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Good Life with Dementia Feasibility Study

Submission date
17/09/2025

Recruitment status
Recruiting

Registration date
09/02/2026

Overall study status
Ongoing

Last Edited
04/06/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Receiving a diagnosis of dementia is a major life event which can leave people feeling worried about the future. Research has repeatedly highlighted gaps in support following dementia diagnosis, and people with dementia report not knowing where to turn for help.
The Good Life course is a community-based course co-produced by people with dementia for people with dementia. The course provides peer-support, including the sharing of experiences and resources, and is exclusively for people living with a diagnosis of dementia. Each course is tailored and delivered by people already living with dementia, who act as peer-tutors (together with a facilitator) to support people more recently diagnosed.

This study aims to find the best ways to evaluate the Good Life course. A first step is to see if we can run the course consistently in different places and with different communities, including a dedicated South Asian Good Life course. We will collaboratively develop a manual and with training for the Good Life facilitators to help ensure the course is delivered the same way everywhere and we will also develop and test a plan to evaluate the outcomes of the course. This information will tell us what we need to know to run a larger trial in the future.

Who can participate?
Adults who have received a diagnosis of any type of dementia in the last 12 months and live in a community local to one of the proposed Good Life courses. They must have mental capacity to give informed consent. In one site, all participants must also self-identify as South Asian.

What does the study involve?
Participants are asked to join this study through memory clinics and GP services. A series of health and wellbeing questionnaires are asked at the start of the data collection period (baseline). Participants are then randomly allocated to one of two groups. One group will attend a weekly 2-hour group session for 6 weeks with other people living with dementia (The Good Life course), whilst also receiving their usual care; the other group will just continue to receive usual care. Both groups of participants will be asked the same health and wellbeing questions again at 3 and 6 months. Some participants from each group will be invited to take part in an in-depth interview to find out what they thought about taking part in the study.

What are the possible benefits and risks of participating?
The research will not benefit participants directly, but studying the Good Life course could help

to improve dementia support for people diagnosed with dementia in the future. There are no known risks to taking part in this study.

Where is the study run from?
The Good Life feasibility study is being run from the University of York. The Good Life course will take place at three locations across England: Bristol, Sheffield and Manchester (the course will be dedicated to supporting people from South Asian communities).

When is the study starting and how long is it expected to run for?
February 2026 to August 2027

Who is funding the study?
NIHR Three Schools: Dementia Research Programme (NIHR-SSCR-DP25) (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
356285

Central Portfolio Management System (CPMS)
67436

National Institute for Health and Care Research (NIHR)
NIHR-SSCR-DP25

Study information

Scientific Title
Feasibility study of a post-diagnostic peer-led dementia course: Addressing uncertainties for a randomised controlled trial of the Good Life course

Study objectives
This study aims to resolve key uncertainties concerning the feasibility of conducting an inclusive randomised control trial (RCT) to evaluate the Good Life with Dementia course. The study will focus on key areas of uncertainty including whether manualisation of the course supports consistent delivery across differing communities, how to recruit a diverse range of participants newly diagnosed with dementia, and what adaptations are required for inclusive data collection from people with dementia from South Asian communities.

Specific research questions to be address are:
1. Can the Good Life course be manualised and consistently delivered by community services across settings?
2. What are the likely rates of recruitment, retention and adherence amongst those recently diagnosed with dementia to an RCT of the Good Life course?
3. Is it feasible to collect standardised outcome data from the participants at 3 time points?
4. What constitutes ‘usual care’ (UC) for participants recently diagnosed with dementia?
5. How does culture and language influence the above for South Asian participants, and what adaptations are required for this population?

An embedded qualitative study will provide further valuable insights into:
1. The mechanisms that might improve acceptability and inclusivity
2. The role of carers and the potential for aligned benefits or harms to this group

The primary objectives for this trial are:
1. To calculate conversion rates (from eligible sample to consent to contact to informed consent).

2. To determine overall recruitment rates and barriers to recruitment
3. To determine the number of people who provided data at each time point
4. To estimate the retention rates at 3 and 6 month follow ups including loss to follow up
5. To determine the proportion of people adhering to the intervention
6. To assess the acceptability and feasibility of the outcome measures as methods to measure effectiveness of the intervention in a definitive trial
7. To assess the acceptability of the trial processes to people with dementia/site staff and delivery partners in different community settings

The secondary objectives are:
1. To measure key outcome domains for missing data, and completion rates
2. To hear the views and experiences of delivery partners and peer tutors with regard to intervention implementation, barriers and facilitators.
3.To determine whether manualisation supports consistent delivery across settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2025, Social Care REC (2nd Floor, 2 Redman Place, Health Research Authority, E20 1 JQ, UK; +44 (0)2071048087; socialcare.rec@hra.nhs.uk), ref: 25/IEC08/0032

Primary study design
Interventional

Study design
Feasibility; Randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Management of Care, Inclusive

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementia

Interventions
This research is a randomised feasibility study of trial processes and intervention implementation with an embedded qualitative element. The feasibility study will test processes and gather information for the planning of a definitive randomised trial to evaluate the Good Life course. The embedded qualitative element will enable us to gather further insight into the acceptability and inclusivity of the research processes and intervention implementation. The research study is a 27-month study with three phases:
Phase 1: Development of a manual and training for the Good Life with Dementia course (months 1-7)
Phase 2: Feasibility site set up across three sites in England (months 1-7)
Phase 3: Feasibility trial across three sites with an embedded qualitative element (months 8-27)

Broad timetable for stages of research:
Month 1-7: develop PPIE networks, co-produce inclusive recruitment strategies, undertake GL manualisation, develop facilitator training package, review with stakeholders. Months 8-15: Run the facilitator training, recruit participants with dementia, administer decliner questionnaire,

obtain consent, collect baseline data and undertake randomisation. Newly trained facilitators support tailoring of the course to local contexts with peer-tutors. Months 16-18: GL course delivery, IiD to assess fidelity, T1 data collection, qualitative interviews and FGs. Months 19-22; complete qualitative and T2 quant data collection. Months 23–27 analysis, writing, knowledge exchange.

Phase 1:
We will host three workshops with a range of stakeholders, two for the manual development and one for the training development. The Three Strand Advisory network (practitioners, experts by experience, South Asian subgroup) and Project Management Group (co-applicants and delivery partners) will feed into this. The development of the manual is the first step to developing the facilitator training. The training will be built around the model's core constructs, be consistent with the manual and culturally inclusive.

Phase 2:
We will continue working with the three sites across England. Discussions will feed into excess treatment cost calculations, HRA ethics, PPIE network development and the development of inclusive recruitment processes. A key aim of this phase is the development of materials for the recruitment of people with dementia from South Asian communities.

Phase 3: feasibility trial:
The feasibility trial will take place across three locations in England, one of which will be a dedicated site for a South Asian intervention group. We are working with LMCP, a research-experienced community development organisation and are committed to providing the South Asian focused GL course and supporting NHS partners with recruitment.

Training delivery and assessment of fidelity:
The facilitators will attend a 2-day in-person training course on how to set up and deliver the Good Life course with particular focus on supporting peer tutors, the core constructs of Good Life and tailoring to local contexts. The facilitators will receive ongoing monthly online supervision throughout the setup and delivery of the course.

Trained facilitators and peer tutors:
During the training facilitators will receive guidance on how to recruit and support people living with dementia to be volunteer peer-tutors. The facilitators will also be asked to complete a fidelity checklist after each session.

Feasibility study:
We will recruit 18 people with dementia per site, they will be randomised on a 2:1 ratio, 12 to the intervention + usual care (intervention group) and 6 to usual care only (control group). We are including a control group as this is a feasibility trial to test the acceptability of research processes including retention of a control group during study duration to understand the implications of this for a definitive randomised control trial. The recruitment period is up to 7 months.

Informed consent:
The participants recruited to the feasibility study will be people with dementia who have the capacity to give informed consent when recruited (assessed using Mental Capacity Act guidance). Informed consent will be received (pre-randomisation) by research-trained staff at recruitment sites or members of the research team.

Baseline data collection:
A series of health and wellbeing questionnaires will be tested for feasibility and acceptability at 3 time points: T0 (for baseline, pre-randomisation, 4-6 weeks pre-course), T1 (upon course completion) and T2 (6 months post-baseline). T0: The questionnaires will comprise of ICECAP-O, My Life Questionnaire, EQ-5D, Geriatric Depression Scale and De-Jong Gierveld Loneliness scale and a demographic and usual care survey. The questionnaires will be administered verbally by a member of the research team (i.e. with the researcher asking the participant the questions and recording their answer on Qualtrics) face to face in the participant's home or other venue of their choice. If a participant has a strong preference for remote data collection this can be accommodated. We expect the questionnaires to take 45-60 min to complete. After completion of questionnaires, participants will be offered a leaflet detailing sources of further support and reminded of how to contact the research team if they have any questions before the next data collection timepoint. Their next contact with the research team will be to be informed of the outcome of randomisation (see below).

Randomisation:
Once informed consent and baseline data collection have taken place the participant will then be randomised by site on a 2:1 ratio (intervention or control). The sealed envelope online system will be used for randomisation. Upon completion of the randomisation process the researcher will inform the participants of the outcome via telephone or the participant's preferred method of communication. This will be confirmed in a letter or email to the participants. Delivery partners will be given the names and contact details of the participants in the intervention group via a secure means. They will then contact the participants allocated to the group following guidance from the course manual.

Both arms of the trial:
Data collection T1 (course completion) and T2 (6 months post-baseline). The questionnaires will comprise of ICECAP-O, My Life Questionnaire, EQ-5D, Geriatric Depression Scale and De-Jong Gierveld Loneliness scale and a usual care survey. These will be administered the same as at T0 baseline.

For the dedicated SA group, LMCP will support with interpretation and relationship building /overcoming cultural barriers where required during the waiting period and at T0. If further interpretation is required at the T1, T2 or qualitative interviews (for the embedded qualitative study, see below), a professional interpretation company will be used as LMCP will be delivering the course at this point and it would no longer be appropriate for them to be present at data collection.

Intervention group:
12 participants per locality will attend six weekly 2 h sessions of the Good Life course. As part of this they will complete a short 'in the moment' wellbeing scale at the beginning and end of each session (10 min for each completion), 12 times in total. This will be facilitated by the professional facilitator (by reading out questions) and completed by each participant individually (documenting answers on answer sheets).

Control group:
These participants will continue to access the usual care in their area.

Embedded qualitative element:
The embedded qualitative element will provide further insight into the implementation of the

feasibility study, mechanisms to improve inclusivity and acceptability, the role of carers and the potential for aligned benefits or harm to carers. The information sheets and consent forms for this part of the study are separate to the feasibility trial (as this element is optional).

Participants with dementia:
Individual one-off interviews (30-45 min) with a subset of purposely sampled participants with dementia (15 across all three sites) from both arms of the trial (intervention group and control group). We will identify participants purposively to represent a diverse range of characteristics including gender, age, ethnicity, living situation (alone/with a carer) and type of dementia. The interviews will explore how participants found being involved in the project, the acceptability of data collection methods and the inclusivity of recruitment. Interviews will take place in the participant's home or other venue of their choice, unless they have a strong preference for an online or telephone interview. Interpretation will be provided where required.

Carers:
Individual one-off interviews (30-45 min) with a sub-set of carers (15 in total across all three sites) across both arms of the trial (intervention and control). Carers will be sent information about the interviews and can express interest by returning a consent to contact form. The interviews will explore the carer's role in supporting participation in the study including the Good Life course (if in the intervention group). Interviews will take place either at a venue of the carer's choosing, by telephone or online. Interpretation will be provided where required.

Peer tutors:
Individual one-off interview in person (30-45 min) exploring becoming a peer tutor and co-producing the course n = 6. All peer tutors will be invited for an interview. This will be in person unless the peer tutor has a strong preference for telephone or online.

Delivery partners (facilitators):
Online one-off focus group with professional facilitators n = 6 (60-90 min) to discuss mechanism that might improve the inclusivity and acceptability of the Good Life course. All professional facilitators will be invited to this focus group.

Site staff (recruitment partners):
Information about recruitment barriers and facilitators collected in an ongoing capacity throughout the recruitment period in researchers' field notes will be supplemented by qualitative interviews once recruitment has closed with a subset (n = 6) of recruiting staff across the 3 sites. Staff will be invited by email to take part in an online one-off 30-45 min interview, guided by a topic guide focusing on the feasibility of recruitment in their locality and service setting.

The participant information sheets and consent forms have been designed with insights from our project management group, including experts by experience. We are continuing a consultation process with LMCP, who are supporting us with producing accessible and inclusive research materials for the dedicated South Asian site.

Intervention Type
Behavioural

Primary outcome(s)
1. Conversion rates (from eligible sample to consent to contact to informed consent) measured using screening log, (study-specific) records and consent records, calculated at the close of recruitment

2. Overall recruitment rates and barriers to recruitment measured using screening logs and consent records (including reasons for declining) completed at a) initial approach and b) after giving consent to contact)
3. The number of people who provided data at each timepoint measured using research data at baseline, 3 and 6 months
4. Retention rates at 3 and 6 month follow ups including loss to follow up measured using research data at 3 and 6 months, and withdrawal records reviewed monthly
5. The proportion of people adhering to the intervention measured using weekly attendance records (for the 6-week intervention period)
6. The acceptability and feasibility of the outcome measures as methods to measure effectiveness of the intervention in a definitive trial measured using research data, at baseline 3 and 6 months. and qualitative interviews and focus groups after 6-month follow-up
7. The acceptability of the trial processes to people with dementia/site staff and delivery partners in different community settings measured using qualitative interviews and focus groups after 6-month follow-up

Key secondary outcome(s)
1. Key outcome domains for missing data, and completion rates measured using research data at baseline, 3 and 6 months
2. The views and experiences of delivery partners and peer tutors with regard to intervention implementation, barriers and facilitators measured using qualitative interviews and focus groups after 6-month follow-up
3. Whether manualisation supports consistent delivery across settings, determined using fidelity checks at facilitator supervision sessions and through observation of the delivery of at least one course session in each site, together with qualitative interviews and focus groups after 6-month follow-up

The following outcome measures are being tested for feasibility and will not be used to measure outcomes definitively in this trial:
1. Capability wellbeing measured using ICECAP-O at baseline, 3 months, 6 months
2. Living well with dementia measured using My Life Questionnaire at baseline, 3 months, 6 months
3. Health related quality of life measured using EQ-5D-5L at baseline, 3 months, 6 months
4. Depression measured using Geriatric Depression Scale at baseline, 3 months, 6 months
5. Loneliness measured using De Jong Gierveld Loneliness Scale at baseline, 3 months, 6 months
6. Experience ‘in the moment’ measured using Canterbury Wellbeing Scale before and after 6 intervention sessions

Completion date
31/08/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 04/06/2026:

1. Adults of any age
2. Has received a diagnosis of dementia of any type from a medical professional or other practitioner empowered to assess this (For recruitment through NHS)
3. Self- identifies as having a dementia diagnosis (For recruitment through community organisations)

4. Living in a community local to the proposed Good Life course (bounded by memory service or community organisation recruiting)
5. With mental capacity to give informed consent
6. Willing and able to attend a 6-week in person group intervention
For dedicated South Asian Group
7. Self-identify as a member of a South Asian Community

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Previous key inclusion criteria:

Adults of any age:
1. Has received a diagnosis of dementia of any type from a medical professional or other practitioner empowered to assess this (for recruitment through the NHS)
2. Self- identifies as having a dementia diagnosis (for recruitment through community organisations)
3. Diagnosed within the previous 12 months (from consent to contact)
4. Living in a community local to the proposed Good Life course (bounded by memory service or community organisation recruiting)
5. With mental capacity to give informed consent (at baseline)
6. Willing and able to attend a 6-week in-person group intervention

For the dedicated South Asian Group:
Self-identify as a member of a South Asian Community

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 04/06/2026:

1. People with dementia
2. People without the mental capacity to give informed consent at baseline
3. People with dementia living in care homes
4. People attending or booked to attend similar group-based interventions (such as LivDem) other than those that form part of usual care such as CST.
5. If the trajectory of the person's health (based on clinical judgement) suggests that they will be unable to participate to the end of the planned data collection (six months post course attendance)

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Previous key exclusion criteria:

1. People without the mental capacity to give informed consent at baseline
2. People with dementia living in care homes
3. People diagnosed more than 12 months ago (from consent to contact)
4. People attending or booked to attend similar group-based interventions (such as LivDem) other than those that form part of usual care such as CST
5. If the trajectory of the person's health (based on clinical judgement) suggests that they will be unable to participate to the end of the planned data collection (6 months post course attendance)

Date of first enrolment
28/02/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
England
EX2 5AF

Study participating centre
Sheffield Health Partnership University NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
England
S4 7QQ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital

Herries Road
Sheffield
England
S5 7AU

Study participating centre
Dovercourt Group Practice
Dovercourt Surgery
3 Skye Edge Avenue
Sheffield
England
S2 5FX

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
England
OL6 7SR

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type

Government

Funder Name
NIHR Three Schools Dementia Research Programme

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	01/12/2025	03/02/2026	No	Yes
Participant information sheet	version 4	20/05/2026	04/06/2026	No	Yes
Protocol file	version 2	12/11/2025	03/02/2026	No	No
Protocol file	version 3	20/05/2026	04/06/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes