7, the person with dementia will be eligible to take part in the study.

The patient record will also be used to confirm the presence of depression and/or anxiety and the outcome recorded using the following criteria:

- Is there evidence of low mood within the participants NHS notes (seek the following key words: low mood/ anxiety/ anxious/ depressed/ depression) YES/NO

If the answer is YES and the HADS score is 5-7, the person with dementia is eligible to take part in the study. Confirming the presence of depression and/or anxiety via the patient record is required for people with dementia who do not have a caregiver.

In cases where the clinician or researcher determines that the participant is experiencing significant psychological distress, an upper HADS score is not required for inclusion. This adjustment reflects clinical practice, as the HADS is not always a reliable measure of mood, particularly in dementia participants whose mood can fluctuate alongside cognitive changes.

By allowing clinical judgment to take precedence, we enhance the ability to include participants who may benefit from the study despite potential underreporting or inconsistent mood scoring, especially in cases where mood fluctuations are common.

This flexible approach—incorporating clinical assessment, the carer's perspective and patient record review—acknowledges the complexities of self-reporting in individuals with dementia and provides a more comprehensive assessment of their psychological well-being.

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 informed consent will be received from the participant and the carer / supporter.
Consent for participants with dementia and their carers can be received either in person (in writing or verbally) or remotely (verbally). In remote scenarios, the researcher will engage with the participant/carer over the phone or via an online conference platform, discussing each element of the consent form verbally, marking the researcher initials next to each consent statement to indicate participant consent and signing off the form on the ICF as indicated. One copy of the signed consent form will be provided to the participant, one will be securely stored in a locked cabinet at the research site, and one will be added to the participant's medical records. 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 32 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 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). Making use of our learning from the feasibility trial, we will if necessary revise the CSRI questions, for instance to clarify wording of items or interviewer instructions, or to remove resource use items that have high levels of missingness or indicate very low levels of use (suggesting lack of relevance to the population). We will ensure that the data already collected is comparable with data collected in the full RCT.

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	~ 15 minutes

		reliability and validity have been demonstrated.	
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	~ 10 minutes

		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).	
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 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
Resource use	The Client Service Receipt Inventory (CSRI)	The Client Service Receipt Inventory (CSRI) is used extensively in economic studies of dementia: it gathers data on accommodation, medication, use of public, private	~ 20 minutes

	(Chisholm et al., 2000)	and voluntary sector services, and inputs from carers / supporters.	

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 (for sites offering online delivery only, participants will not be asked to indicate a preference) From this the researcher will construct “randomisation blocks” based on their ability to attend either format. Once the recruiting site reaches approximately 13 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 ~7 participants per

group, we require approximately 13 participants (approx. 6 TAU, 7 Intervention) per "randomisation block" However, if required, smaller groups may be randomised and constructed. 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 13 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 1:1.17 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 (face to face or online).

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 sent via email to the unblinded researcher and relayed to the participants, arrangements can then be made to begin the intervention or for treatment as usual. The intervention should begin 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 and where possible a different researcher will conduct future assessments. Due to the unequal allocation ratio the trial statistician will not be blinded.

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, audio files of the meditation/ compassion building exercises 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).

8.5 Follow up data collection

Follow-up assessments will take place at approximately 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 must be completed within approximately 2 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.

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8.6 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. Sensitivity analysis around this will be considered. .

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.

8.10 Post-diagnostic Survey

A survey will be conducted to explore how post-diagnostic dementia support is delivered across NHS memory services, with a particular focus on the implementation and utilisation of Cognitive Stimulation Therapy (CST). The survey addresses the types of post-diagnostic support offered, satisfaction with current services, and challenges in CST delivery. Findings will provide valuable insights into barriers and facilitators of CST implementation and broader trends in dementia care, supporting the study's objective to improve post-diagnostic services. The survey is coordinated solely by NELFT, no additional involvement from other sites is required. Further details on the survey are outlined in the Appendix.

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.

9.3 Post-diagnostic Survey

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)..

UCL is the data controller for the trial. All quantitative data will be entered onto the REDCap database and will be held on the REDCap server. The data held on the REDCap server will be pseudonymised. Personal identifiable information will be stored securely at local sites. Sites will process, store and dispose of self-report data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. Paper data will be stored in a locked filing cabinet 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. In the unlikely event that the researcher's laptop fails or REDCap is unavailable, paper completion of the CRF is required. The local research team will be asked to enter the data into REDCap at their earliest opportunity, scan the paper CRF and save it in their electronic site files.

ata entered directly onto the REDCap electronic data capture system, 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

A total randomised sample of 304 will provide 90% power to detect a 0.4 standardised effect on the Cornell scale at a 5 % significance level [40]. This accommodates a 20% attrition rate, a 0.4 assumed R^2 of covariates within the model and an intervention arm design effect of 1.168 (5 completers per cluster, ICC 0.04 and a 0.2 cluster variation). This results in an unequal allocation ratio of 1:1.17 (TAU:Intervention). As 73 participants have already been

recruited and randomised as part of the feasibility trial and the data for this is being treated as an internal pilot for the full RCT, this would require a further 231 participants to be recruited.

11.2 Statistical analysis

11.2.1 Quantitative Analysis

All quantitative analysis will be undertaken on an intention to treat basis and will be undertaken at NWORTH Clinical Trials Unit, led by Co-applicant (RE). A full statistical analysis plan will be written and agreed by the trial team prior to the completion of data collection. This will be made available for comment by the independent committees. .

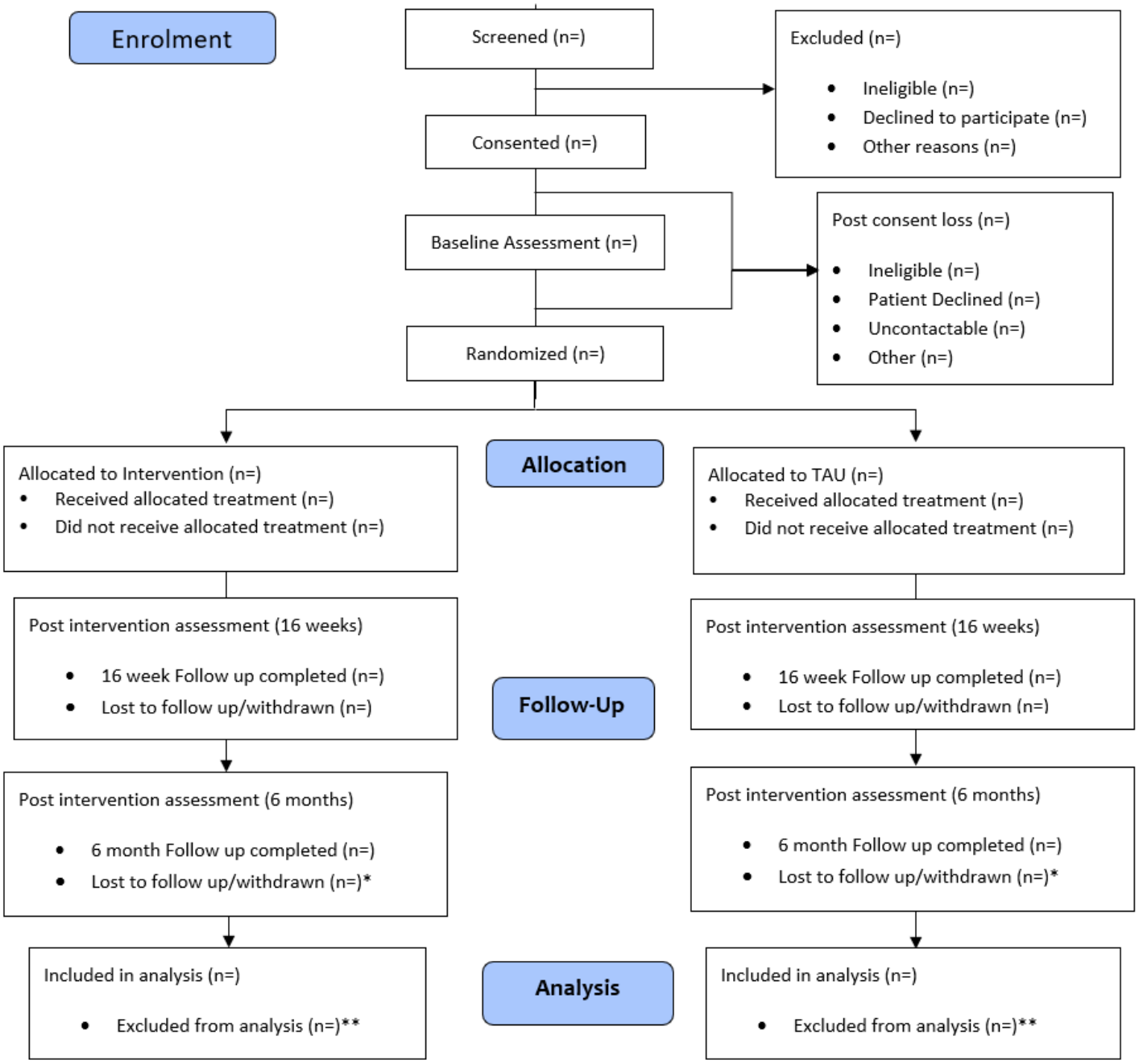
11.2.2 Summary of baseline data and follow-up of participants

Baseline characteristics will be summarized presented overall and split by treatment group (intervention and control). Descriptive statistics will be produced for all of the outcome variables within the trial at all time points.

Categorical variables will be presented using counts and percentages and continuous variables will be presented with means, standard deviations and ranges. Any non-normally distributed continuous variables will be reported using medians and interquartile ranges.

The CONSORT information (figure 2) will be completed with values relating to participant numbers.

Figure 2
Consort Flow Diagram



*reasons given where possible

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

Reasons for ineligibility

Inclusion criteria:

- Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type
- Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR) Scale, a score of 0.5, 1, or 2 (Morris, 1997).
- Experience symptoms of depression and/or anxiety as determined by either:
    - A HADS score ≥ 8 on the anxiety and/or depression subscale (Zigmond & Snaith, 1983), OR
    - A HADS score of 5–7, accompanied by evidence of low mood as reported by a caregiver or clinician, OR
    - Significant psychological distress, as assessed by a clinician or researcher, regardless of the HADS score.
- Have capacity to consent to take part in research
- Can communicate in English
- Have sufficient hearing to engage in group discussions (with or without hearing aids).
- Have access to WiFi, enabling them to partake in online CFT groups, OR the ability to attend a face-to-face group;
- Are not participating in another interventional research programme concurrently.
- Aged 18 and over

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
- Does not have the time
- Other

11.2.3 Analysis of Primary outcome

Analysis of the primary outcome, The Cornell Scale at 16-weeks, will be by linear mixed modelling, taking account of clustering by therapy group in the treatment arm, adjusting for baseline scores, allocation group and stratification factors (site and delivery format). Any additional covariates will be assessed for their appropriateness and defined a priori. All analyses will be performed on an intent to treat basis and per-protocol will be undertaken as secondary analyses. Patterns of missing data will be assessed, and multiple imputation will be employed to address missing outcomes where appropriate. Model testing and missing data

assumptions via sensitivity analyses will be undertaken. All treatment effect estimates will be presented with 95% confidence intervals

11.2.4 Analysis of Secondary outcomes

All other collected outcomes described in section 8.2 and 8.5 will be assessed following the same analysis model as the primary analysis where possible

12. Health Economics

12.1 Health economic analysis

The aim is 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.

Primary outcome will be 16-week QALY gain using utilities derived from mapping EQ-5D-5L to EQ-5D-3L (Hernández Alava et al., 2023); and secondary outcome will be a 2.5-point difference at 16 weeks on Cornell depression score and 16-week QALY gain derived from DEMQOL-U (Rowen et al., 2012 ; Smith et al., 2005).

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.

12.3 Resource use and costs

The economic evaluation will take (i) a health and social care and (ii) a societal perspective (including unpaid care costs).

Besides QALYs, the economic evaluation 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.

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).

Primary analyses will consist of cost and outcome regressions that account for skew in these variables (at 16 weeks), clustering effects and potential residual correlations between these variables, include factors for allocation group, stratification variables and control for baseline scores (utilities, CDS, costs) and any other baseline covariates agreed upon a priori. Sensitivity analyses will explore key assumptions underlying costs, and probabilistic sensitivity analyses will explore impacts on the cost-effectiveness decision given sampling uncertainty (Glick 2007, Drummond 2015). The base-case analyses will consider health and social care costs. Secondary analyses will examine societal costs including unpaid care costs and health and social care costs and societal costs at 6 months.

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 quarterly 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 six times throughout the project. 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 and help to interview the new research assistant.

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).

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. NIHR209908 – They have agreed to provide a funding of £500,000

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 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.

19. 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.

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.

21. References

Alexopoulos, G. S., Abrams, R. C., Young, R. C., & Shamoian, C. A. (1988). Cornell scale for depression in dementia [Article]. *Biological Psychiatry (1969)*, *23*(3), 271–284. https://doi.org/10.1016/0006-3223(88)90038-8

Allain, H., Schück, S., Bentué-Ferrer, D., Bourin, M., Vercelletto, M., Reymann, J.-M., & Polard, E. (2000). Anxiolytics in the Treatment of Behavioral and Psychological Symptoms of Dementia [Article]. *International Psychogeriatrics*, *12*(S1), 281–289. https://doi.org/10.1017/S1041610200007158

Aminzadeh, F., Byszewski, A., Molnar, F. J., & Eisner, M. (2007). Emotional impact of dementia diagnosis: Exploring persons with dementia and caregivers' perspectives [Article]. *Aging & Mental Health*, *11*(3), 281–290. https://doi.org/10.1080/13607860600963695

American Psychiatric Association (APA) (1994). Diagnostic and statistical manual of mental disorders (4th ed.) (DSM-IV), Washington DC: American Psychiatric Association.

Braun, V., & Clarke, V. (2019). Reflecting on reflexive thematic analysis [Article]. *Qualitative Research in Sport, Exercise and Health*, *11*(4), 589–597. https://doi.org/10.1080/2159676X.2019.1628806

Cheston, R. (2005). Shame and avoidance: issues of remembering and forgetting with people with dementia. *Context: the Magazine for Family Therapy and Systemic Practice*, *77*, 19-22.

Chisholm, D., Knapp, M. R., Knudsen, H. C., Amaddeo, F., Gaite, L., & van Wijngaarden, B. (2000). Client Socio-Demographic and Service Receipt Inventory--European Version: development of an instrument for international research. EPSILON Study 5. European Psychiatric Services: Inputs Linked to Outcome Domains and Needs. *The British journal of psychiatry. Supplement*, (39), s28–s33. https://doi.org/10.1192/bjp.177.39.s28

Collins, R. N., Gilligan, L. J., & Poz, R. (2018). The Evaluation of a Compassion-Focused Therapy Group for Couples Experiencing a Dementia Diagnosis [Article]. *Clinical Gerontologist*, *41*(5), 474–486. https://doi.org/10.1080/07317115.2017.1397830

Craig, C., Hiskey, S., Royan, L., Poz, R., & Spector, A. (2018). Compassion focused therapy for people with dementia: A feasibility study [Article]. *International Journal of Geriatric Psychiatry*, *33*(12), 1727–1735. https://doi.org/10.1002/gps.4977

Craig, C., Hiskey, S., & Spector, A. (2020). Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations [Article]. *Expert Review of Neurotherapeutics*, *20*(4), 385–400. https://doi.org/10.1080/14737175.2020.1746184

Dementia: assessment, management and support for people living with dementia and their carers NICE guideline. (2018). www.nice.org.uk/guidance/ng97

Dudas, R., Malouf, R., McCleery, J., & Dening, T. (2018). Antidepressants for treating depression in dementia [Article]. *Cochrane Database of Systematic Reviews*, *8*(8), CD003944–CD003944. https://doi.org/10.1002/14651858.CD003944.pub2

Gibbons, L. E., Teri, L., Logsdon, R., Mccurry, S. M., Kukull, W., Bowen, J., Mccormick, W., & Larson, E. (2002). Anxiety Symptoms as Predictors of Nursing Home Placement in Patients With Alzheimer's Disease. In *Journal of Clinical Geropsychology* (Vol. 16, Issue 4).

Gilbert, P. (2009). Introducing compassion-focused therapy [Article]. *Advances in Psychiatric Treatment : The Royal College of Psychiatrists' Journal of Continuing Professional Development*, *15*(3), 199–208. https://doi.org/10.1192/apt.bp.107.005264

Henderson, C., Knapp, M., Nelis, S. M., Quinn, C., Martyr, A., Wu, Y.-T., Jones, I. R., Victor, C. R., Pickett, J. A., Hindle, J. V., Jones, R. W., Kopelman, M. D., Matthews, F. E., Morris, R. G., Rusted, J. M., Thom, J. M., Clare, L., Clare, L., Jones, I. R., … Thom, J. M. (2019). Use and costs of services and unpaid care for people with mild-to-moderate dementia: Baseline results from the IDEAL cohort study [Article]. *Alzheimer's & Dementia : Translational Research & Clinical Interventions*, *5*(1), 685–696. https://doi.org/10.1016/j.trci.2019.09.012

Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L) [Article]. *Quality of Life Research*, *20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Hernández Alava, M., Pudney, S., & Wailoo, A. (2023). Estimating the Relationship Between EQ-5D-5L and EQ-5D-3L: Results from a UK Population Study. *PharmacoEconomics*, *41*(2), 199–207. https://doi.org/10.1007/s40273-022-01218-7

Jones, K., Weatherly, H. L. A., Birch, S., Castelli, A., Chalkley, M. J., Dargan, A., Forder, J., Gao, M., Hinde, S., Markham, S., Ogunleye, D., Premji, S., & Roland, D. (2022). *Unit Costs of Health and Social Care 2022* [Book]. Personal Social Services Research Unit, University of Kent at Canterbury.

Kuring, J. K., Mathias, J. L., & Ward, L. (2020). Risk of Dementia in persons who have previously experienced clinically-significant Depression, Anxiety, or PTSD: A Systematic Review and Meta-Analysis. In *Journal of Affective Disorders* (Vol. 274, pp. 247–261). Elsevier B.V. https://doi.org/10.1016/j.jad.2020.05.020

Kwak, Y. T., Yang, Y., & Koo, M.-S. (2017). Anxiety in Dementia. *Dementia and Neurocognitive Disorders*, *16*(2), 33. https://doi.org/10.12779/dnd.2017.16.2.33

Malterud, K., Siersma, V. D., & Guassora, A. D. (2016). Sample Size in Qualitative Interview Studies [Article]. *Qualitative Health Research*, *26*(13), 1753–1760. https://doi.org/10.1177/1049732315617444

Marmarosh, C., Holtz, A., & Schottenbauer, M. (2005). Group Cohesiveness, Group-Derived Collective Self-Esteem, Group-Derived Hope, and the Well-Being of Group Therapy Members [Article]. *Group Dynamics*, *9*(1), 32–44. https://doi.org/10.1037/1089-2699.9.1.32

May, C., Finch, T., Mair, F., Ballini, L., Dowrick, C., Eccles, M., Gask, L., MacFarlane, A., Murray, E., Rapley, T., Rogers, A., Treweek, S., Wallace, P., Anderson, G., Burns, J., & Heaven, B. (2007). Understanding the implementation of complex interventions in health care: The normalization process model [Article]. *BMC Health Services Research*, *7*(1), 148–148. https://doi.org/10.1186/1472-6963-7-148

McDermott, O., Charlesworth, G., Hogervorst, E., Stoner, C., Moniz-Cook, E., Spector, A., Csipke, E., & Orrell, M. (2019). Psychosocial interventions for people with dementia: a synthesis of systematic reviews [Article]. *Aging & Mental Health*, *23*(4), 393–403. https://doi.org/10.1080/13607863.2017.1423031

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D., & Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance [Article]. *BMJ (Online)*, *350*(mar19 6), h1258–h1258. https://doi.org/10.1136/bmj.h1258

Morris, J. C. (1997). Clinical Dementia Rating: A Reliable and Valid Diagnostic and Staging Measure for Dementia of the Alzheimer Type [Article]. *International Psychogeriatrics*, *9*(S1), 173–176. https://doi.org/10.1017/S1041610297004870

Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., Cummings, J. L., & Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: A Brief Screening Tool For Mild Cognitive Impairment [Article]. *Journal of the American Geriatrics Society*, *53*(4), 695–699. https://doi.org/10.1111/j.1532-5415.2005.53221.x

NHS Business Services Authority, *Prescription cost analysis - England 2021/2022. Statistical Summary Tables - Financial Year 2021/22 - National level*. 2022, NHS Business Services Authority.

NHS England, *National Cost Collection: National schedule of NHS costs - Year 2021/22 - NHS trusts and NHS foundation trusts*. 2023, NHS England: London.

Noone, D., Stott, J., Aguirre, E., Llanfear, K., & Spector, A. (2019). Meta-analysis of psychosocial interventions for people with dementia and anxiety or depression [Article]. *Aging & Mental Health*, *23*(10), 1282–1291. https://doi.org/10.1080/13607863.2018.1495177

O'Cathain, A., Croot, L., Duncan, E., Rousseau, N., Sworn, K., Turner, K. M., Yardley, L., & Hoddinott, P. (2019). Guidance on how to develop complex interventions to improve health and healthcare [Article]. *BMJ Open*, *9*(8), e029954–e029954. https://doi.org/10.1136/bmjopen-2019-029954

Orgeta, V., Qazi, A., Spector, A., & Orrell, M. (2015). Psychological treatments for depression and anxiety in dementia and mild cognitive impairment: Systematic review and meta-analysis. In *British Journal of Psychiatry* (Vol. 207, Issue 4, pp. 293–298). Royal College of Psychiatrists. https://doi.org/10.1192/bjp.bp.114.148130

Pfadenhauer, L. M., Gerhardus, A., Mozygemba, K., Lysdahl, K. B., Booth, A., Hofmann, B., Wahlster, P., Polus, S., Burns, J., Brereton, L., & Rehfuess, E. (2017). Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework [Article]. *Implementation Science : IS*, *12*(1), 21–21. https://doi.org/10.1186/s13012-017-0552-5

Prince M, Knapp M, Guerchet M, McCrone P, Prina M, Comas-Herrera M, Adelaja R, Hu B, King B, Rehill D, Salimkumar D. Dementia UK: update. Alzheimer's Society. 2014.

Raes, F., Pommier, E., Neff, K. D., & Van Gucht, D. (2011). Construction and factorial validation of a short form of the Self-Compassion Scale [Article]. *Clinical Psychology and Psychotherapy*, *18*(3), 250–255. https://doi.org/10.1002/cpp.702

Rowen, D., Mulhern, B., Banerjee, S., van Hout, B., Young, T. A., Knapp, M., Smith, S. C., Lamping, D. L., & Brazier, J. E. (2012). Estimating Preference-Based Single Index Measures for Dementia Using DEMQOL and DEMQOL-Proxy [Article]. *Value in Health*, *15*(2), 346–356. https://doi.org/10.1016/j.jval.2011.10.016

Shankar, K. K., Walker, M., Frost, D., & Orrell, M. W The development of a valid and reliable scale for rating anxiety in dementia (RAID) [Article]. *Aging & Mental Health*, *3*(1), 39–49. https://doi.org/10.1080/13607869956424

Smith, S., Lamping, D., Banerjee, S., Harwood, R., Foley, B., Smith, P., Cook, J., Murray, J., Prince, M., Levin, E., Mann, A., & Knapp, M. (2005). Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology [Article]. *Health Technology Assessment (Winchester, England)*, *9*(10). https://doi.org/10.3310/hta9100

Spector, A., Thorgrimsen, L.,Woods, B., Royan, L., Davies, S., Butterworth, M., & Orrell,M (2003). Efficacy of an evidence-based cognitive stimulation therapy programme for people with dementia: Randomised controlled trial [Article]. *British Journal of Psychiatry*, *183*(3), 248–254. https://doi.org/10.1192/bjp.183.3.248

Spector, A., Charlesworth, G., King, M., Lattimer, M., Sadek, S., Marston, L., Rehill, A., Hoe, J., Qazi, A., Knapp, M., & Orrell, M. (2015). Cognitive-behavioural therapy for anxiety in dementia: pilot randomised controlled trial. *The British journal of psychiatry : the journal of mental science*, *206*(6), 509–516. https://doi.org/10.1192/bjp.bp.113.140087

Spruytte, N., Van Audenhove, C., Lammertyn, F., & Storms, G. (2002). The quality of the caregiving relationship in informal care for older adults with dementia and chronic psychiatric patients [Article]. *Psychology and Psychotherapy*, *75*(3), 295–311. https://doi.org/10.1348/147608302320365208

Wolgensinger, L. (2015). Cognitive behavioral group therapy for anxiety: recent developments [Article]. *Dialogues in Clinical Neuroscience*, *17*(3), 347–351. https://doi.org/10.31887/DCNS.2015.17.3/lwolgensinger

Zarit, S.H., Orr, N., & Zarit, J.M. (1985). The Hidden Victims of Alzheimer's Disease: Families Under Stress.

Zigmond, A. S., & Snaith, R. P. (1983). Hospital Anxiety and Depression Scale (HADS) [Database record]. PsycTESTS.

22. Appendix 1

Title:
State of Post-Diagnostic Support Including Cognitive Stimulation Therapy (CST) in the UK: Survey

Purpose:
A survey to explore post-diagnostic dementia support in NHS memory services, with a focus on the delivery and utilisation of Cognitive Stimulation Therapy (CST).

Survey Design:
The survey comprises up to 40 closed- and open-ended questions covering:

1. Types of post-diagnostic support offered.
2. CST delivery practices and challenges.
3. Barriers and facilitators of CST implementation.

Questions were iteratively reviewed for relevance and clarity. The survey is hosted on the GDPR-compliant Qualtrics platform.

Link to survey: https://brainplus.qualtrics.com/jfe/form/SV_8BUTWwzLOzQWKaO

Recruitment:
Eligible respondents (e.g., psychologists, occupational therapists, nurses) will be invited via professional networks and email outreach. Memory clinics across the UK will also be contacted. Services not offering CST are encouraged to complete initial questions.

Key distribution channels:

- Mental Health Network NHS Confederation Bulletin
- British Psychological Society Faculty of Psychiatry for Older People
- NHS Healthcare Leaders Bulletin

Incentives and Confidentiality:

- Participants can enter a prize draw to win a £25 voucher (via a separate form).
- Survey responses are anonymised, with data stored securely on Qualtrics.