RESEARCH PROTOCOL

Title: A multi-centre effectiveness and cost-effectiveness superiority Randomised Controlled Trial of a group-based intervention for family carers of people living with dementia, called Empowered Conversations, compared to Treatment As Usual

Protocol version 1.1
Date: 23/02/2026

Protocol prepared in accordance with the SPIRIT guidelines, which recommend standard protocol items for interventional trials.

Protocol changes:

Protocol version and date	**Changes**
V1.0 17/12/2025	N/A
V1.1 23/02/2026	Clarified processes: - Participant ID provision - End of study definition - Change of participation, including more detail regarding capacity protocol Typographical and formatting error corrections

Contents

Abbreviations

AE	Adverse Event
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CI	Chief Investigator
CMHT	Community Mental Health Team
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTIMP	Clinical trial of an investigational medical product
CTU	Clinical Trials Unit
DEEP	Dementia Engagement and Empowerment project
dHCI	Disaggregated hyperconverged infrastructure
DMEC	Data Monitoring and Ethics Committee
DoR	Delegations of Responsibilities
EC	Empowered Conversations
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GIAM	The Geller Institute of Ageing and Memory
GLM	Generalised Linear Model
GMMH	Greater Manchester Mental Health
GP	General Practitioner
GRIPP2	Guidance for Reporting Involvement of Patients and the Public
HEAP	Health economic analysis plan
HRA	Health Research Authority
ICC	Interclass correlation
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
ID	Identification
IRAS	Integrated Research Application System
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials
LIS	Library & Information Services
LGBTQ+	Lesbian, gay, bisexual, transgender and queer
LIS	Library & Information Services
MAT	Memory assessment team
NELFT	North East London NHS Foundation Trust
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NHS	National Health Service
PPI	Patient and Public Involvement and Engagement
PI	Principal Investigator
PIS	Participant Information Sheet
PSS	Perceived Stress Scale
QALYs	Quality-adjusted life years
QoL	Quality of Life
R&D	Research & Development
R&I	Research & Innovation

RA	Research Associate
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RfPB	Research for Patient Benefit
SAE	Serious Adverse Event
SD	Standard Deviation
SES	Standard Effect Size
sPCI	Stroke Patient Concerns Inventory
SOP	Standard Operating Procedure
TAU	Treatment-as-usual
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UCL	University College London
UK	United Kingdom
UoM	University of Manchester
WL	Waiting list

1) ROLES & RESPONSIBILITIES (RESEARCH TEAM & KEY CONTACTS)

Research Team & Protocol Authors

CI, Dr Lydia Morris (Senior Clinical Lecturer and Clinical Psychologist); University of Manchester

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Sponsor

The University of Manchester will act as nominated Sponsor for the project. Implementation of the project will be coordinated between the research team and nominated CTU (Lancashire CTU). Activities associated with trial conduct will be outlined within a Delegations of Responsibilities (DoR) document that is reviewed and agreed upon by the Sponsor.

Trial Steering Committee (TSC)

We will form a Trial Steering Committee (TSC). The TSC will meet two or three times a year and more often if indicated. The role of the TSC is to provide overall supervision for the trial, concentrate on the progress of the trial and adherence to the protocol and provide advice through its independent Chair. Adverse Event (AE) or Serious Adverse Event (SAE) will be

reported to the TSC; however, this a very low risk trial so these will be reported prior to each steering group. If any AE or SAE are assessed as related to the trial, then these will be reported to the TSC immediately. Other members of the TMG may be invited to the TSC as Observers (e.g. member(s) of the statistical team) at key points in the trial, as deemed appropriate.

The TSC will have an independent Chair and the following proposed independent membership:

Name	Affiliation	Role
Professor Emma Wolverson	The Geller Institute of Ageing and Memory (GIAM), University of West London	Independent chair
Dr Natalie Berry	Trafford Older Adult CMHT, GMMH	Independent clinician
Professor Heather Brown	Lancaster University	Independent Health Economist
Manoj Mistry	N/A	Independent carer representative
Dr Alex Mitchell	York Clinical Trials Unit, University of York	Independent statistician
Sarah Jewell	Age UK National	Independent Age UK representative

Trial Management Group (TMG)

The TMG, comprising the Chief Investigator (CI), co-CI, co-applicants, the RA and designated members of the Lancashire CTU will be assigned responsibility for the clinical set-up, on-going management, promotion of the trial and for the interpretation and publishing of the results. The TMG will be responsible for auditing consent procedures, data collection, trial end-point validation and database development. The TMG will be the main decision-making body, but key protocol changes will be reported to and discussed with the TSC. The TMG will report to the Sponsor (University of Manchester) and the funder (NIHR RfPB), but all reports will be shared with the TSC.

Data Monitoring and Ethics Committee (DMEC)

This is a very low risk trial and, as such, it has been deemed unnecessary to form an independent data monitoring (and ethics) committee. The TSC will perform the basic functions of a DMEC, where necessary.

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2) TRIAL REGISTRATION

ISRCTN

3) PROTOCOL & STATISTICAL ANALYSIS PLAN

The protocol will be published. The approved Statistical Analysis Plan will be available via a publicly available platform.

4) DATA SHARING

In line with NIHR guidelines, fully anonymised quantitative data will be deposited in a public repository (Figshare). This is a publicly available and searchable platform where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check the analysis and results.

5) INTRODUCTION

There are 700,000 family carers for people living with dementia in the UK. Sixty-four percent of carers who are unpaid in England say they have limited support for the range of psychological and social needs they experience. It can be difficult to keep communicating well due to thinking and memory changes that arise when someone is living with dementia. This can lead to frustration, low-mood and stress for both people living with dementia and their carers.

The six-session Empowered Conversations (EC), delivered across six weeks, is designed to enable carers to establish and maintain good communication and relationships with those they support. Course facilitators are trained to provide specific communication techniques, ways of managing conflicts and working with difficult emotions. EC can be delivered in person or online.

The current study followed on from our feasibility trial, which found that EC was feasible, safe and effective for carers. Consequently, this RCT will be conducted with a larger sample to help us identify whether EC is effective. 336 participants will be recruited consisting of EC (n=224) +Treatment-As-Usual (TAU) vs TAU (n=112). As such, 66% of participants will receive the intervention compared to 33% in TAU. The TAU participants will be offered the EC course online six months later, after their involvement in the trial ends.

Participants will be identified and recruited through NHS and non-clinical teams (such as Age UK) in foundation trusts such as Greater Manchester Mental Health, Pennine Care, Lancashire and South Cumbria, and North East London.

Detailed information will be collected about participants at three time points across the trial intervention period of six months: baseline, 16 weeks and 26 weeks post-randomisation (follow up; primary outcome time-point). Assessment packs will contain measures related to stress (primary outcome), peer support, quality of life, cost effectiveness and dementia symptom severity.

6) BACKGROUND

The disease, social and economic burden of dementia is substantial. Family and informal carers

provide intense practical support, while coming to terms with changes in their relationship (Morris et al., 2018). Within the United Kingdom (UK) it is estimated that 944,000 people have dementia (Alzheimer's Research UK, 2024) and there are approximately 700,000 informal carers (Lewis et al., 2014). Informal care, defined as unpaid support given to a family member, partner or friend who could not otherwise cope because of their physical or mental health needs (NHS England, 2014), is an essential component of dementia care. It incurs a cost of £13.9bn per year for unpaid care, compared with £15.7bn spent on formal social care (Wittenberg et al., 2019). Furthermore, an informal carer can be the primary support for someone living with dementia for a significant number of years; for example, 30% of informal carers for people living with dementia had been doing so for between 5 and 10 years and 22% for over 10 years (Office of National Statistics, 2016-2017). [Hereafter 'carers' will be used at times for informal / family carers; if professional carers are being referred to then this will be indicated]. Therefore, it is likely that carers will need to access more than one intervention, because the support they provide regarding the changing needs of someone with a degenerative condition will change over time (Bressan et al., 2020).

It has been identified that caring for a person with dementia is more stressful than caring for someone with a physical health condition (Brodaty & Donkin, 2009) and that about 40% of carers of people living with dementia experience significant depression or anxiety (Cooper et al., 2007). As carers witness significant changes within someone that they are very close too, they can experience significant changes in role and significant losses. For example, a spouse or child may feel increasingly cast in a parent role and carers commonly expressed that they can feel they have 'lost' the person to the ongoing changes of dementia (Pozzebon et al., 2016). In addition to practical stressors, carers can be experiencing major relationship changes and complex grief (Morris et al., 2018; Pozzebon et al., 2016). Furthermore, a systematic review and meta-ethnographic synthesis of 25 high-quality studies found that the two main reasons for behaviours of people living with dementia being reported as challenging by carers were: firstly, changes in communication and relationships and, secondly, perceptions of transgressions against social norms associated with 'misunderstandings about behaviour' in the relative with dementia (Feast et al., 2018). Difficulties with communication are also associated with increased carer stress, low mood and burden and can contribute to the breakdown of the interpersonal relationship between the carer and person with dementia (Dooley et al., 2015; Stedje et al., 2023; Steeman et al., 2006).

Given the high social, economic and individual costs of dementia, and the impact on carers, it is important to ensure evidence-based treatments are available. Sixty-four percent of carers in England say they have limited support for the range of psychological and social needs they experienced (Health and Social Care Information Centre, 2017). Our team have developed the EC (six-session group, delivered weekly) intervention in collaboration with carers (Eastham et al., 2023; Innes et al., 2022; Morris et al., 2021; Morris et al., 2024; Morris et al., 2018). EC is based on the Communication Empowerment Framework, which integrates evidence-based models (of psychological health, communication and relationships) to address the specific psychological, relationship and communication needs of carers (Morris et al., 2018). It is a psychosocial intervention that supports carers to improve their communication and relationships with the person living with dementia. It also aims to reduce carer stress levels,

which can then have an impact on the person living with dementia they are supporting. It is integrative and draws on a range of theoretical accounts, such as Attachment Theory (a key theory of how we relate to each other in times of stress), given its unique focus on relationship stress. EC has been delivered and evaluated online and in-person, via two initial feasibility studies and three qualitative studies of informal carers' experience of EC (Eastham et al., 2023; Innes et al., 2022; Morris et al., 2021; Morris et al., 2024). The intervention content and delivery have been enhanced, with significant PPIE input, based on the detailed carer feedback collected through these qualitative studies. EC is delivered as a manualised intervention but with some optional components (as well as compulsory ones) to ensure flexibility to the needs of diverse carers (Bieber et al., 2019).

In addition to very limited availability of psychosocial interventions to support carers within the UK (Frost et al., 2020), there has been limited evaluation of the interventions that are available. Across recent reviews of psychosocial interventions for informal carers of people living with dementia, including a meta-review (Cheng & Zhang, 2020; Gilbert et al., 2023; Walter & Pinquart, 2019), key recommendations focused on the need to improve the quality of the research evidence, to focus on contextual and implementation mechanisms underlying psychosocial interventions and to evaluate the needs of different carer subgroups (Cheng & Zhang, 2020; Wiegelmann et al., 2021). A meta-review identified that psychoeducation, psychotherapy, occupational therapy, communication skills and multicomponent interventions could all impact on outcomes for informal carers; however, the authors note that no intervention type had broad effects on carer outcomes (Cheng & Zhang, 2020). A review focusing on mental health outcomes for carer interventions, found some traditional CBT interventions impacted carer depression (4 out of the 6 reviewed); significant effects of CBT interventions were not found for most other outcomes (including Quality of Life and anxiety) (Wiegelmann et al., 2021).

A consistent theme across reviews is highlighting methodological limitations of intervention studies with informal carers. Recommendations include the need for future studies: a) evaluating interventions that address the distress caused by changing roles and relationships, b) using a robust and different theoretical standpoint from the dominant traditional cognitive-behavioural one, c) using group delivery, with carers interacting during the intervention; d) with good supervision, adherence to treatment fidelity, and use of blinded assessors, e) online options, d) thorough reporting of the intervention and research, e) interventions that have been developed with strong PPIE (consumer) involvement; f) RCT data is limited and there are other issues with study quality, e.g. very short or no follow-up (Cheng & Zhang, 2020; Elvish et al., 2013; Folder et al., 2024). The proposed study will respond directly to all of these recommendations. The proposed study will go one step further to provide the first (to the applicants' knowledge) quantitative data on video-conference vs in-person delivery within the context of psychosocial interventions for informal carers of people living with dementia.

Prior to our RfPB funded feasibility trial, there was some limited quantitative evidence of promise of EC, primarily from an earlier pre-post follow-up study of the in-person version (N = 159), in which the Standardised Effect Size (SES) on the Perceived Stress Scale (PSS) from pre-treatment to four month follow-up was 0.48 (Morris et al., 2021). Some limited further

evidence of promise of a potential small to moderate effect was obtained from the feasibility trial, with an estimated effect of SES=0.13, 95%CI -0.32 to 0.57 on stress reduction (PSS). Significant qualitative data has been collected regarding EC and used to inform intervention development and understand key mechanisms of change from a carer perspective (in addition to substantial PPIE input). Twenty-eight carers were interviewed about their experiences of in-person EC, including exploration of the acceptability of EC; 27 described feeling able to better connect with the person they support after attending EC (Morris et al., 2024). Within the recent feasibility trial, a nested qualitative study was conducted within which 15 semi-structured interviews were completed with carers who had attended online EC. The 15 carers expressed general satisfaction with the online version of EC and identified advantages to this format (such as not needing to travel and being more able to manage caring responsibilities at home); however, most participants felt that an in-person course would provide a better environment for communicating and connecting with others.

Finally, detailed qualitative interviews (N = 10) were conducted with Punjabi Sikhs regarding the cultural appropriateness of EC and adaptations that would make EC more culturally appropriate (Dowson et al., 2025). Key findings included: offering EC in-person (also recommended for other minoritised communities (Choi et al., 2015) potentially offering EC in community hubs (unless stigma could limit accessibility), intervention should be run by facilitators with knowledge of Punjabi Sikh culture, intervention should represent more people who look and sound like the attendees. In-person delivery will be offered within this trial; adaptations have already been made to the manual based on the recommendations of relevant studies and budget included for producing specific video resources designed to be culturally appropriate for minoritised groups.

EC is a group, community-based intervention, with a manualised video-conference version and delivered through the third sector as well as NHS services. A definitive trial is now required to examine the effectiveness and cost-effectiveness of EC, using both the online and in-person versions (in line with carer preference). Within the feasibility trial EC was only offered online, this was in direct response to the COVID-19 pandemic and restrictions on vulnerable groups. Offering the EC intervention online meant the trial could commence and carers who were vulnerable could access the intervention. However, previous research had involved EC being delivered in person and as mentioned, there is also evidence that some minoritised communities can prefer in-person delivery (Choi et al., 2015; Dowson et al., 2025). The intervention will be compared with TAU which is likely to be limited in terms of support, but is likely to include support from services (e.g. Age UK or Alzheimer's Society) in some cases. Given that there is rarely a specific carer service or pathway offered within the NHS, the nature of this support will vary. Participants allocated to TAU will be offered the EC course following completion of their participation in the trial; this is designed to improve acceptability of the trial to potential participants and help maintain engagement of those allocated to TAU throughout the trial. Participants in both the intervention and the control group will be able to access TAU, but the services accessed will be monitored via the Healthcare service use questionnaire.

Two qualitative studies will be conducted by London-based (North Thames, UCL) Trainee

Clinical Psychologists under the supervision of Professor Georgina Charlesworth and Dr Lydia Morris. These qualitative studies will explore the experience of marginalised carers. They do not form part of the trial dataset, and a separate Participant Information Sheet (PIS) and Consent forms will be used (these will be submitted as an amendment). The psychometric properties of the peer support measure (described below in outcomes section) will be analysed as part of a Doctoral level project of a trainee Clinical Psychologist based at University of Manchester and with Dr Morris as the primary supervisor. A supplementary qualitative project will be conducted by a Trainee Clinical Psychologist, with Dr Morris as primary supervisor, focusing on the experience of the EC facilitator team of cultural humility training specific to EC.

This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR208874).

7) STUDY OBJECTIVES

7.1 Primary Aim

The primary aims of the study are to examine the effectiveness and cost-effectiveness of EC, a psychosocial group-based intervention for carers of people living with dementia.

7.2 Objectives

Primary objectives are: (1) Assess the effectiveness of EC in reducing carer stress (Perceived Stress Scale [PSS] at 26-weeks post-randomisation) compared to a TAU Control.

(2) Determine the cost-effectiveness of EC.

Secondary objectives are

(3) Assess the effectiveness of EC on secondary outcomes: anxiety and depression (Hospital Anxiety and Depression Scale [HADs]); relationship strain (Dyadic Relational Scale); quality of life (Carer QOL and carer perceived rating for person living with dementia); carer goals (Goal-based outcome measure); activities of daily living; peer support; communication at 16- and 26-weeks post-randomisation.

(4) Assess the effectiveness of EC in reducing carer stress (PSS) at 16-weeks post-randomisation.

(5) Assess fidelity to the intervention protocol using a fidelity checklist that is observer and facilitator rated.

(6) Provide the first examination of whether effectiveness is different in the in-person version compared to the online version of EC.

(7) Explore whether the effectiveness of EC on reducing carer stress varies according to key carer status factors (e.g. providing ‘full-time’ vs ‘part-time’ support; and an estimate of symptom severity of the person living with dementia).

(8) Provide initial psychometric properties and analysis of the Peer Support measure.

(9) Provide the first full evaluation of safety indices in a randomised controlled evaluation trial of EC.

(10) Provide initial acceptability data on the adaptations made to EC, and additional training for facilitators, to make EC more accessible to minoritised (global majority) communities.

8) PATIENT, PUBLIC INVOLVEMENT AND ENGAGEMENT

The PPIE lead and Carer Co-I will be responsible for delivery of the PPIE strategy within the project, with support from the Chief Investigator and the GMMH Research Associate. This will include refining the PPIE strategy as the project progresses, communicating with the Trial Management Group (TMG) throughout the research project, acting as points of contact for all PPIE colleagues, and implementing monitoring and reporting of PPIE using an Impact Log and following Guidance for Reporting Involvement of Patients and the Public (GRIPP2) guidance (Staniszewska et al., 2017). We have budgeted for an Independent Carer Representative who will attend Trial Steering Committee (TSC) meetings throughout. PPIE activities will follow INVOLVE guidance.

PPIE will be embedded in all elements of the research project, including: (1) management of the research, with carers attending both TMG and TSC meetings; (2) collaborating in developing participant resources and advising on ways to maximise recruiting participants into the trial; (3) advising on safety indices to monitor and report on throughout the trial; (4) contributing to study reporting and dissemination, by co-writing the lay summary of findings, co-producing the video and co-presenting findings.

We will outreach through existing networks (e.g. Sahara- South Asian Project Greater Manchester; African Caribbean Care Group; Dementia United Carers Forum, DEEP [Dementia Engagement and Empowerment project] and Greater Manchester LGBTQ+ Dementia Support Group) to further involve carers from diverse backgrounds within the PPIE. To facilitate the involvement of diverse and geographically dispersed carers, we will run both in-person and online meetings. This provides greater options and flexibility for those with demanding ongoing caring responsibilities and responds to feedback from previous PPIE groups and representatives.

To ensure that PPIE meetings have a meaningful impact, we will have a greater number of meetings in the first year (four meetings) and final year (four meetings). This is to ensure that PPIE group members can directly influence the trial set-up and dissemination activities. To embed meaningful PPIE within the health economic analysis, health economist will meet with the PPIE group to (1) explain the health economic analysis methods in lay terms and (2) obtain an interpretation of the health economic findings from the perspective of carers (for example, interpreting changes in EQ-5D-5L dimensions and downstream healthcare resource use).

9) STUDY DESIGN

9.1 Design

Randomised (2:1) controlled trial (N = 336) of EC (224) +TAU vs TAU (112). The design is a multi-centre, parallel-group RCT comparing EC + TAU (intervention condition) with TAU alone (control condition). TAU will be measured and remain as usual in both groups. Assessments will be carried out at baseline, post-intervention (16 weeks post-randomisation) and follow-up (26 weeks post-randomisation, primary analysis timepoint).

9.2 Participants and setting

Participants will be 336 carers, recruited across three geographical locations and several NHS trusts. Sites are Greater Manchester, Lancashire and London with confirmed NHS trusts including Greater Manchester Mental Health and Social Care, Pennine Care NHS Foundation Trust, Lancashire, and South Cumbria NHS Foundation Trust and North East London NHS Foundation Trust.

EC is delivered online and in person. If accessing online, participants will take part from their own homes or any other suitable place of their choice. If accessing in person, the course will be accessed in community locations. The baseline and follow-up questionnaires will be offered online (using REDCap) or in person with a trained researcher (e.g. Research Associate or Research Assistant, Clinical Studies Officer). Any face-to-face research activities, such as interviews, will take place at the participant's home or another appropriate venue of their choice.

9.3 Study Intervention

Intervention: EC is a six-session weekly, group-based psychosocial intervention; each session lasts 2 hours. We will offer carers the opportunity to access EC either in-person or online via video conference (e.g. Zoom) (it has been previously evaluated separately in each of these formats, but these have not been used in the same evaluation or compared). Travel expenses will be provided for the in-person groups to improve accessibility. Across previous studies the average number of carers per group was six (projection of 56 groups in total; 37 within intervention arm). However, we will aim for seven to eight per group to allow for potential drop out from the group intervention. We will clearly specify that EC will be delivered in-person and online within key study documents, we will advise carers again regarding this at the screening appointment, at baseline we will ask carers what mode of course delivery they would prefer (and give them a further opportunity to ask questions).

Intervention: Training, Delivery, Supervision and Fidelity Assessment: There are seven current trained EC facilitators (based at Age UK Salford). Additional facilitators with appropriate personal or professional experience will be recruited and trained for both online and local delivery. Facilitators have either personal or professional experience working with people with dementia and their carers (e.g. Occupational Therapists).

EC is a manualised intervention; a detailed manual has been produced and refined. A 'Train the Facilitator' approach has been developed by the EC team over the last four years to provide trainees with a combination of theory and practice to help effectively deliver the course

material. Alongside accessing the manual and course materials, trainee facilitators will attend a total of nine hours of online training on course material (split into Stage 1 and Stage 2), along with supervised course delivery with an experienced EC Facilitator (minimum of two courses per trainee), i.e. someone will facilitate with them and provide feedback. Trainees will receive post session de-brief and supervision support and will attend monthly reflective practice sessions to build understanding and knowledge.

Facilitators of EC receive monthly external clinical supervision. New facilitators are always paired with a more experienced facilitator. The Clinical project director meets with the pair after Session 3 and 6 of each course but can be contacted for support throughout course delivery.

We plan to measure facilitator fidelity and participant 'enactment' (putting learning into practice in everyday life). Fidelity: for each facilitator, two sessions will be independently rated by an observer familiar with the course but not directly involved in the research broader data collection for the research (e.g. the Clinical project director or a placement student who would not be involved in collecting baseline or follow-up data). The team will utilise a combination of supervision, reflective practice, and/or booster training sessions to meet the training needs identified through the fidelity checklist.

TAU comparator: Most carers will be offered limited support. Some carers may choose to access support groups, such as dementia cafes aimed at the person with dementia, but specific carer support is limited. NHS services are based around the person with dementia. We will collect this information from carers so we can describe TAU in both groups.

We will also offer those in the TAU group the option of accessing EC online after their six month follow-up.

9.4 Equality Diversity and Inclusion

It is important to the EC team to ensure that the study is accessible to as many potential participants as possible. In order to ensure that any adjustments are captured by the trial team, participants/referrers will be asked about requirements during screening tools and assessments so the research team can assess the best way to accommodate.

We have a key focus on improving access by ensuring a range of language needs are met. Within the Trusts that we are recruiting from some languages are particularly widely spoken; Urdu is the most widely spoken language within our recruitment areas and so the manual will be translated into Urdu. We will also translate research materials into key languages and offer interpreters within EC for those who have language needs other than Urdu. As not all measures have been validated in the required languages (e.g. Urdu), if translation is needed then we will just collect key outcomes, e.g. primary outcome and cost-effectiveness measures, given that these measures have translated versions. We have budgeted for measures' translation where measures can be translated without affecting psychometric properties (e.g. demographics).

We are building on previous research regarding the cultural relevance of EC, and ways in which it could be adapted, to make specific changes (such as greater representation of people of colour, choices in some of the examples used to ensure broader cultural relevance). Research and PPIE has indicated that core components (enhancing communication and relationships, etc.) are relevant, but some minor adaptations are required and have been made to the content to increase cultural sensitivity. Another adaptation that has been made is discussing and scaffolding the idea that taking time for oneself is not necessarily selfish and it might be helpful to express difficulties to resolve them; whilst this could be relevant to all carers, previous qualitative work has identified it might be of particular relevance to those from minoritised communities (such as Punjabi Sikhs, Orthodox and non-Orthodox Jews). We will develop and qualitatively evaluate additional adaptations to EC. We have budgeted for EC facilitators attending cultural competence (humility) training.

The Clinical Director for EC chairs the monthly Greater Manchester LGBTQ+ Dementia Support Group. We will invite carers and people living with dementia to be part of the PPIE group and share information about the study through these networks.

10) METHODS

10.1 Inclusion Criteria

Inclusion criteria:

- Current unpaid or family carer for someone living with dementia (any sub-type or severity) in the community.
- Provide emotional or practical support at least weekly.
- Aged 18 or over.
- Have capacity to give informed consent for the study.
- Either the carer, or the person living with dementia that they are supporting, live within the boundaries of recruiting Trusts.

10.2 Exclusion Criteria

- Unable to provide informed consent.
- Currently enrolled in a concurrent non-pharmacological (psychosocial intervention) carer research study.
- Caring for someone living with dementia in a Nursing or residential care home.
- The person living with dementia being cared for is receiving palliative care or considered to be in the last six months of their life.

10.3 Recruitment

Recruitment will be through the team's extensive carer networks, e.g. Age UK, Alzheimer's society and relevant third sector and community organisations. We will also reach out to local places of worship. We will recruit carers from community groups for Black African-, Asian- and Caribbean-heritage people and other racialised groups, such as Sahara - South Asian Project

Greater Manchester; African Caribbean Care Group. Carers who may have language needs, or where English may not be their first language, will in addition be provided the information regarding language provision within the trial. We will also recruit EC facilitators from minoritised backgrounds.

Carers will be visited by researchers at community group meetings to be informed about the study or given the brief study information sheet by staff/facilitators of those groups. Carers will then be able to 'self-refer' into the study by contacting the trained Researchers (e.g. Research Associate or Research Assistant) using the contacts provided. If researchers are attending in-person meetings, then carers will also be able to complete a consent to contact form and give this to researchers.

Carers will also be recruited through NHS practitioners, e.g. Memory Assessment Teams (MATs). Dementia workers and MATs team clinicians will provide information about the study to family and informal carers of people living with dementia by providing the brief information sheet at routine assessment and service advice appointments. If the appointments are in-person meetings (and carers prefer this option) then carers will be able to complete a consent-to-contact form and give this to the clinician to securely convey to the Research Associate or Research Assistant. Where a physical consent-to-contact form cannot be used, the clinical care team will pass personal identifiable contact details of potential participants to the trained research team following verbal consent by the carer. This will be documented locally (on the clinical records) by the clinical care team that the potential participant has given their verbal consent for this to happen.

If a ward manager agrees that it is appropriate for their individual circumstances (i.e. there are carers attending the wards), the research team will promote the study on inpatient wards at NHS premises. This will use approved advertising materials, and research team presentations at team meetings and/or ward activities. Similarly, participants maybe recruited through relevant social care channels.

Recruitment will also be supported by the communication teams at NHS trusts. This will include using ‘splash screens’ to advertise the trial on staff computer wallpaper, publishing an article about recruitment on the trial on the Trusts’ internet and intranet sites, and promoting the trial on social media (linking to the article to give more information).

Carers will be able to ‘self-refer’ for the trial by contacting the Research Associate, Research Assistant or Clinical Study Officer. The study will also be ‘advertised’ in GP practices and community venues, and on social media including targeted paid advertising on Facebook if needed. Several versions of the Facebook advert will be designed and submitted for approval if required in accordance with Facebook’s restrictions and guidance for advertising e.g. character count. This will allow the research team to test different styles of advertising, including changes to wording and images, in addition to reviewing the effect of changing the demographic settings of the advert. The same advert will be used as a poster and on social media. Study- specific accounts will be set up to gain visibility and further advertisement will be completed by other involved organisations (GMMH R&I, Age UK, etc.).

Both consent-to-contact and self-referral recruitment methods were used successfully within the feasibility trial with community-based and NHS / social care referrers.

Consent processes are detailed in the participant journey section.

Table 1: List of outcome, process and other measures

Outcome or construct	Measure	Function	Measure Category	Number of items	Baseline	Post & follow-up
Stress	Perceived Stress Scale- total score	Primary outcome	Effectiveness	10	X	X
Perceived support from other group members	Peer Support in groups	Process measure	Process	24	X	X
Relationship strain (e.g. I felt resentful)	Dyadic Relationship Scale (Caregiver)	Secondary outcome	Effectiveness	11	X	X
Specific goals that the carer has for the course	Goal-based outcome measure	Secondary outcome	Effectiveness	4	X	X
Carer perceptions of communication	Carer Communication Questionnaire	Secondary outcome	Effectiveness	8	X	X
Quality of life (carer)	C-DEMQOL	Secondary outcome	Effectiveness	30	X	X
Quality of life (person living with dementia)	DEMQOL-Proxy	Secondary outcome	Effectiveness	31	X	X
Anxiety and Depression	Hospital Anxiety & Depression Scale (HADS)	Secondary outcome & sample descriptor	Effectiveness	14	X	X
Ability of someone with dementia to carry out daily activities such as dressing and preparing food	Bristol Activities of Daily Living Scale (BADLS)	Indication of dementia severity & moderator	Effectiveness	20	X	

Outcome or construct	Measure	Function	Measure Category	Number of items	Baseline	Post & follow-up
Age, Sex, Gender, Ethnicity, Sexual orientation, Religious Faith, Relationship to cared-for person, Dementia diagnosis, Geographical location, Household composition, income and government assistance, Education history, Employment status, Chronic health conditions	Demographic questionnaire	Sample description; moderators. Moderators incl. carer status, e.g. providing 'full-time' vs 'part-time' support.	Participant characteristics		X	
Health-related quality of life	EQ-5D-5L	Cost-effectiveness	Cost Effectiveness	5	X	X
Hospital, primary, community and social care use	Healthcare service use	Cost-effectiveness & service use	Cost Effectiveness	-	X	X
Harms and adverse effects	Adverse events; side effects of intervention measured via adapted adverse effects of therapy checklist (see also section 13, regarding harms and adverse events reporting)	Secondary outcome	Participant Safety	11		X

11) ASSESSMENT POINTS, OUTCOME MEASURES & SAMPLE SIZE

All outcome and other key measures are detailed in Table 1. A fidelity checklist will also be used but this will not be completed by participants.

Assessment points: Baseline, 16 weeks post-randomisation and 26 weeks post-randomisation (follow up; primary outcome time-point). The 16-week time-point has been included as this is close to when carers will finish EC (this was not included as an assessment point in our feasibility trial). Our primary outcome is at 26-weeks post-randomisation as it allows for carers who are allocated to receive EC to enact what they have learnt over a longer period, and it is more indicative of lasting impact.

Primary Outcome measure: Stress (Perceived Stress Scale; PSS (Cohen et al., 1983) at 26 weeks post-randomisation. The PSS is a 10-item measure of stress with good internal consistency (α = .78; .84; .90; alphas collected in different populations, (Taylor, 2015)) and has been used previously with carers (Volkmer et al., 2023). A total score is most commonly used and will be the primary outcome, but it is also recommended to examine the two factors of perceived helplessness and perceived self-efficacy. These will be secondary outcomes.

Justification for primary outcome: Stress was identified as the primary outcome for the trial with the following justification: 1. Stress is more directly relevant to carers than clinical measures in this context because we are not restricting recruitment to those carers with mental health needs; 2. Stress is commonly evaluated in other carer psychosocial interventions and so allows comparison with other studies; 3. Stress was recommended as the primary outcome within a key stakeholders and PPIE consultation session (11 informal carers for people with dementia, 10 service providers/clinicians, 3 researchers) and by members of the PPIE group from the feasibility trial (many of whom wished to be involved in the ongoing programme of research).

Carer quality of life was also considered to be a key outcome, and is one of our secondary outcomes. The C-DEMQOL is a 30 item self-report quality of life measure which aims to measure how much carers feel supported and are meeting their personal needs alongside their own wellbeing, confidence in the future and their relationship with the person they care for. The C-DEMQOL has been positively received by carers and is reliable in measuring overall and all subdomains of Quality of life (Brown et al., 2019).

Further, from the PPIE consultation and further discussions, peer support within the group itself was identified to be an important process measure; as no specific measure is available, one has been devised based on relevant qualitative data and peer support measures in other contexts.

11.1 Sample Size

In our feasibility trial, for the PSS at 6 months, the estimated within-group SD was 6.71, the estimated baseline-outcome correlation was 0.68, 22.7% had missing data, and the estimated ICC for the EC group intervention was 0.00, with an average 5.57 participants per EC group providing data. To achieve 80% power to detect a target effect size of 2 points on our primary

outcome measure Perceived Stress Scale at 26 weeks post-randomisation, assuming a common SD of 6.71 (Standardised Effect Size 0.298), a baseline-outcome correlation of 0.6, and 5.6 participants per group providing outcome data with a conservative group ICC of 0.02 (in the EC intervention arm only) and 20% attrition would require randomisation of 336 participants (EC:TAU allocation ratio: 2:1). Within the feasibility trial we had 22.7% attrition at follow-up, therefore we will employ extra strategies to improve retention.

12) PARTICIPANT JOURNEY, RANDOMISATION AND PROCEDURES

12.1 Participant journey

See Figure 1

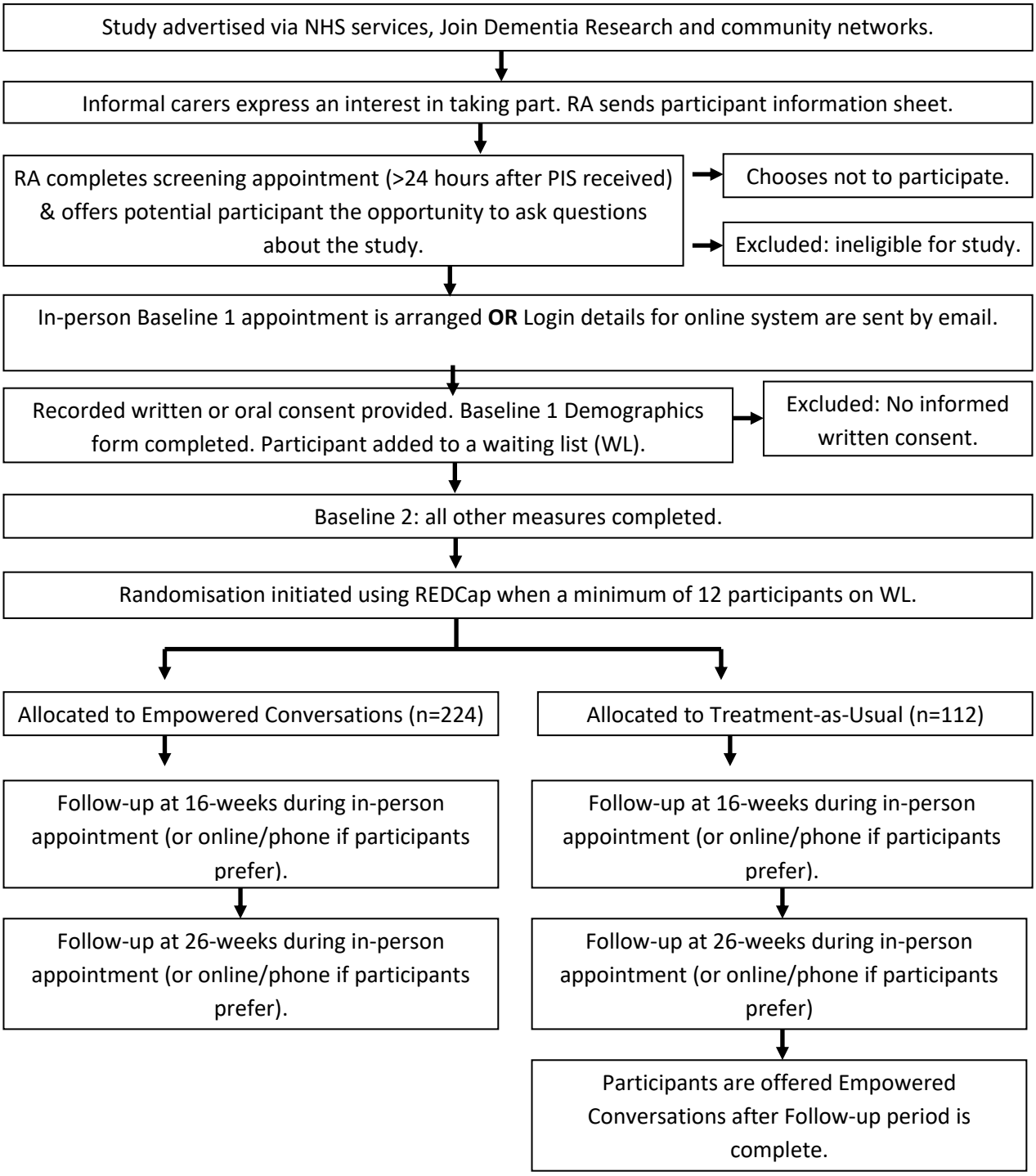

Figure 1: Participant journey through the study

Recruitment

Carers will be provided brief information regarding the study through a variety of mediums (see Methods section). They will be able to self-refer directly to the site research team or will be referred by professionals. On referral (and prior to referral in most cases) carers will be provided with the full participant information sheet via email or post, they will also be given the opportunity to ask questions. Potential participants will be given at least 24 hours to decide if they want to take part in the study.

We will also provide travel expenses for participants where assessment appointments involve travel.

Initial Screening Appointment

Once a referral or expression of interest has been received, the trained researcher (e.g. Research Associate or Assistant) will contact the potential participant to arrange an initial appointment. They will send them the Participant Information Sheet (by email or post if email is not available).

At the screening appointment, which will be conducted online via Teams if possible or over the telephone, the researcher will ask the carer some brief questions in order to confirm eligibility for the study. This information will be entered into the data management system anonymously (with no identifiers) by the Researcher. This data will not form part of the research data and as it is being collected before consent and will only be used for the purposes of eligibility checking via established procedures. If carer is not eligible or decides they do not want to proceed then personal data will not be kept it will be immediately deleted.

If the initial screen indicates eligibility, then the study will be explained to them, and they will be given the opportunity to ask questions. Study information and this initial conversation will make it clear that participants have a 2/3 chance of receiving EC (plus TAU) and a 1/3 chance of TAU following an initial appointment. All participants who are randomised to the control group will be offered EC following their 26-week follow-up appointment. This information will also include details of the locations of where EC courses will be held so that carers can start considering if they want to go for the in person or online EC.

At this initial screening appointment, eligible carers will be asked to indicate whether they wish to complete the baseline measures in person or online. Interested carers will be offered the consent and baseline measures appointment at home, online or at local community venues. There will be a minimum period of 24 hours between the referral being received, the Participant Information Sheet being provided and the appointment to provide informed consent and complete baseline measures. Participants will be texted/emailed prior to the appointments to remind then and give them the option to cancel. As this is before consent, personal data will not be recorded, the screen is to establish eligibility. However, contact details for eligible participants will be recorded during the consent to contact phase in order to arrange the first appointment.

Informed recorded consent and baseline appointment 1

Informed consent to participate in the RCT will be obtained at the first baseline appointment. Participants will be offered in person assessment appointments or REDCap (online survey set up) as the first option; phone or online (Teams) appointments can be offered if in person or REDCap does not work for the participant. Participants will only proceed with the study if they give informed consent.

Carers will be able to choose to participate in the RCT, and will have the option to provide consent to be contacted regarding the qualitative studies (via a specific statement on the consent form). There will be the option of providing written consent and completing the baseline measures via an online University-approved platform (REDCap). Demographic data will also be collected at this point. Participants will also be asked to indicate their preference for accessing the intervention online or in person (online, in person, no preference).

If the carer is completing their baseline measures in person, they will receive the Participant Information sheet at least 24-hours before this initial appointment.

If the carer is completing their baseline measures online, they will be sent details of how to access this at least 24-hours after being sent the PIS.

As described earlier, in the case of both formats, they will be given at least two opportunities to ask questions.

The participant identification (ID) number will be provided at the consent and baseline 1 appointment.

Waiting lists for groups

As the EC group intervention can only run with a minimum of five to six initial participants, we will create internal waiting lists to ensure that participants are not waiting too long for a relevant group. These waiting lists will be based on the preferences specified by participants in Baseline 1. The waiting lists will be:

1. Online
2. Greater Manchester in-person
3. Lancashire in-person
4. London in-person.

Participants who did not have a preference would be added both to the relevant site-specific in-person list and the overall online list.

When 10-12 participants are on a waiting list then they will be contacted about their Baseline 2 appointment.

If any participant has been on a waiting list for over four weeks, then they will be contacted to see if they want to join a different waiting list and check they want to continue with the study.

Baseline appointment 2

Carers will complete the remining measures (all measures apart from demographics) at the second baseline appointment. These can be completed via an online University-approved platform (REDCap), or in person. If neither of these options work for the participant, then the measures can be completed over the phone or via video call (Teams).

Participants will be randomised following this second baseline appointment.

Follow-up appointment 1 (16 weeks)

All participants will be contacted by the Data Management Team at least four weeks before the follow-up point. This will be in the form of a telephone call to check that the participants want to remain involved with the study and if so, to check their preferred format for follow-up appointment (online, in-person or by phone). At the recommendation of the trial's carer representative, the call will also be an opportunity for the team to reconnect with the participants, remind them of the purpose of their involvement and advise them of the next steps.

Participants preferring an in-person (or telephone) format will then be contacted by the research team within two weeks of the initial phone call to arrange a suitable appointment. Participants will be reminded about the importance of the researcher remaining blinded to their group status.

Participants who choose online questionnaires will receive their invitation by email; this will be sent by the research team within two weeks of the initial phone call.

Following discussion with the trial's carer representative, participants using online questionnaires who do not complete them within 14 days will be sent reminders to complete these. These are explained below.

If the questionnaires are not completed 14-days after the invitation was sent, a reminder message will be sent by email and text (if the participant has provided mobile phone number).

If the questionnaires remain uncompleted seven days after the reminder message was sent, the participants will be contacted by phone call to check that they want to remain involved in the study and to offer additional support or an alternative format for completing the questionnaires. If the questionnaires are not completed four weeks after the participant's 16-week follow-up date, a final email will be sent. This will include the link to the questionnaires and inform the participant that if these are not completed within a week and they do not contact the team, it will be assumed that they are unable to complete the 16-week follow-up, but they will still be contacted regarding the 26-week follow-up.

If a participant completes the measures significantly outside of the above five week timeframe, then it will be considered whether this data should be used for the 26-weeks follow-up. If they compete the first follow-up at 22-weeks or later then this data will be recorded as the second follow-up.

It is possible that some participants would have received further interventions, e.g. support groups provided by Age UK or Alzheimer's society, before the final follow-up. We will collect information about other interventions via the measures described subsequently (particularly the service use questionnaire).

Follow-up appointment 2 (26-weeks)

All participants will be contacted by the Data Management Team at least four weeks before the follow-up point. This will be in the form of a telephone call to check that the participants want to remain involved with the study and if so, to check their preferred format for follow-up appointment (online, face-to-face or by phone). At the recommendation of the trial's carer representative, the call will also be an opportunity for the team to reconnect with the participants, remind them of the purpose of their involvement and advise them of the next steps.

Participants preferring an in-person or telephone format will then be contacted by the research team within two weeks of the initial phone call to arrange a suitable appointment. Participants will be reminded about the importance of the researcher remaining blinded to their group status.

Participants who choose online questionnaires will receive their invitation by email; this will be sent by the research team within two weeks of the initial phone call.

Following discussion with the trial's carer representative, participants using online questionnaires will be sent reminders to complete these. These are explained below and summarised in the following table and flowchart.

If the questionnaires are not completed 14 days after the invitation was sent, a reminder message will be sent by email and text (if the participant has provided mobile phone number).

If the questionnaires remain uncompleted 14 days after the reminder message was sent, the participants will be contacted by phone to check that they want to remain involved in the study and to offer additional support or an alternative format for completing the questionnaires.

If the questionnaires are not completed six weeks after the participant's 26 weeks follow-up date, a final email will be sent. This will include the link to the questionnaires and inform the participant that if these are not completed within two weeks and they do not contact the team, it will be assumed that they are unable to complete the follow-up. Participants will complete their follow-up questionnaires no more than four weeks prior to the 26-weeks point and no more than eight weeks after the 26-weeks point.

It is possible that some participants would have received further interventions, e.g. support groups provided by AgeUK or Alzheimer's society, before the final follow-up. We will collect information about other interventions via the measures listed earlier.

Strategies to promote participant retention and completion of follow-up

Three ways of increasing retention have been identified from the feasibility trial and informed by the previous literature and consultation with the PPIE group: 1) use of text reminders and follow-up phone calls, as well as email reminders (to support those who opt to complete measures online); 2) providing shopping vouchers (not offered in feasibility trial); 3) If it does not seem likely that participants will complete all outcome measures, as a last resort, we will have an option (via phone) to just complete the primary outcome (with other key outcomes, if possible).

Qualitative studies

Two studies will be conducted by North Thames (UCL) Trainee Clinical Psychologists into how religion or spirituality can be a resource and support carers within their caring role. The study documents will be submitted via an amendment. Participants will only be approached if they have provided consent to contact (an item on the initial consent form). These studies will have a separate consent form and Participant Information Sheets.

Upon giving consent to participate in the RCT participants will be asked if they give consent to be contacted again with information about taking part in a qualitative interview, if agreed, they will be contacted by the trial team following completion of the 16-week follow-up with further information. If they express an interest, then information will be securely conveyed to the North Thames (UCL) Trainee Clinical Psychologists who will contact them about the study. A consent form will then be completed via oral recorded consent for Teams interviews or via written consent for in person interviews.

Interviews will be conducted with: 1) 12-15 carers from the Muslim community, and 2) 12-15 carers who are Black African or Black Caribbean and identify as Christian. Semi-structured interviews will be conducted, using a topic guide, with eligible participants from either the intervention or control arm following informed recorded consent. Qualitative data will be analysed using Reflexive Thematic Analysis.

12.2 Randomisation

In line with our feasibility trial, there will be a 2:1 allocation in favour of the EC intervention arm. We anticipate that this will aid recruitment and, due to the clustering effect induced by the group intervention, the impact of unequal allocation on overall sample size will be limited.

Sequence generation

The allocation sequence will be generated by a statistician independent of the trial. Randomisation will be stratified by course type/location (four strata: Online; Greater Manchester in-person; Lancashire in-person; London in-person): participants will be asked as part of the baseline data collection which type of course (online or in-person) they wish to attend.

Concealment mechanism

The randomisation will be performed from the REDCap Electronic Data Capture (EDC) system. The independent statistician will upload the allocation sequence generated to REDCap and will then store this securely in a location not accessible to the Research Associate, Research Assistant, CI, Lead or Trial Statistician, or local PIs. Recruitment and registration into the trial, together with collection of baseline data, will be completed prior to the randomisation of participants.

Implementation

Randomisation to EC (or TAU) will be performed by the CTU Team, when a minimum of 12 carers are ready to be randomised (i.e. have completed informed written consent and baseline measures). This is an extension of the process used within the single-centre feasibility trial (with a lower recruitment rate and target) and no issues were reported. This will maintain each EC course size at approximately six to eight participants and, as follow-up time is relative to randomisation, will balance 'mean time since baseline' between trial arms.

The results of the randomisation (i.e. the ID member and allocated group) will be communicated directly to the intervention providers; however, participant contact details will be conveyed securely by the Data Management Team using a secure channel (secure Teams or OneDrive).

Blinding

The trial will be data-collector blind (the Research Associate and Assistant who will be conducting in-person follow-up assessments will be blind to treatment allocation). The Lead and Trial Statisticians will remain blind to treatment group allocation until the Statistical Analysis Plan has been finalised, but the statistical analysis will not be performed blind to treatment group. We cannot blind participants or those delivering the intervention to treatment group. Emergency unblinding could occur if the facilitators or researchers identify a high risk of self-harm or suicide, or of harm from others (e.g., safeguarding concerns).

12.3 End of study

For participants, the end of study will be following the completion of the 26-week assessment or earlier if withdrawn. The end of the whole study is four weeks after the point at which all data have been collected for the study from the final participant and contact with participants completed, i.e. the end of planned follow-up.

12.4 Change in participation: Participants who withdraw consent or lose capacity to consent

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

If the person living with dementia dies, the carer would be asked whether or not they wish to withdraw. Follow-up procedure specifies asking if people want to continue with the trial, because if carers experience a significant change in circumstance they may not want to.

It is considered unlikely that the carer participants would lose capacity during the course of the study. Researchers will not conduct a formal capacity assessment, but researchers will intervene if a participant exhibits behaviour that indicates potential loss of capacity. Prior to this, all participants will be made aware that, if they lose capacity, any data collected previously will be included in the study.

If a participant expresses that they want to change their participation, e.g. no longer continue with the intervention or follow-up, for reasons other than loss of capacity, then they will be asked if they can provide a reason for this. If a participant requests their data is removed from the trial, then this will be discussed with them. In line with HRA guidance, it may not be possible to remove certain data from the trial because this will be needed for analysis (e.g. allocation to treatment group) or safe conduct of the trial and appropriate record keeping (e.g. Serious Adverse Events data).

Participants will also not be able to request to withdraw their data once anonymised and forms part of the data set. They will be informed of this in the PIS, and this is indicated on the consent form.

13) HARMS, SAFETY CONSIDERATIONS AND ADVERSE EVENTS

The participants in this trial will be community-based informal carers caring for people living with dementia. This is a group that does not have a particular elevated risk for adverse safety events. The Trusts will follow internal guidance for recording and reporting adverse safety events for non-CTIMPs at the trust. As an additional step we will measure safety outcomes via an adapted adverse effects of therapy checklist (see outcomes section).

Safety events will be compiled as part of a technical report that furnishes TSC sessions. Additionally, certain events are expected to be reported to Lancashire CTU/Sponsor and are outlined below. Safety events may be reported through a variety of sources, including AgeUK representatives, research team members and via an adapted adverse effects of therapy checklist provided to the participants.

The detailed safety reporting process is outlined in the study-specific safety guideline document.

This is a low-risk trial and, as such, it has been deemed unnecessary to form an independent data monitoring (and ethics) committee. Safety events will be compiled as part of a technical report that furnishes TSC sessions.

Reportable events

The following events are expected to be reported to the Lancashire CTU/Sponsor:

- Adverse Events (AEs) related to mental health
- All Serious Adverse Events (SAEs), including those that are not mental health related

Events that do not require to be reported:

Expected adverse events would include mild anxiety or depression, therefore only increasing in psychological distress and related events (such as suicidal thinking) would be reported as AEs.

Reporting procedure

Adverse events will be recorded on the trial database. The CI will provide the relatedness and seriousness assessment. Any serious events will be also recorded on the SAE form and reported to the Lancashire CTU and the Sponsor within one day of becoming aware of the event. If the SAE is both related and unexpected, the event will be reported to HRA within 15 days.

Reporting timelines

Safety events will be recorded from the time of consent until the final follow-up.

14) DATA COLLECTION, MANAGEMENT AND CONFIDENTIALITY

Data Management

The study will be subject to the audit and monitoring regime of the University of Manchester.

The CTU has a unit specific Data Management Plan in accordance with local standard operating procedures that will cover how data is handled specifically within the context of REDCap for the study.

The trial team will employ data quality checking processes. For example, verification of any data entry via hard-copy questionnaires. We will obtain a 20% sample of each set of questionnaires (i.e. all the baseline and follow-up measures for 20% of the sample) and record the number of errors. Any errors will then be corrected, and if there are more than a small percentage (1- 2%) of fields with errors detected, then we will repeat this data checking process for all the questionnaires.

Lancashire CTU Data Management Team will check 100% of eCRFs on REDCap for completeness, in line with our central monitoring procedures.

Data Protection and Patient Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act 2018 and General Data Protection Regulation (GDPR). The final trial data will be anonymised and cannot be linked back to the individual through research outputs.

Only minimum required data will be collected from the individuals and recorded on the CRFs. All data will be stored on secure dedicated web and database virtual servers. Access will be restricted by user identifiers and two-factor authentication, consisting of passwords (encrypted using a one-way encryption method), together with time-based, single-use codes generated by a mobile app or emailed to the user. Information about the trial in the

participant's medical records/hospital notes will be treated confidentially in the same way as all other confidential medical information.

The virtual machines comprising the data capture system (REDCap) are hosted as a service by University of Lancashire's information technology department (Library & Information Services; LIS) and are backed-up automatically as a part of the overall LIS infrastructure backup process. Each REDCap implementation (screening log, registration form and eCRFs) consists of a web server paired with a database server. Neither is directly accessible from public networks – the web service is accessed through an industry grade firewall.

All communications are encrypted – through mandatory digital certificates (also known as Secure Sockets Layer) in the case of web interfaces. All staff and site user accounts require two-factor authentication.

All backups which are transferred out of the data centres hosted by the University of Lancashire are encrypted.

Storage level snapshots are taken on the dHCI (disaggregated hyperconverged infrastructure) storage every two hours. These snapshots are retained for seven days, after which they are deleted.

Daily backups are taken using a solution provided by the backup vendor Rubrik, and are stored on encrypted, immutable resilient storage. Thirty-one daily backups are retained on University of Lancashire Preston Campus, after which they are deleted.

An additional weekly backup is taken, which is archived to Rubrik's Cloud Vault service. Twenty-six weekly backups (six months) are retained in the Cloud Vault, after which they are deleted. This service is hosted by Rubrik on Microsoft's Azure platform, and is similarly encrypted, immutable and resilient.

Lancashire CTU will be the data processor for any personal information collected as part of this study. Under the GDPR, participants have certain rights when personal data is collected about the participants. They will have the right to access any personal data held about them, to object to the processing of personal information, to rectify personal data if it is inaccurate, the right to have data about them erased and, depending on the circumstances, the right to data portability.

Data Storage

All personal information will be kept strictly confidential and held in accordance with the principles of the Data Protection Act (2018).

All procedures for handling, processing, storing and destroying the data will be compliant with the Data Protection Act 2018. Physical copies of consent forms will be kept separately in locked cabinets in personal offices within the NHS sites or University of Manchester (for local sites). All consent forms will be kept for seven years after the study ends in line with University of Manchester policy.

Participant ID will be provided at the consent and baseline 1 appointment. Data will be fully anonymised towards the end of the project (after the data has been analysed and is ready to be archived).

In line with the requirements set out by the University of Manchester, the name and email address of participants who have been provided with the shopping voucher will be securely retained by the research team on the UoM Research Data Storage Service for a period of up to seven years for audit purposes only and then destroyed. It will not be used for any other purpose.

Research data generated by the study will be kept for seven years after the study ends.

In line with the policies and guidelines from the University of Manchester, the following arrangements will be in place for long term storage of research data. Paper copies of research data (e.g. completed questionnaires) will be archived in locked cabinets in The University of Manchester or secure premises within NHS Trusts with access restricted to those working on the study (researchers) and those from organisations who may need access for audit or monitoring purposes (NHS, University of Manchester). Data will be archived for a period of years after the study ends. After this point, research data will be destroyed.

Once the retention period has passed, paper records and electronic data will be destroyed, following approval from the Sponsor.

Confidentiality

The research team will have access to the participant's name, address and contact details, once they have consented to be contacted to take part in the study. This will only be used to arrange for their participation and will only be available to key members of the research team.

To ensure pseudo-anonymisation following screening, all participants will be given a screening code. Pseudo- anonymisation will be completed by the researcher worker assigned to the participant. The research team will use REDCap, which is only accessible by authorised members of the research team, to record the screening code and pseudo-anonymisation key that links participants with their contact details. Data on personal information such as names and addresses will be stored separately within REDCap. Dr Lydia Morris (University of Manchester) will act as custodian of the data. The key will be destroyed after the end of the study in line with UoM guidelines.

Data will be shared between UoM and Lancashire CTU systems via REDCap or secure email in line with UoM guidelines. Data shared between these sites will be pseudo-anonymised.

Qualitative study data

This is not part of the trial dataset. It will be conducted by North Thames (UCL) Trainee Clinical Psychologists. Recordings will be securely stored in accordance with data protection requirements and securely transferred for transcription. Transcription of audio-recordings will be carried out by supervised Trainee Clinical Psychologists (NHS employees and concurrently registered at UCL on the clinical psychology doctoral programme) with relevant confidentiality agreements in place. Supervision will be provided by an experienced, Health and Care

Professions Council registered Clinical Psychologist (Georgina Charlesworth) who is also a member of the research team. Recordings and transcripts will be available to Georgina Charlesworth for quality control. All potential personal identifiers (e.g. location) within qualitative interviews will be removed as part of the transcription process. Audio recordings will be deleted once checked for accuracy after transcription. Electronic files of transcribed, pseudonymised interviews will be stored on Data Safe Haven. Policies and procedures for data processing, storage, use, deletion and right to withdraw will be in accordance with requirements of the data controller, made clear in the consent process.

Participants will be asked for their consent to report their comments anonymously, labelled by pseudonyms or numbers, on the consent form before qualitative interview begins.

15) STATISTICAL METHODS

We will follow the CONSORT 2010 statement for analysis and reporting. Primary analyses will be conducted on an intention-to-treat basis and follow a pre-specified Statistical Analysis Plan, approved by the TSC. A flow chart will show the numbers of participants who were approached and/or assessed for eligibility, randomly assigned for treatment, completed treatment, and by treatment group completed follow-up as planned and were included in the main analyses. Baseline demographic and clinical characteristics will be summarised for each group through appropriate descriptive statistics.

The Primary analysis for PSS at 16- and 26-weeks post-randomisation will use a partially-nested repeated measures mixed-effects model, adjusting for the stratification factor (course type/location), and baseline PSS as fixed effects, course (nested within the course type/location factor for the EC group only) and participant as random effects, and a time-by-group interaction (with time as a nominal factor) as part of the fixed-effects specification. The estimate of the effect of EC on the primary outcome, PSS at 26 weeks, will be taken as the contrast between the EC+TAU and TAU arms at 26 weeks (i.e. the sum of the estimates of the EC main effect and its interaction with time at 26 weeks). The effect of potential moderators of treatment, including preferred mode of delivery of EC (online vs. in-person), part-time vs full-time carer status and symptom severity (of the person with dementia) will be investigated by adding three-way interactions (i.e. between the potential moderator, time and group) individually to the primary analytic model.

Secondary outcomes will be analysed similarly, using longitudinal generalised mixed models appropriate to the type of outcome measure, including a time-by-group interaction effect as part of the fixed-effects specification. Models will be adjusted for the stratification factor (course type/location), baseline value of the corresponding outcome and participant and course (nested within the course type/location factor for the EC group only) as random effects.

The following safety indices will be monitored and recorded throughout the trial serious adverse events; adverse events; side effects of EC (See section 13).

Health Economic Analysis: An intention-to-treat within-trial cost-effectiveness analysis will be performed (perspective: NHS) and reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS 2022) statement. A health economic analysis plan

(HEAP) will pre-specify the methods. Quality-adjusted life years (QALYs) will be calculated from EQ-5D-5L observations using the area under the curve method. A micro-costing analysis will estimate the cost of the EC intervention (including training and delivery costs). Mean costs and QALYs per arm will be estimated by generalised linear model (GLM) regression, controlling for baseline EQ-5D-5L and cost. Missing data will be handled with multiple imputation by chained equations. Uncertainty will be handed by bootstrapping. Results will be presented as an incremental cost-effectiveness ratio and compared against the relevant threshold recommended by the National Institute for Health and Care Excellence (NICE) at the time of analysis. A cost-effectiveness acceptability curve will express the probability of EC being cost-effective. input parameter values and structural assumptions (complete case analysis, per protocol analysis, GLM specifications).

16) OVERSIGHT & MONITORING

Progress criteria

Progress will be assessed against pre-specified milestones and monitored by the TMG and TSC. Failure to meet milestones will be addressed by the CI and Co-CI in consultation with the Lancashire CTU and contingency planning agreed with the TMG and our PPIE group.

Trial Steering Committee (TSC)

The TSC will meet two or three times a year and more often if indicated. The role of the TSC is to provide overall supervision for the trial, concentrate on the progress of the trial and adherence to the protocol and provide advice through its independent Chair.

Trial Management Group (TMG)

The TMG, comprising the Chief Investigator (CI), co-CI, co-applicants and the RA, will be assigned responsibility for the clinical set-up, on-going management, promotion of the trial and for the interpretation and publishing of the results.

DMEC

This is a very low risk trial and, as such, it has been deemed unnecessary to form an independent data monitoring (and ethics) committee. The TSC will perform the basic functions of a DMEC, where necessary.

17) PEER REVIEW

The research plan for this study was reviewed in detail as part of the NIHR's (funder) review process. The review process for Research for Patient Benefit funding includes review by an independent scientific committee.

The research plan and protocol have been further reviewed by the research team for the study and by researchers from the multi-centre steering group.

18) ETHICAL and REGULATORY CONSIDERATIONS

18.1 Approvals

Before the start of the study, a favourable opinion will be sought from an NHS REC and HRA for the study protocol, informed consent forms and other relevant documents.

Before any site can enrol patients into the study, the Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

18.2 Risks

The researchers do not expect any significant risks or burden for participants as a result of the study. However, since the project focuses on carers and the potential emotional distress associated with caring, some disclosure and experiences of distress are possible. All experiences of distress that meet the threshold for an Adverse Event will be reported in line with the safety reporting guidelines.

Distress during research appointments:

The research procedures used in the current study are modelled on those used in previous studies in this area (Morris et al. 2021). In our experience, research participants (Carers) not only tolerate these tested procedures, but welcome the opportunities to discuss their caring role and current difficulties. However, if this is not the case and for any reason participants become distressed during research assessments, we will follow distress protocols adapted from our previous studies. Data collection will be stopped immediately and will only continue if the participant feels comfortable doing so. Participants will also be reminded that they can withdraw from the study at any time. If so, the research worker will debrief the participant and discuss whether the participant might wish to arrange a meeting with the project lead (a clinical psychologist with extensive experience in this topic area) or another member of staff they feel comfortable with.

Distress during Intervention:
Two thirds of trial participants will be randomised to receive the Empowered Conversations Course delivered by trained course facilitators. Within the Empowered Conversations course facilitators are trained to respond to carers who are distressed. They discuss the fact that some of the topics discussed maybe sensitive with carers and support them if distress arises. They have a distress management protocol that they used within sessions for both online and in-person groups (see supporting documents, Distress protocols). Distress will be monitored in sessions and if significant distress arises, this will be managed according to the protocol and the research team informed.

Data Protection:
The study involves the collection of sensitive personal information. To protect against potential data protection and confidentiality risks, all data collected from participants will be pseudo-

anonymised using unique participant identification numbers. Hard and electronic data will be handled in strict accordance with data management policies of the University of Manchester, national legislation (GDPR) and GCP best-practice principles.

Confidentiality:
If a participant discloses something which raises serious concerns about their safety or the safety of others, it may be necessary to break confidentiality and inform relevant parties. This would be discussed with the participant during the consenting process and is expanded on further in the information sheet.

19) STATEMENT OF INDEMNITY

The University of Manchester will arrange insurance for research involving human participants that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.

20) FUNDING and RESOURCES

This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR208874).

The study has been funded for 32 months. A total of £711,074.44 has been secured; £508,354.00 are the research costs. £202,720.44 are the NHS Support and Treatment costs.

As there are Trainee Clinical Psychologist's projects nested within trial, expenses for these will be paid by the relevant affiliated institution (University of Manchester or UCL).

Relevant equipment will be covered by the RfPB funding and sourced via the relevant trust or UoM. Ownership will remain will the relevant trust or university at the end of the study.

21) PUBLICATION POLICY

Outputs: Five academic publications are planned: 1) reporting the trial protocol, 2) reporting the effectiveness and cost-effectiveness trial outcomes (and process evaluation), 3) reporting PPIE activities and impact, 4) further reporting on the process of adapting EC for minoritised communities, 5) Initial findings regarding the psychometric properties of novel measures, specifically the 'Peer support in groups' measure.

Results will be reported on ISRCTN (trial registry).

The results of the trial will be disseminated via peer reviewed scientific journals, internal reports, conference presentation and publication on the Empowered Conversations website.

Participants will be given the option of providing their contact details to receive a summary of the study results. A summary of the study and findings will also be made available on the Empowered Conversations website, and this will be advertised through their organisation's social media channels. The summary will be available for free download and will be accessible to participants and the wider public.

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