STUDY PROTOCOL

Protocol of a feasibility randomised controlled trial of Empowered Conversations: training family carers to enhance their relationships and communication with people living with dementia. [version 1; peer review: 3 approved]

Cassie Eastham[1], Warren Mansell[2,3], Chris Sutton[3], Yeliz Prior[4], John Keady[3], Gemma Shields[3], Cathy Riley[1], Gail Bowker[5], Yvonne Sylvestre[3], Lydia Morris[3]

[1]Greater Manchester Mental Health NHS Foundation Trust, Prestwich, England, M25 3BL, UK
[2]Curtin University, Perth, Western Australia, 6102, Australia
[3]The University of Manchester, Manchester, England, M13 9PL, UK
[4]University of Salford, Salford, England, M5 4WT, UK
[5]Independent Researcher, Manchester, England, UK

v1 **First published:** 10 Jul 2023, **3**:36
https://doi.org/10.3310/nihropenres.13441.1
Latest published: 10 Jul 2023, **3**:36
https://doi.org/10.3310/nihropenres.13441.1

Abstract

Background: Communication difficulties can cause frustration, low mood, and stress for people living with dementia and their carer. Carers should be offered training on adapting their communication skills. However, it is not common for skills-based education to examine emotional aspects of care and the effect of dementia on relationships. The Empowered Conversations (EC) training course was developed in response to a gap in service provision and has been adapted to a virtual format (Zoom). It addresses the specific psychological, relationship, and communication needs of informal and family dementia carers. The primary aim of the study is to investigate the feasibility of conducting a multi-centre randomised controlled evaluation trial of EC. Secondary aims include exploring the acceptability of delivering the intervention online and examining the optimum way of establishing cost-effectiveness.

Methods: The feasibility trial uses a pragmatic data-collector blind parallel two-group RCT design with two arms (EC intervention plus treatment as usual, and treatment as usual waitlist control). There will be a 2:1 allocation in favour of the EC-training intervention arm. 75 participants will complete baseline outcome measures exploring their role as a carer, including their physical and mental health, attitudes to caring, quality of life, and use of health and social care services. These will be repeated after six-months. Participants allocated to the treatment group who complete the course will be invited to participate in a qualitative interview discussing their experience of EC.

Open Peer Review

Approval Status ✓ ✓ ✓

	1	2	3
version 1 10 Jul 2023	✓ view	✓ view	✓ view

1. **Joan K. Monin**, Yale University, New Haven, USA
2. **Juanita Hoe**, The University of West London, London, UK
3. **Patricia Masterson-Algar**, Bangor University, Bangor, UK

Any reports and responses or comments on the article can be found at the end of the article.

Discussion: The study will investigate recruitment pathways (including facilitators and barriers to recruitment), estimate retention levels and response rates to questionnaires, obtain additional evidence regarding proof of concept, and consider the most appropriate primary outcome measures and methods for evaluating cost-effectiveness. The results of the feasibility study will be used to inform the development of a multicentre randomised controlled trial in the United Kingdom.
Registration: ISRCTN15261686 (02/03/2022)

Keywords
Dementia, Carers, Caregivers, Stress, Burden, Psychosocial intervention, Training, Communication

Corresponding author: Lydia Morris (lydia.morris@manchester.ac.uk)

Author roles: Eastham C: Conceptualization, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; **Mansell W**: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; **Sutton C**: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; **Prior Y**: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; **Keady J**: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; **Shields G**: Conceptualization, Funding Acquisition, Methodology, Writing – Review & Editing; **Riley C**: Conceptualization, Writing – Review & Editing; **Bowker G**: Conceptualization, Writing – Review & Editing; **Sylvestre Y**: Methodology, Writing – Review & Editing; **Morris L**: Conceptualization, Funding Acquisition, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This project is funded by the National Institute for Health Research (NIHR) under its 'Research for Patient Benefit (RfPB) Programme' (Grant Reference Number NIHR201093). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Eastham C, Mansell W, Sutton C *et al.* **Protocol of a feasibility randomised controlled trial of Empowered Conversations: training family carers to enhance their relationships and communication with people living with dementia. [version 1; peer review: 3 approved]** NIHR Open Research 2023, **3**:36 https://doi.org/10.3310/nihropenres.13441.1

First published: 10 Jul 2023, **3**:36 https://doi.org/10.3310/nihropenres.13441.1

Plain language summary

There are 700,000 family and informal carers for people living with dementia in the UK alone. Sixty-four percent of informal carers 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 caused by dementia. This can lead to frustration, low-mood and stress for both people living with dementia and their carers.

The 6-session online Empowered Conversations course is designed to enable carers to maintain and improve 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. The course has been tried out over the last 4-years and changes made. Feedback from informal carers indicates it is in an optimum form and we are ready to test it further in a large trial. Before this is done, it is necessary to complete a smaller 'feasibility' trial to check whether such a larger trial is possible. This article explains how the feasibility trial will be carried out.

Our 'feasibility' trial will check several things. We want to make sure that carers would be willing to have an only 66% chance of receiving the course straight away, because it is essential to have a comparison group. The remaining 33% of carers would be offered the course 6-months later. We want to ensure that our design is good enough to identify any improvement in carers' well-being, relationships and communication. We will also ask carers to take part in a one-to-one interview about their experiences of the course, including their views on the course being delivered on Zoom.

Introduction

Background and rationale

In the UK, around 61% of people who are aged over 60 and have a diagnosis of dementia live at home (Wittenberg *et al.*, 2019a) 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 therefore an essential component of dementia care with a cost of £13.9bn per year for unpaid care, compared with £15.7bn spent on formal social care (Wittenberg *et al.*, 2019b).

Informal carers in the UK report significantly lower life satisfaction, happiness, and self-worth (Carers UK, 2022), sixty-four percent of informal carers in England say they have limited support for their psychological and social needs (Health and Social Care Information Centre, 2017). It is widely recognised that the availability of dementia post-diagnostic support varies both internationally and across the UK (Alzheimer's Disease International, 2022; Alzheimer's Society, 2022; Frost *et al.*, 2021).

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 informal carers of people living with dementia experience significant depression or anxiety (Cooper *et al.*, 2007). The ongoing cognitive, communication, and perceptual changes caused by all types of dementia present significant challenges for informal carers (Clare *et al.*, 2019; Moniz-Cook *et al.*, 2011).

Informal carers of people living with dementia can benefit from support and interventions that address their needs. For example, certain tailored psychosocial interventions can reduce carer depression and anxiety (Morris *et al.*, 2018) and multicomponent psychosocial interventions (combining two or more different approaches, such as counselling and support) for carers can prevent care breakdown and delay care home admission(Elvish *et al.*, 2013; Mittelman *et al.*, 1993; Olazarán *et al.*, 2010).

Difficulties with communication cause frustration, low mood, and stress for both people living with dementia and their carers (Dooley *et al.*, 2015; Holst & Hallberg, 2003; Steeman *et al.*, 2006). Conversely, research has found that improving communication can enhance relationships and support people living with dementia to feel connected and understood (Judge *et al.*, 2013; La Fontaine & Oyebode, 2014).

Communication skills training for carers can improve the well-being and quality of life of the person living with dementia, and result in positive interactions during the delivery of care (Eggenberger *et al.*, 2013; Morris *et al.*, 2018; Perkins *et al.*, 2022). However, although skills-based interventions may improve carers' knowledge and communication skills, it is not common for communication skills training to include emotional aspects of care and the changing role dynamics within the caring relationship (Morris *et al.*, 2018; Williams *et al.*, 2018). The Empowered Conversations (EC) communication training course for carers was developed in response to the gap in service provision identified through reviewing research literature and carrying out scoping exercises and public engagement work (Innes *et al.*, 2022; Morris *et al.*, 2020; Morris *et al.*, 2021). In addition, a further systematic review of communication training programmes identified that interventions were often based only on basic models of communication, lacked post-intervention follow up and used a variety of non-standardised outcome measures (Perkins *et al.*, 2022).

More recently, acceptability and feasibility work has been published regarding an emotional intelligence focused training workshop for professional and family carers (Heid *et al.*, 2022). Although emotional intelligence skills can be developed through EC, the course also includes relational dynamics and specific communication skills. The course integrates evidence-based models to address the specific psychological, relationship, and communication needs of carers (Morris *et al.*, 2020). Earlier research, using a pre-post-follow-up design, has demonstrated that carer stress was significantly reduced, and communication significantly improved over time following participation in the course (Morris *et al.*, 2021). Twenty-eight of the 159 carers

who participated in the study agreed to be interviewed after the course and twenty-seven described feeling able to better connect with the person they support after attending EC (Innes *et al.*, 2022; Morris *et al.*, 2020).

Currently, EC is only routinely provided in Greater Manchester. The intervention is delivered in a group format and includes multiple components, including both educational and therapeutic components. This is in line with evidence that concludes the most effective interventions for improving carers' psychological health include these features (Dickinson *et al.*, 2017).

Initially, EC courses were delivered as in person (face-to-face) groups but, following restrictions caused by COVID-19, EC was adapted to an online format delivered using Zoom. A review with meta-analysis of online interventions for family carers indicated that multicomponent interventions achieved the best results as regards reducing depression, anxiety, grief, and burden and increasing quality of life, empathy, and knowledge about dementia; however, online interventions focusing on more specific aspects also contributed to a range of improvements (Etxeberria *et al.*, 2021). In addition, comparisons of support packages delivered in in person and online versions have shown that both formats offer similar effectiveness (Karagiozi *et al.*, 2022; Noel *et al.*, 2022; O'Connor *et al.*, 2023). However, it is possible that online interventions could also exclude certain individuals (Giebel *et al.*, 2021; Wheatley *et al.*, 2022).

The proposed feasibility RCT, with nested qualitative study, will provide data to inform a fully powered multi-centre RCT of an intervention delivered online that could satisfy a currently unmet need for carers in the UK.

Study objectives

The primary aim of the study is to establish the feasibility of examining the EC intervention within a multi-centre RCT.

The study's key objectives are:

1. To establish recruitment pathways.
2. To identify facilitators and barriers to recruitment, including whether the online format of the intervention presents a barrier to under-served or other groups.
3. To estimate retention levels and response rates to questionnaires.
4. To obtain additional evidence regarding proof of concept.
5. To estimate potential effectiveness on a range of candidate primary outcome measures, and their standard deviations (SDs).
6. To identify the most appropriate primary outcome measure for a multi-centre evaluation trial.
7. To establish the optimum way of evaluating cost-effectiveness in a multi-centre evaluation trial.

Primary outcome(s)

1. Recruitment numbers per month.
2. Retention rate recorded as the number of participants who remain in the study at the 6-month follow-up.
3. Feasibility of an evaluation trial, as indicated by 1 & 2 above, and informed by the qualitative data

Key secondary outcomes

1. Obtain estimates of the standard deviations of measures.
2. Explore 'proof of concept'. Establish the optimum way of evaluating cost-effectiveness.
3. Identify the most suitable primary outcome measure(s) for a subsequent evaluation trial.
4. Explore acceptability of delivering the intervention online

Candidate primary outcome measure(s) for a subsequent evaluation trial include:

1. Carer anxiety and depression measured using Hospital Anxiety and Depression Scale Total Score (HADS-T), or HADs depression or anxiety subscales
2. Carer stress measured using Perceived Stress Scale
3. Carer relationship stress using the Dyadic relationship scale
4. Carer sense of competence in their caring role measured using Short Sense of Competence

Trial design

The trial will use a pragmatic data-collector blind parallel two-group RCT design. The two arms will be the EC training-intervention (plus Treatment as Usual), or Treatment as Usual (TAU) waitlist control.

There will be a 2:1 allocation in favour of the EC training-intervention arm.

The comparator is a Treatment as Usual (TAU) waitlist control. This comparator is helpful in an effectiveness design (and so within a feasibility trial that aims to scale up to an effectiveness trial). Participants in the TAU arm will be offered the EC intervention after completing their 6-month follow up questionnaires.

The trial will also include a nested qualitative study. This will involve interviews with participants who attended at least three sessions of the EC intervention, as well as individual or focus group interviews with participants who declined to take part in the trial or have attended two or fewer sessions of the course.

Protocol

Trial registration: ISRCTN15261686 (registered on February 3rd, 2022)

Protocol version: 2.6 21/11/2023

Methods: Participants, interventions, and outcomes

Study setting

The study will take place across the ten boroughs (Bolton, Bury, Manchester, Oldham, Rochdale, Salford, Stockport, Tameside, Trafford, and Wigan) within Greater Manchester, a metropolitan county in the Northwest of England with varying levels of deprivation (Table 1). The study will be hosted by Greater Manchester Mental Health NHS Foundation Trust with a study site at Pennine Care NHS Foundation Trust. Recruitment will also take place within the third sector and community organisations across Greater Manchester.

EC is an online intervention and participants will take part from their own homes or any other suitable place of their choice. The baseline and six-month follow-up questionnaires will be offered online (using REDCap) or in person with a researcher. Any face-to-face research activities, such as interviews, will take place at the participant's home or another appropriate venue of their choice.

Eligibility criteria

The trial aims to recruit 75 carers of people living with dementia.

To be included in the main study, participants must:

- Be the current unpaid or informal carer for someone living with dementia (any sub-type or severity)
- Live in Greater Manchester
- Be aged 18 or over.
- Have capacity to give informed consent for the study.
- Have sufficient English language skills to understand and participate in the training and research activities.
- Be interested in taking part in a training course for carers of people living with dementia.

Where appropriate, the Clinical Dementia Rating (CDR) scale will be used to assess the person with dementia's level of cognitive impairment.

The researcher will ask the carer if it is appropriate to approach the person with dementia about completing the CDR. Carers will be asked to consider significant issues such as the person being unaware of their dementia diagnosis, being distressed by cognitive testing or discussing their memory, or if the person has significant unmanaged behavioural or psychological symptoms of dementia. Such concerns would exclude the person with dementia from participating.

The person living with dementia will need to have capacity to give informed consent to completing the CDR scale. If they appear to lack capacity, they will need to have a personal consultee who can be approached to discuss their involvement in the research.

The carer's eligibility to participate is not conditional on the person living with dementia being offered or completing the CDR.

Intervention

This version of EC is delivered online using Zoom by two trained facilitators from Age UK Salford. Each group will comprise 6–10 participants.

Facilitators follow a course manual to deliver a structured framework of core topics, discussions, and activities over six-weeks (Table 2). However, they also have flexibility to

Table 1. Deprivation indicators by Greater Manchester borough. Lower numbers indicate greater deprivation. Most of these boroughs are in the lowest quartile, indicating high levels of deprivation across Greater Manchester (Ministry of Housing, Communities and Local Government, 2019).

Borough	Index of Multiple Deprivation Rank of Average Score	Health Deprivation and Disability - Rank of average score
Bolton	27	36
Bury	69	54
Manchester	6	4
Oldham	16	31
Rochdale	14	17
Salford	15	9
Stockport	86	52
Tameside	24	15
Trafford	118	88
Wigan	58	33

Table 2. Session content for EC course.

	Theme
Week 1	Introducing Curiosity
Week 2	What Gets in the Way of Our Conversations?
Week 3	Stop, Listen, Look
Week 4	Empathy and Memory
Week 5	Building on Strengths and Resources
Week 6	Summing Up – Drawing the Course to a Close

adapt the material to the different needs of participants, including optional and extra activities that can be used if appropriate. Each session lasts for 2-hours and is held at the same time and day for the duration of the course. Where possible, participants will be offered a choice of morning, afternoon, or evening sessions to accommodate their needs. Participants are sent a workbook before the start of the course and additional (optional) learning materials are sent to participants in a weekly email from the facilitator. The course summary can be found in the Extended data (Morris *et al.*, 2023).

Each session begins with a 'Pause for Breath' (a short breathing exercise led by a facilitator) and an opportunity to reflect on both the previous week's session and the participants' experiences during the week. This is followed by the week's activities and each session is closed with a summary, including prompts for reflection or actions that the participants can try during the week.

Facilitators are trained to deliver the course using the manual and will have participated in an EC course before their training begins. New facilitators receive nine hours of one-to-one training provided across the duration of two EC courses. New facilitators begin to deliver aspects of these courses with support from an experienced facilitator, weekly debriefs and supervision.

All course facilitators access weekly supervision with an experienced facilitator and monthly external clinical supervision.

Fidelity and competence of the course facilitators will be monitored using an adapted version of checklist that has been used in two previous studies of a group-based intervention using similar techniques to EC (the Take Control Course) (Morris *et al.*, 2016; Morris *et al.*, 2018).

Adherence of the course to the intervention will be monitored by Age UK Salford. Staff will record attendance at each session. Participants completing three or more sessions will be considered to have completed the intervention.

TAU

TAU will be the medical, psychological, and social support that is available to the care dyad within their local area. This may include, but is not limited to, services such as NHS memory assessment or community mental health teams, dementia cafés, social care, and carers support groups.

There will be no restriction on treatment as usual. This is intended to be a pragmatic trial and preventing carers from accessing services would be unethical.

Any services that carers access will be captured with the Healthcare Service Use questionnaire.

Outcomes

The study will measure outcomes in terms of (1) identifying the most appropriate primary clinical outcome measures and (2) the feasibility of conducting a multi-centre study.

Participants will complete ten clinical outcome measures at baseline and at 6-month follow-up to address objectives 4–6. These will be Short Sense of Competence Questionnaire, Dyadic Relationship Scale (Caregiver), Carer Communication Questionnaire, Perceived Stress Scale, Hospital Anxiety & Depression Scale (HADS) (potential primary outcome measures), C-DEMQOL, Caregiving Ambivalence Scale, Bristol Activities of Daily Living Scale, EQ-5D-5L, and Healthcare service use.

A 'shortlist' of potential primary outcome measures will be developed using the evidence of proof of concept/proof of efficacy and carers' views discussed in the qualitative interviews. Participants will also be asked to record key demographic data at baseline and complete a feedback form when they finish the course sessions.

Exploratory analysis of cost-effectiveness measures (objective 7) will be conducted using data from the EQ-5D (a commonly used measure of health status) and healthcare service use questionnaires. The CDR scale will be used as a measure to directly assess the supported person's level of cognitive impairment. This clinical interview assessment will be conducted at baseline with the care dyad. This will help describe the sample and establish whether using this measure would be feasible within the proposed multi-centre trial.

The feasibility of proceeding to a multi-centre study (objectives 1, 2 and 3) will be judged on the recruitment and retention of participants.

- If an average of 6–10 carers were recruited per month from the proposed Greater Manchester recruitment site, then this would be expected to be at a sufficient level for a multi-centre trial. This would need to be fulfilled in addition to the below stop/go criterion.

- Stop/go criteria for retention (baseline to primary outcome completion at 6-month follow-up out of number randomised) is:
    - o Green (progress to full trial): At least 80% retention:
    - o Amber (full trial considered feasible if reasons for poor retention identified and can be addressed): 65%–<80% retention.
    - o Red (unlikely to progress to full trial): Below 65% retention.

Sample size

The target sample size for the RCT will be 75 (50 EC training-intervention:25 TAU). However, to account for withdrawals and to ensure each course cohort is an appropriate size (6–10 participants), up to 90 participants will be recruited.

This is a typical sample size for feasibility trials and, assuming a minimum of 80% retention (60 participants) will enable the SD to be estimated with satisfactory precision (Sim & Lewis, 2012) and the overall retention rate to be estimated by a 95% confidence interval with width 19.2%. It will also enable estimation of efficacy (Standardised Effect Size [SES]) using an 80% confidence interval with width ≤0.4.

Recruitment

The participant timeline is summarised in Figure 1. Potential participants will be identified through NHS memory services, established carer and dementia support groups, health and social care networks, and Join Dementia Research. The study team will attend groups and meetings, both online and in person, to talk about participation in the trial. The study will also be promoted on social media channels (Twitter and Facebook), organisational newsletters/blogs, and via professional and service user/carer networks.

Updates about the trial will be sent by email to community and professional stakeholders to maintain interest in recruitment.

Professionals will give carers a short summary of the trial and ask them to complete a consent to contact form if they are interested in knowing more. Where a physical consent to contact form cannot be used (e.g., telephone appointments), verbal consent will be documented by the professional in their usual records. Alternatively, carers can self-refer by telephone or email, or give consent to contact directly to the study team during promotional activities.

The study team will then provide a detailed participant information sheet and, after a minimum of 24-hours, contact the carer to answer any questions and discuss the trial in more detail.

Recruitment levels will be monitored and reviewed by the study's trial management group. If targets are not being achieved, the group will discuss strategies to address this.

Methods: Assignment of interventions

This is a feasibility trial using pragmatic data-collector blind parallel two-group RCT design. The two arms will be the EC training-intervention (plus TAU), or TAU waitlist control.

Allocation: Sequence generation

Randomisation will be performed as block randomisation with a 2:1 allocation, in favour of the immediate intervention arm. A computer-generated randomisation schedule with randomly permuted blocks, of randomly-selected block sizes, will be used to ensure allocation concealment.

Unbalanced randomisation is used to provide more information on aspects of the EC intervention, such as barriers to participation and intervention acceptability. In addition, it is anticipated that this design will make the trial more ethically acceptable if used for a subsequent effectiveness trial. Moreover, although imbalance tends to make evaluation trials less efficient (increasing the overall sample size to achieve target power), it is expected that there will be some degree of clustering (by group) in the EC arm which will lessen the impact of the imbalance, meaning that a ratio between 1:1 and 2:1 would provide the optimal design. We would, however, expect to retain a 2:1 allocation ratio for an evaluation trial, should this be found to be feasible.

Randomisation process

A researcher will contact carers who are interested in taking part and screen their eligibility using the defined recruitment criteria. Eligible carers who are agreeable to taking part in the research will then complete the baseline questionnaires in a face-to-face appointment with the researcher or be sent an electronic invitation to complete these online.

On completion of the consent form and baseline measures, the researcher will send the participant's details to the EC administrator, who will then randomise the participant to the treatment or control group using the online Sealed Envelope application. This ensures concealment from members of the research team completing recruitment.

Blinding

The trial will be data-collector blind. 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); in this scenario it would be likely that unblinding would be needed to best support the participants well-being.

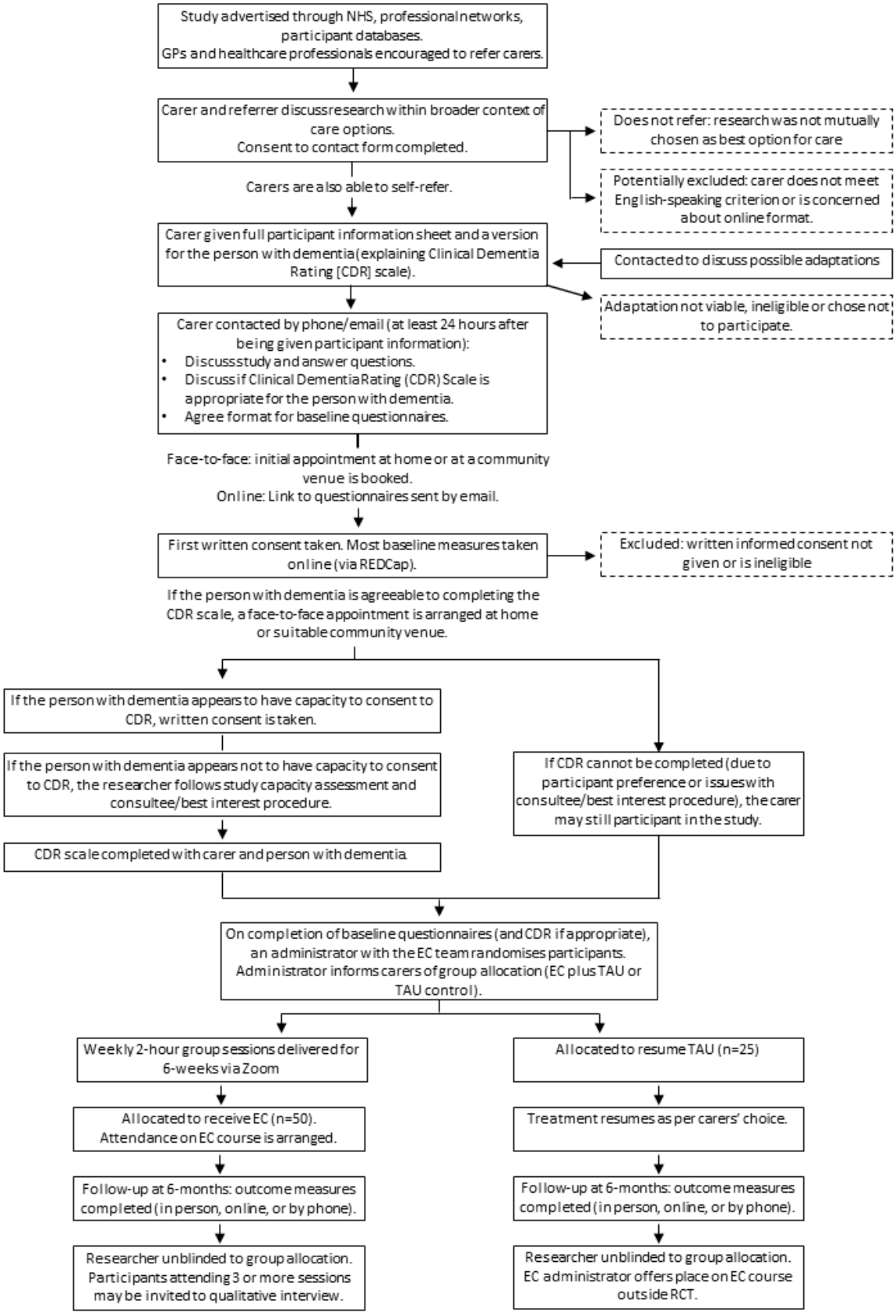

Figure 1. Participant timeline.

The research team will be unblinded after the participant completes the 6-month follow up questionnaires. The statistical team will remain blind until the Statistical Analysis Plan has been approved.

Methods: Data collection, management and analysis

Quantitative data collection methods

Participants will complete the baseline and follow-up questionnaires (Table 3) during a face-to-face appointment with the researcher or online using the REDCap system. Participants completing the questionnaires online will be encouraged to complete the questionnaires in one session.

The CDR scale is completed with the care dyad. If appropriate, this will be completed in a face-to-face appointment or by collecting the carer's responses by telephone before a face-to-face appointment with the person they support.

Demographic questionnaire: This is a non-standardised questionnaire to collect demographic information about the carer and the dementia diagnosis of the person they support.

Short Sense of Competence Questionnaire: The 7-item measures the carer's feeling of being capable to care for the person they support on a 5-point Likert scale (Strongly Disagree [1] to Strongly Agree [5]). Validated with carers of people living in the Netherlands; Cronbach's alpha .79 (Vernooij-Dassen *et al.*, 1996); used with a range of populations, including UK carers (Stansfeld *et al.*, 2019).

Dyadic Relationship Scale (Caregiver): The 11-item scale asks carers to consider positive and negative aspects within their relationship with the person they support. Carers complete a four-point scale (Strongly Agree [0] to Strongly Disagree [3]) in response to statements about their relationship during the previous month. Validated with urban and rural populations in the United States; Cronbach's alpha .84–.89 (Sebern & Whitlatch, 2007).

Carer Communication Questionnaire: Carers reflect on a recent, familiar act of communication with the person living with dementia and score eight statements against a 7-point scale (Strongly Disagree [1] to Strongly Agree [7]).

Perceived Stress Scale: This is a 10-item scale measuring an individual's perceived stress levels in situations during the previous month. Carers rate the frequency of their feelings on a 5-point scale (Never [0] to Very Often [4]). This has been

Table 3. Use of study outcome measures.

Measure	What this measures	Number of items	Baseline	Follow Up
Demographic questionnaire	Age, Gender, Ethnicity, Sexual orientation, Relationship to cared for person, Dementia diagnosis, Geographical location, Household composition, income and government assistance, Education history, Employment status, Chronic health conditions		X	
Short Sense of Competence Questionnaire	Relational competence	7	X	X
Dyadic Relationship Scale (Caregiver)	Relationship strain (e.g., I felt resentful)	11	X	X
Carer Communication Questionnaire	Carer perceptions of communication	10	X	X
Perceived Stress Scale	Stress	10	X	X
Hospital Anxiety & Depression Scale (HADS)	Anxiety and Depression	14	X	X
C-DEMQOL	Quality of life	30	X	X
Caregiving Ambivalence Scale	Goal conflict	6	X	X
Bristol Activities of Daily Living Scale (BADLS)	Ability of someone with dementia to carry out daily activities such as dressing and preparing food	20	X	X
EQ-5D-5L	Health-related quality of life	5	X	X
Healthcare service use	Hospital, primary, community and social care use	-	X	X
Clinical Dementia Rating (CDR) scale	Severity of dementia.	-	X	

validated in various populations; Cronbach's alpha .74–.91 (Lee, 2012).

HADS: The HADS is a self-rating inventory developed to identify depression and anxiety in non-psychiatric settings. Fourteen items (seven relating to depression and seven to anxiety) are rated on a four-point scale (eight items are reverse-scored). The HADS has been evaluated in somatic, psychiatric, primary care, and general populations and is considered a robust tool for screening anxiety and depression; Cronbach's alpha .68 to .93 (mean .83) for HADS-A (anxiety) and .67 to .90 (mean .82) for HADS-D (depression) (Bjelland *et al.*, 2002).

C-DEMQOL: This tool measures the quality of life experienced by carers of someone living with dementia. Thirty items are used to rate five domains that are relevant to quality of life (Feeling Supported, Carer Patient Relationship, Meeting Personal Needs, Confidence in the Future, Carer Wellbeing) on a five-point scale. Validated with carers in the United Kingdom; Cronbach's alpha .93 (Brown *et al.*, 2019).

Caregiving Ambivalence Scale: Ambivalence describes the presence of concurrent positive and negative feelings towards the caring role and cared for person (Losada *et al.*, 2017). Carers use a four-point scale (Never [0] > Always [3]) to rate the frequency of feelings presented in six statements. Validated with family carers in Spain; Cronbach's alpha .86 (Losada *et al.*, 2017).

BADLS: The BADLS is an informant rated scale measuring the person with dementia's ability to complete personal and domestic activities of daily living. Carers rate the person's ability to complete twenty individual tasks on a four-point scale (or scoring zero if the person has never completed the activity). The tool was developed and evaluated specifically for use with people living with dementia (Bucks & Haworth, 2002).

EQ-5D-5L: This health status measure asks participants to rate the presence of problems across five domains (Mobility, Self-care, Usual Activities, Pain or Discomfort, Anxiety or Depression) on a five-point scale (No problems to unable to complete the domain / extreme presence). In addition, a visual analogue scale is provided for the informant to rate their current health on a scale from 0–100 (where 100 represents the best health possible).

Healthcare Service Use: This is a questionnaire designed to capture the carer's use of health and social care services in the previous 6-months, adapted from similar questionnaires used in other trials with economic evaluation components (Lovell *et al.*, 2019; Morrison *et al.*, 2019). This includes recording inpatient admissions, hospital outpatient or day appointments, accident and emergency (A&E) visits, and use of primary, community and social care services.

CDR: Following a structured interview with the carer and person living with dementia, the interviewer's clinical judgement and interpretation of the responses is used to score the person's level of impairment across five domains (Memory, Orientation, Judgment & Problem Solving, Community Affairs, Home & Hobbies, and Personal Care). This can be rated on a 5-point scale of impairment (0=none, 0.5=questionable, 1=mild, 2=moderate, 3=severe) across the individual domains, or a global score can be produced using the tool's scoring algorithm (0=Normal, 0.5=Very Mild Dementia, 1=Mild Dementia, 2=Moderate Dementia, 3=Severe Dementia). The CDR has good psychometric properties and has been validated in a range of populations (Olde Rikkert *et al.*, 2011).

Following the initial invitation to complete their follow up questionnaires, participants will be prompted to complete these after 14 days (email and text), 28 days (phone call) and 6-weeks (email and text).

Qualitative data collection methods

Qualitative data will be collected from two groups; (1) participants who completed three or more sessions of EC as part of the treatment arm, and (2) participants who completed two or fewer sessions of the course and people who declined to take part in the study.

After unblinding, participants in the treatment group will be invited to complete the appropriate qualitative interview (based on the number of sessions attended).

1) Semi-structured interviews will be used to ask participants who complete three or more sessions about life before the course, deciding to take part in the study, their experience of the course, life now, and taking part in a research study. This includes their feelings of engagement with the research, the timing of being offered the course in relation to their dementia 'journey', and their feelings about the relative importance of the study's outcome measures.

2) These interviews will focus on identifying any barriers to attending the course (including the online format) or taking part in the study, and ideas for ways to facilitate access to the course and research activities. This aspect of the project will be conducted by a trainee clinical psychologist and form part of a wider project to explore barriers to attending an online psychosocial training intervention for carers.

Participants who attended two or fewer sessions will be asked to complete an individual interview about their experiences.

Participants who were allocated to the treatment arm but did not attend any sessions will be asked for brief feedback about their reasons in a telephone call with a researcher. During this conversation, they will be asked if they would like to take part in a more detailed, individual interview.

People who declined to take part in the trial itself will be given the option to take part in an individual interview or focus group.

Data management

Personal information will be pseudonymised and all procedures for handling, processing, storing, and destroying the data will be compliant with the Data Protection Act 2018. Personal data, such as names and addresses, and recorded interviews will be stored on secure servers within the University of Manchester.

Participants will be allocated a unique, 6-character participant identifier e.g., ZABC01 that will be used on case report forms (CRF), the REDCap system, and local and central portfolio management systems. A modified identifier (Unique ID+A, e.g., ZABC01A) will be used on the CDR scale documentation and to record participation on local and central portfolio management systems.

Data will be fully anonymised after the data has been analysed and is ready to be archived.

Outcome measures completed in a face-to-face interview will be recorded by a researcher on the CRF and entered on to the REDCap system by the researcher. Data, including consent, will be automatically entered, and recorded on the REDCap system by participants who choose to use it.

Access to REDCap will be restricted to essential members of the research team who will have individual login and passwords. Physical copies of consent forms will be kept separately in locked cabinets in personal offices within the University of Manchester. All consent forms will be kept for 10 years in line with University policy.

Any other paper documentation e.g., CDR, CRF, interview transcripts, will be stored in locked cabinets at the University of Manchester.

Encrypted University of Manchester devices will be used to record interviews. Recordings will be transferred directly to a (password protected) university computer and securely transferred for transcription. Transcription of audio-recordings will be carried out by a member of the research team, University of Manchester employee or an external supplier, who is one of the approved suppliers for the University of Manchester, where there is a confidentiality agreement in place. Audio recordings will be deleted once checked for validity after transcription.

Research data generated by the study will be kept for 10 years in line with the policies and guidelines from the University of Manchester.

Data quality processes

Data quality-checking processes will be used to verify data entered via hard-copy questionnaires. For 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.

Statistical methods

Overall recruitment and retention data will be presented in a CONSORT diagram. Monthly recruitment data will be presented, both overall and by borough. Retention will be presented as number (%), both overall and by treatment group, and will be accompanied by 95%CIs. Summaries of baseline characteristics and outcome measures at baseline and follow-up will be presented (mean, SD; frequency %, as appropriate).

Statistical analysis of outcome data will be 'as randomised' and include available data from all participants regardless of protocol adherence. No imputation of missing outcome data will be performed.; however, if there are any missing baseline values of the corresponding outcome data, we will use simple mean imputation (across the groups) to avoid exclusion of such participants in the proposed complete-case analysis. Mixed-effects regression analysis will be used to analyse the candidate primary outcome measures (at follow-up), and for the three pathways targeted by EC (ambivalence [goal conflict], relational stress and communication). In each case, models will include the treatment factor (fixed effect), the baseline value of the corresponding outcome measure (fixed effect) and 'course' (random effect [or fixed effect if convergence is not achieved] in a partially-nested model).

For the pathways targeted by EC, this analysis will be used to provide further evidence of proof of concept. For the candidate primary outcome measures, these analyses will be used to consider evidence as to potential proof of efficacy/effectiveness and will also provide estimates of their SD to assist with the estimation of the required sample size for a full effectiveness trial, should that measure be retained for consideration as primary.

The correlations between candidate outcomes to help interpret potential efficacy on the different potential primary outcome measures (well-being, relational distress, communication, and competency) will be explored to help inform our proposed primary outcome for a potential main trial.

Potential proof of concept / proof of efficacy will be examined using adjusted point estimates and confidence intervals (CIs), ranging from 75% to 95% confidence (steps of 5%, following the approach proposed by Lee *et al.*, 2014), for the between-groups differences in means for the candidate primary outcomes measures at the end of treatment, and the same measures at follow-up obtained from the analyses described above (Lee *et al.*, 2014). This approach is based on a minimally important difference (MID) between trial arms and is therefore more appropriate than formal hypothesis testing when a study is underpowered. A clinically meaningful difference between arms is generally around an effect size of 0.3–0.4 (Rothwell *et al.*, 2018); however, analysis will consider

the confidence intervals in relation to MIDs documented in the literature and, if necessary, will explore the perceived size of MID during this study.

Exploratory analysis will be conducted to inform a cost-effectiveness analysis within a definitive trial, including: an analysis of the range of services used and ability of participants to report complete service use data; the ability of the quality-adjusted life-year (QALY) (informed by the EQ-5D-5L) to discriminate between groups based on changes in clinical outcomes; factors likely to influence the incremental cost per QALY ratio.

Full details of the quantitative analyses will be included in a Statistical and Health Economic Analysis Plan (SHEAP) which will be written by the Trial Statistician, with input from the other members of the Trial Management Group. It will then be discussed and, following any agreed revisions, approved by the Trial Steering Committee prior to database 'lock'. The approved version of the SHEAP will be made available on the University of Manchester repository (Figshare) in advance of commencing the statistical analysis.

Qualitative analysis

The qualitative data from participants completing three or more sessions will be analysed using thematic analysis (Guest, 2012). Computer-assisted qualitative data analysis software (NVivo) will be used for the analysis. Themes identified will be reviewed by a qualitative methods expert independent of the study (peer verification).

Member checking will be used to verify the trustworthiness and potentially to refine key themes. A key informants approach to member checking (Onwuegbuzie & Leech, 2007) will be used so that feedback could be obtained from participants who gave both positive and critical feedback.

The themes and rationale for these (relevant quotes and description) will be fed back to participants to establish whether the themes reflect their experiences and perspectives.

Qualitative data from people who decline to participate in the research or complete two or fewer sessions will be analysed using framework analysis.

Methods: monitoring

Data monitoring

This is a very low risk trial and, as such, it has been deemed unnecessary to form an independent data monitoring (and ethics) committee. No formal interim analysis will be conducted.

A Trial Management Group will meet regularly to monitor the delivery of the trial. A Trial Steering Committee comprising an independent Chair, four other independent members (including PPI and Statistician) and the Chief Investigator and Research Associate will have overall supervision of the trial and will meet three times a year, or more if indicated. The trial will also have ongoing feedback from its public involvement and engagement group who meet on a quarterly basis.

Harms

The primary participants in this trial will be community-based informal carers caring for people living with dementia. Although this is a group that does not have a particular elevated risk for Adverse Event (AE) or Serious Adverse Event (SAE), we will follow the host NHS organisation's guidance for recording and reporting adverse events for non-CTIMPs.

Auditing

There are no planned audits from external organisations. However, data from the project may be audited by relevant agencies from the project sponsor. We have made this clear to all participants before they agree to take part in the study. The chief investigator and trial management team monitors study protocol adherence. The TSC and sponsor will also be able to request audits.

Ethics and dissemination

Research ethics

The study has been reviewed by the Wales Research Ethics Committee 2 and received approval in February 2022 (REC: 22/WA/0010).

Protocol amendments

Protocol amendments will be submitted in the first instance to the University of Manchester as the project Sponsor. Following authorisation by the Sponsor, protocol amendments will be submitted to the REC for review. Approved modifications to the amended protocol will be shared with trial sites, research team, and members of the TMG and TSC.

Consent - Carers

All participants will provide informed, written consent for their research activities.

Carers will be given a detailed participant information sheet and can discuss this with a member of the research team, and ask questions, before giving consent. Consent will be completed at the time of the baseline outcome measures. If these are completed in a face-to-face appointment with a researcher, the consent form will be completed with the carer and a copy given to the participant prior to commencement of data collection.

Participants using the REDCap system must complete an electronic consent form before they can access the online measures.

An additional consent form will be completed by participants who take part in the qualitative interviews.

Consent – person with dementia

In line with the Mental Capacity Act (MCA; 2005) the research team will assume capacity of the person living with dementia unless it is established otherwise. All practicable steps will be taken to help the person make the decision to take part in the study. This will include creating information and consent resources in an easy-to-read format, presenting explanations

in various ways, and ensuring that the time and location of the appointment optimises the person's participation.

The researcher will refer to the study's standard operating procedure for assessing capacity. If the researcher feels that the person living with dementia lacks capacity to consent to participate, this will be documented and discussed with the person and the carer. The researcher will check whether the carer is suitable and willing to act as a personal consultee. If they are not suitable or willing, another friend/relative will be sought to act as a personal consultee.

The researcher will discuss the person's participation with the personal consultee. Following the capacity assessment and best interest forms, the researcher will seek the consultee's views on whether it is in the person's best interest to take part in the research. This decision will also be documented.

Confidentiality
After consent to contact has been obtained, the research team will have access to the participant's name and contact details. These will only be used to arrange for their participation in the research activities and intervention and will only be available to key members of the research team.

A confidentiality agreement is in place with the University's approved transcription services.

All potential personal identifiers (e.g., location) within qualitative interviews will be removed as part of the transcription process.

During the consent process, participants will be made aware that study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may include access to personal information.

Participants will also be informed that members of the research team have a professional responsibility to break confidentiality if there are concerns the participant or anyone else might be at risk of serious harm.

Declaration of interests
The authors and trial team report no conflict of interest.

Access to data
In line with NIHR guidelines, fully anonymised 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.

Patient and Public Involvement and Engagement (PPIE)
A PPIE advisory group was set up during the development of the trial and its protocol and will continue to meet quarterly for the length of the study. A PPIE representative (a former carer of a person living with dementia) will also contribute trial management group and trial steering committee meetings.

The PPIE group's responsibilities will include monitoring study progress (following research team updates), giving carer perspectives on potential outcome measures, advising on recruitment methods and materials, reviewing public-facing documents, exploring and commenting on emerging analyses of interviews, and involvement with dissemination activities, including conference presentations and writing for publication.

All PPIE activities will follow INVOLVE guidance.

Dissemination policy
The results of the trial will be disseminated to key audiences including feasibility study participants, potential future trial participants (carers of people living with dementia within and outside Greater Manchester), health and social care professionals, MPs and other regional government representatives, organisational leadership in the NHS, social care and the third sector, and academic audiences.

The results of the trial will be disseminated using methods that are appropriate for the intended audience. These will include peer reviewed scientific journals, conference presentations, internal reports, plain English summaries, presentations, social media, digital media (podcasts and webinars) and press releases.

Participants will be given the option of providing their contact details to receive a summary of the study results.

Authorship eligibility will be in accordance with University of Manchester guidelines, which conforms to the International Committee of Medical Journal Editors guidance.

The trial has been registered on the ISRCTN registry (ISRCTN15261686) which gives public access to key details of the study.

Study status
Closed to recruitment.

Data availability
Underlying data
No data are associated with this article.

Extended data
Figshare at The University of Manchester: Course Summary-Empowered Conversations (6 session; family care partners). https://doi.org/10.48420/23592378.v1 (Morris *et al.*, 2023)

Reporting guidelines
Figshare at The University of Manchester: SPIRIT Checklist: Protocol feasibility trial Empowered Conversations. https://doi.org/10.48420/23214125 (Morris, 2023)

Acknowledgements

We would like to thank Emma Smith (Project Manager) and the Empowered Conversations team at Age UK Salford for their contribution to delivering the study, the Research and Innovation teams at Greater Manchester Mental Health NHS Foundation Trust and Pennine Care NHS Foundation Trust for their support in recruitment and delivery of the study, and members of the Trial Steering Committee for their advice and guidance.

References

Alzheimer's Disease International: **World Alzheimer Report 2022 - Life after diagnosis: Navigating treatment, care and support.** 2022.
Reference Source

Alzheimer's Society: **Left to Cope Alone.** 2022.
Reference Source

Bjelland I, Dahl AA, Haug T, *et al.*: **The validity of the Hospital Anxiety and Depression Scale. An updated literature review.** *J Psychosom Res.* 2002; **52**(2): 69–77.
PubMed Abstract | **Publisher Full Text**

Brodaty H, Donkin M: **Family caregivers of people with dementia.** In: *Dialogues Clin Neurosci.* 2009; **11**(2): 217–28.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Brown A, Page TE, Daley S, *et al.*: **Measuring the quality of life of family carers of people with dementia: development and validation of C-DEMQOL.** *Qual Life Res.* 2019; **28**(8): 2299–2310.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Bucks RS, Haworth J: **Bristol activities of daily living scale: A critical evaluation.** In: *Expert Rev Neurother.* 2002; **2**(5): 669–76.
PubMed Abstract | **Publisher Full Text**

Carers UK: **A snapshot of unpaid care in the UK State of Caring 2022.** 2022.
Reference Source

Clare L, Wu YT, Quinn C, *et al.*: **A Comprehensive Model of Factors Associated With Capability to 'Live Well' for Family Caregivers of People Living With Mild-to-Moderate Dementia Findings From the IDEAL Study.** *Alzheimer Dis Assoc Disord*. 2019; **33**(1): 29–35.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Cooper C, Balamurali TBS, Livingston G: **A systematic review of the prevalence and covariates of anxiety in caregivers of people with dementia.** In: *Int Psychogeriatr.* 2007; **19**(2): 175–95.
PubMed Abstract | **Publisher Full Text**

Dickinson C, Dow J, Gibson G, *et al.*: **Psychosocial intervention for carers of people with dementia: What components are most effective and when? A systematic review of systematic reviews.** In: *Int Psychogeriatr.* Cambridge University Press, 2017; **29**(1): 31–43.
PubMed Abstract | **Publisher Full Text**

Dooley J, Bailey C, McCabe R: **Communication in healthcare interactions in dementia: A systematic review of observational studies.** In: *Int Psychogeriatr.* Cambridge University Press, 2015; **27**(8): 1277–300.
PubMed Abstract | **Publisher Full Text**

Eggenberger E, Heimerl K, Bennett MI: **Communication skills training in dementia care: A systematic review of effectiveness, training content, and didactic methods in different care settings.** In: *Int Psychogeriatr.* 2013; **25**(3): 345–58.
PubMed Abstract | **Publisher Full Text**

Elvish R, Lever SJ, Johnstone J, *et al.*: **Psychological interventions for carers of people with dementia: A systematic review of quantitative and qualitative evidence.** *Couns Psychother Res.* 2013; **13**(2): 106–125.
Publisher Full Text

Etxeberria I, Salaberria K, Gorostiaga A: **Online support for family caregivers of people with dementia: a systematic review and meta-analysis of RCTs and quasi-experimental studies.** In: *Aging Ment Health.* Routledge, 2021; **25**(7): 1165–1180.
PubMed Abstract | **Publisher Full Text**

Frost R, Walters K, Wilcock J, *et al.*: **Mapping post-diagnostic dementia care in England: an e-survey.** *J Integr Care.* 2021; **29**(1): 22–36.
Publisher Full Text

Giebel C, Hanna K, Tetlow H, *et al.*: **"A piece of paper is not the same as having someone to talk to": accessing post-diagnostic dementia care before and since COVID-19 and associated inequalities.** *Int J Equity Health.* 2021; **20**(1): 76.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Guest G: **Applied thematic analysis.** (K. M. MacQueen & E. E. Namey, Eds.) [Book]. SAGE Publications, 2012; 295.
Reference Source

Health and Social Care Information Centre: **Personal Social Services Survey of Adult Carers in England, 2016-17.** 2017.
Reference Source

Heid AR, Heppner A, Cheatham D, *et al.*: **Emotion-focused communication training online: Development and evaluation of acceptability.** *Gerontol Geriatr Educ.* 2022; 1–14.
PubMed Abstract | **Publisher Full Text**

Holst G, Hallberg IR: **Exploring the meaning of everyday life, for those suffering from dementia.** *Am J Alzheimers Dis Other Demen.* 2003; **18**(6): 359–65.
PubMed Abstract | **Publisher Full Text**

Innes A, Morris L, Wyatt M, *et al.*: **Communication skills training for family caregivers of people living with dementia: the experiences of peer facilitators and course attendees.** *Educational Gerontology.* 2022; **48**(3): 103–113.
Publisher Full Text

Judge KS, Yarry SJ, Looman WJ, *et al.*: **Improved strain and psychosocial outcomes for caregivers of individuals with dementia: Findings from project *answers*.** *Gerontologist.* 2013; **53**(2): 280–92.
PubMed Abstract | **Publisher Full Text**

Karagiozi K, Margaritidou P, Tsatali M, *et al.*: **Comparison of on Site versus Online Psycho Education Groups and Reducing Caregiver Burden.** *Clin Gerontol.* 2022; **45**(5): 1330–1340.
PubMed Abstract | **Publisher Full Text**

La Fontaine J, Oyebode JR: **Family relationships and dementia: A synthesis of qualitative research including the person with dementia.** *Ageing and Society.* 2014; **34**(7): 1243–1272.
Publisher Full Text

Lee EH: **Review of the psychometric evidence of the perceived stress scale.** In: *Asian Nurs Res (Korean Soc Nurs Sci).* 2012; **6**(4): 121–7.
PubMed Abstract | **Publisher Full Text**

Lee EC, Whitehead AL, Jacques RM, *et al.*: **The statistical interpretation of pilot trials: should significance thresholds be reconsidered?** *BMC Med Res Methodol.* 2014; **14**(1): 41.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Losada A, Pillemer K, Márquez-González M, *et al.*: **Measuring ambivalent feelings in dementia family caregivers: The caregiving ambivalence scale.** *Gerontologist.* 2017; **57**(3): e37–e46.
PubMed Abstract | **Publisher Full Text**

Lovell K, Bee P, Bower P, *et al.*: **Training to enhance user and carer involvement in mental health-care planning: the EQUIP research programme including a cluster RCT.** *Programme Grants for Applied Research.* 2019; **7**(9): 1–140.
PubMed Abstract | **Publisher Full Text**

Mittelman MS, Ferris SH, Steinberg G, *et al.*: **An Intervention That Delays Institutionalization of Alzheimer's Disease Patients: Treatment of Spouse-Caregivers.** *Gerontologist.* 1993; **33**(6): 730–40.
PubMed Abstract | **Publisher Full Text**

Moniz-Cook E, Vernooij-Dassen M, Woods B, *et al.*: **Psychosocial interventions in dementia care research: The INTERDEM manifesto.** In: *Aging Ment Health.* 2011; **15**(3): 283–90.
PubMed Abstract | **Publisher Full Text**

Morris L: **SPIRIT checklist: protocol feasibility trial Empowered Conversations.** University of Manchester. Report. [dataset], 2023.
http://www.doi.org/10.48420/23214125.v1

Morris L, Horne M, McEvoy P, *et al.*: **Communication training interventions for family and professional carers of people living with dementia: a systematic review of effectiveness, acceptability and conceptual basis.** In:

Aging Ment Health. Routledge, 2018; **22**(7): 863–880.
PubMed Abstract | **Publisher Full Text**

Morris L, Innes A, Smith E, *et al.*: **A feasibility study of the impact of a communication-skills course, 'Empowered Conversations', for care partners of people living with dementia.** *Dementia (London).* 2021; **20**(8): 2838–2850.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Morris L, Mansell W, Emsley R, *et al.*: **Prospective cohort feasibility study of a transdiagnostic group intervention for common mental health problems: The Take Control Course.** *Psychol Psychother.* 2016; **89**(2): 163–180.
PubMed Abstract | **Publisher Full Text**

Morris L, Mansell W, Williamson T, *et al.*: **Communication Empowerment Framework: An integrative framework to support effective communication and interaction between carers and people living with dementia.** *Dementia (London).* 2020; **19**(6): 1739–1757.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Morris L, Smith E, McEvoy P: **Course Summary- Empowered Conversations (6 session; family care partners).** University of Manchester. Online resource. [dataset], 2023.
http://www.doi.org/10.48420/23592378.v1

Morrison AP, Pyle M, Gumley A, *et al.*: **Cognitive-behavioural therapy for clozapine-resistant schizophrenia: The FOCUS RCT.** *Health Technol Assess.* 2019; **23**(7): 1–144.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

NHS England: **Commissioning for Carers: Principles and resources to support effective commissioning for adult and young carers.** 2014.
Reference Source

Noel MA, Lackey E, Labi V, *et al.*: **Efficacy of a Virtual Education Program for Family Caregivers of Persons Living with Dementia.** *J Alzheimers Dis.* 2022; **86**(4): 1667–1678.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

O'Connor MK, Nicholson R, Epstein C, *et al.*: **Telehealth Support for Dementia Caregivers During the COVID-19 Pandemic: Lessons Learned From the NYU Family Support Program.** *Am J Geriatr Psychiatry.* 2023; **31**(1): 14–21.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Olazarán J, Reisberg B, Clare L, *et al.*: **Nonpharmacological therapies in alzheimer's disease: A systematic review of efficacy.** In: *Dement Geriatr Cogn Disord.* 2010; **30**(2): 161–78.
PubMed Abstract | **Publisher Full Text**

Olde Rikkert MGM, Tona KD, Janssen L, *et al.*: **Validity, reliability, and feasibility of clinical staging scales in dementia: a systematic review.** *Am J Alzheimers Dis Other Demen.* 2011; **26**(5): 357–65.
PubMed Abstract | **Publisher Full Text**

Onwuegbuzie AJ, Leech NL: **Sampling designs in qualitative research: making the sampling process more public.** *Qualitative Report.* 2007; **12**(2): 238–254.
Publisher Full Text

Perkins L, Felstead C, Stott J, *et al.*: **Communication training programmes for informal caregivers of people living with dementia: A systematic review.** In: *J Clin Nurs.* John Wiley and Sons Inc, 2022; **31**(19–20): 2737–2753.
PubMed Abstract | **Publisher Full Text**

Rothwell JC, Julious SA, Cooper CL: **A study of target effect sizes in randomised controlled trials published in the *Health Technology Assessment* journal.** Suzie Cro. *Trials.* 2018; **19**(1): 544.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Sebern MD, Whitlatch CJ: **Dyadic Relationship Scale: A Measure of the Impact of the Provision and Receipt of Family Care.** *Gerontologist.* 2007; **47**(6): 741–51.
PubMed Abstract | **Publisher Full Text**

Sim J, Lewis M: **The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency.** *J Clin Epidemiol.* 2012; **65**(3): 301–8.
PubMed Abstract | **Publisher Full Text**

Stansfeld J, Crellin N, Orrell M, *et al.*: **Factors related to sense of competence in family caregivers of people living with dementia in the community: a narrative synthesis.** *Int Psychogeriatr.* 2019; **31**(6): 799–813.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Steeman E, De Casterlé BD, Godderis J, *et al.*: **Living with early-stage dementia: A review of qualitative studies.** In: *J Adv Nurs.* 2006; **54**(6): 722–38.
PubMed Abstract | **Publisher Full Text**

Vernooij-Dassen MJFJ, Persoon JMG, Felling AJA: **Predictors of sense of competence in caregivers of demented persons.** *Soc Sci Med.* 1996; **43**(1): 41–9.
PubMed Abstract | **Publisher Full Text**

Wheatley A, Poole M, Robinson L, *et al.*: **Changes to postdiagnostic dementia support in England and Wales during the COVID-19 pandemic: A qualitative study.** *BMJ Open.* 2022; **12**(2): e059437.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Williams CL, Newman D, Hammar LM: **Preliminary study of a communication intervention for family caregivers and spouses with dementia.** *Int J Geriatr Psychiatry.* 2018; **33**(2): e343–e349.
PubMed Abstract | **Publisher Full Text**

Wittenberg R, Hu B, Barraza-Araiza L, *et al.*: **CPEC Working Paper 5 The projections were produced using an updated version of a model developed by CPEC at LSE for the Modelling Outcome and Cost Impacts of Interventions for Dementia (MODEM) study (www.modem-dementia.org.uk). The authors would like to thank members of the MODEM study team for their contributions in developing the MODEM models.** DISCLAIMER. 2019a.
Reference Source

Wittenberg R, Knapp M, Hu B, *et al.*: **The costs of dementia in England.** *Int J Geriatr Psychiatry.* 2019b; **34**(7): 1095–1103.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Open Peer Review

Current Peer Review Status: ✔ ✔ ✔

Version 1

Reviewer Report 17 August 2023

https://doi.org/10.3310/nihropenres.14579.r29859

✔ **Patricia Masterson-Algar**
Bangor University, Bangor, Wales, UK

Thank you very much for giving me the opportunity to review this protocol paper. I am familiar with Empowered Conversations and I am please to see that this work will provide an important first step to assess it's potential benefits.

Overall I think this is a very well thought through protocol which, by applying a mixed method approach is very likely to achieve it's aims and objectives.

Issue around how to best address recruitment factors are well described. I am please to see a qualitative component (nested) to data collection. However, I would have liked to see this qualitative aspect as a 'stand alone' process evaluation rather than an 'add on' to data collection. By having a 'process evaluation' running alongside the trial you guarantee that in-depth consideration is given to all implementation and delivery aspects. This in turn will provide an explanatory account of what worked or didn't work during the running of the trial.

I welcome the variety of outcome measures and the flexible research flow that allows for a pragmatic approach to delivering and implementing the RCT.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I am a health researcher with extensive experience in the field or process evaluation and dementia research (with particular focus on caregivers including young carers)

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 17 August 2023

https://doi.org/10.3310/nihropenres.14579.r29864

Juanita Hoe
Geller Institute of Ageing and Memory, The University of West London, London, England, UK

Protocol of a feasibility randomised controlled trial of Empowered Conversations: training family carers to enhance their relationships and communication with people living with dementia.

Full review

This is a well thought out and well written protocol that aims to investigate the feasibility of conducting a multi-centre randomised controlled trial of an Empowered Conversation (EC) training course. The plain language summary and introduction provide sufficient context and rationale for why the intervention is needed, the evidence underpinning the development of the Empowered Conversation training course and objectives of the feasibility trial.

The use of a feasibility RCT is appropriate for meeting the aims and objectives of the study. All aspects of the trial procedure are clearly detailed and justified, including strategies for recruitment, randomisation, data collection, data management and data analysis. The study methods demonstrate adequate rigour and appropriate safeguards are in place including the use of stop/go criteria to track recruitment and retention of the sample and monitor progress of the study. A trial management group will monitor and assess the ability of the feasibility trial to proceed.

The data management strategy is clearly explained. A description of all questionnaires included in the study is provided and an explanation given of what the questionnaires measure in a supporting table (Table 3). Ethical issues are dealt with appropriately. This includes obtaining consent from the person with dementia (or use of a consultee where relevant under the MCA) despite their involvement in study procedures being limited to a clinical interview to assess their CDR score.

I only have two concerns regarding the protocol, which are:

- Use of the term 'informal carer', which is explained, but is not considered to be inclusive as family carers' perceive that it diminishes their contribution. The term 'unpaid carer' may be preferred, alternatively the Alzheimer's Association provide guidance for the use of more positive language informed by carers.

- The protocol states that the Empowered Conversation training course will be delivered by 'trained facilitators from Age UK'. Little background information is provided about the facilitators, and it is unclear what their level of education or experience is, for example do they have professional qualifications, or are they graduate workers?

Brief review
A well-written protocol investigating the feasibility of conducting a multi-centre randomised controlled trial of an Empowered Conversation (EC) training course. The methods demonstrate adequate rigour and all aspects of the trial procedures are clearly detailed and justified, including strategies for recruitment, randomisation, data collection, management and analysis, and ethical considerations.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I am an experienced dementia researcher with experience in both quantitative and qualitative research methods and an experienced clinical trials manager.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 17 August 2023

https://doi.org/10.3310/nihropenres.14579.r30018

Joan K. Monin
Yale University, New Haven, Connecticut, USA

This a study to investigate the feasibility of conducting a multicenter randomized controlled trial of an intervention called Empowered Conversations (EC) that will be delivered on Zoom. The procedures are well-documented and would allow for replication from other researchers. The design is a 2 to 1 allocation of the EC plus usual care to usual care and waitlist. This allows for understanding more of the feasibility metrics for the EC.

The study targets a sample size that is reasonable and substantiated by other similar trials and by statistical considerations. The ethical considerations concerning people living with dementia and care partners are appropriate.

Overall, this is an excellent description of procedures for a trial that is likely to benefit care partners and persons living with dementia greatly with little risk of harm. I have no comments or concerns about any of the details in this report.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I am an expert in caregiving and health. Statistical and design input from other researchers would be helpful to complement this review.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.