PROTOCOL: Version 2.0 (November 2025)

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

IRAS Project ID: **356285**

KEY TRIAL CONTACTS

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Study website	https://www.york.ac.uk/business-society/research/social-policy/post-diagnostic-peer-led-dementia-feasibility/

Contents

ABBREVIATIONS

CI:	Chief Investigator
CST:	Cognitive Stimulation Therapy
GL:	Good Life with Dementia course
HRA:	Health Research Authority
IiD:	Innovations in Dementia
PIC:	Participant Identification Centre
PIS:	Participant Information Sheet
RCT:	Randomised control trial
REC:	Research Ethics Committee
RDN:	Research Development Network
SA:	People from South Asian communities
SoECAT:	Schedule of Events Cost Attribution Tool
UC:	Usual care

TRIAL SUMMARY

Trial Summary	
Trial title	Feasibility study of a post-diagnostic peer-led dementia course: Addressing uncertainties for a randomised controlled trial of the Good Life course
Short title	Good Life feasibility study
Acronym	GLFS
Chief Investigator	Kate Gridley
Sponsor	University of York
Funder	NIHR Three Schools: Dementia Research Programme (NIHR-SSCR-DP25)
Trial design	Feasibility study with embedded qualitative element
Planned sample size	54 people with dementia
Inclusion criteria	People with dementia ● Adults of any age ● Has received a diagnosis of dementia of any type from a medical professional or other practitioner empowered to assess this (For recruitment through NHS) ● Self- identifies as having a dementia diagnosis (For recruitment through community organisations) ● Diagnosed within the previous 12 months (from consent to contact) ● Living in a community local to the proposed Good Life course (bounded by memory service or community organisation recruiting) ● With mental capacity to give informed consent ● Willing and able to attend a 6-week in person group intervention For dedicated South Asian Group ● Self-identify as a member of a South Asian Community
Exclusion criteria	People with dementia ● People without the mental capacity to give informed consent at baseline ● People with dementia living in care homes ● People diagnosed more than 12 months ago (from consent to contact) ● 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. ● 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)
Number of study centres	The Good Life course will be delivered in three sites across England.
Study interventions	

Control group	Usual care	
Intervention group	6 weekly sessions of the Good Life course with primary outcome at course completion and follow up 6 months post-baseline.	
Summary objectives and outcome measures		
	Objectives	**Outcome Measures**
Feasibility	a) Conversion rates (from eligible sample approached to consent to contact to informed consent)	Screening log (study-specific) records and consent records
	b) Overall recruitment rates and barriers to recruitment	Screening logs (including reasons for declining at a) initial approach and b) after giving consent to contact)
	c) Proportion of people with dementia completing the intervention (at least 4/6 GL course sessions)	Research data and attendance records
	d) Proportion of recruited people with dementia completing each round of measures at 3 time points, baseline, course completion and 6 months post-baseline (or at GL sessions, for the 'in the moment' measure)	Research data
	e) Acceptability of the trial processes to site staff, carers and people with dementia.	Qualitative interviews
	f) Acceptability and accessibility of outcome measures to people with dementia.	Research data, Qualitative interviews
	g) Views and experiences of delivery partners to GL implementation, barriers and facilitators	Qualitative interviews
	h) Attrition (including both the proportion of participants not completing the trial protocol and loss to follow up).	Research data and withdrawal records
People with dementia	a) Demographics and usual care	Based on CSRI
	b) Capability wellbeing	ICECAP-O
	c) Living well with dementia	My Life Questionnaire
	d) Health related quality of life	EQ-5D-5L
	e) Depression measure	Geriatric Depression Scale
	f) Loneliness measure	De Jong Gierveld Loneliness Scale
	g) Wellbeing measure	Canterbury wellbeing scale
Study duration	● Funding start date: 1st June 2025 ● Anticipated duration: 27 months ● Anticipated end date: 31st August 2027	

1 BACKGROUND AND RATIONALE

Receiving a diagnosis of dementia is major life event and early diagnosis is seen as important to facilitate referral to specialist services and potentially improve the quality of life for families affected. Research shows that the experience of adjusting to a diagnosis of dementia is very individual but common elements encompass adjusting to a new identity, and wanting to preserve autonomy [1,2].

The Good Life with Dementia course (GL) is a community-based course co-produced by and for people with dementia, providing structured peer-support to live 'as well as possible' after a diagnosis. Peer-tutors living with dementia (PTs) are supported by a specialist dementia provider to tailor (to local contexts) and jointly deliver a 6-week course, with professional facilitation and expert speakers. Typical content includes shared learning about living with dementia, focusing on strengths and making the most of local and national resources. The course has already been run in more than 10 UK sites, despite the absence of a clear evidence base.

Support after a diagnosis is important. Many people have concerns about the future, but evidence suggests the current support offered is inadequate [3]. Post-diagnostic support is often fragmented and gaps in service provision exist throughout England [4]. Staying socially, mentally and physically active is important after a diagnosis of dementia [5], yet evidence suggests social networks can shrink, reducing social support to stay active in these ways [6]. Without post-diagnostic intervention, people may miss the opportunity to live as well as they could and there is a particular association between depression and dementia [7]. Group based activities are likely to be beneficial [8]. Cognitive stimulation therapy (CST), the most widely used group-based therapy available at present, has been shown to have a small but significant effect on depression [9], but this is not its primary function (and less than a third of people diagnosed through memory services were offered CST in 2023/4 [10]).

The UK's dementia strategy identified peer-support as promising but also called for more research [11]. A national evaluation established in response concluded that peer-support could be instrumental in helping people to live well with dementia, giving purpose and access to supportive social networks [12]. One co-produced study of post-diagnosis support found peer support groups provided newly diagnosed people with reassurance in a space free from judgement. It concluded that there needs to be better recognition of the value of peer support groups and more equitable access to them across England [13].

There is equipoise regarding the GL model, demonstrated by the fact that GL is commissioned in some areas of the country and not others. In 2022 the NIHR Three Schools

Dementia Research programme funded the current applicant team to conduct a realist evaluation of the Good Life with Dementia course [14]. Our findings established that equality, positive expectations and a friendly, trusting atmosphere (contexts) supported GL participants to take on meaningful roles, share experiences and deliver and receive personalised learning (mechanisms) which led to feeling valued, re-gained confidence and increased social connections (outcomes). As a result, participants with dementia felt more equipped to face the challenges dementia presents.

GL is designed to improve well-being, and our qualitative findings suggest the course facilitates positive reframing of a future life with dementia and offers the social resources necessary to sustain this positive outlook in the longer term. These qualitative signals of efficacy suggest GL could be a valuable group intervention to support well-being and mental health, alongside provision of NIDUS, which is more family carer focused [15], and GREAT which was designed for one-to-one delivery [16]. However robust evidence of the GL course is lacking, and a randomised control trial would address this lack of an evidence base. Before undertaking a definitive RCT there are key areas of uncertainty we have identified which need addressing. This feasibility trial aims to address these uncertainties including can GL be manualised and consistently delivered across different community settings; appropriateness of trial design; acceptability and inclusivity of data collection methods and what adaptations are required for inclusive delivery and evaluation for South Asian communities.

2 RESEARCH QUESTION AND OBJECTIVES

2.1 Research questions

1.Can GL 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 GL?

3.Is it feasible to collect standardised outcome data from the participants at 3 time points?

4.What constitutes ‘usual care’ (UC) for trial 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?

2.2 Study aims and objectives

This study aims to determine the feasibility of conducting a definitive randomised control trial (RCT) to evaluate the Good Life course. The randomised feasibility trial aims to explore the trial design including recruitment, retention, adherence, and acceptability of outcome measures. The wider study will address other key areas of uncertainty including whether manualisation of the course supports consistent delivery across differing communities, and what adaptations are required for inclusive delivery and evaluation for South Asian participants.

This project also has an embedded qualitative study to provide further insights into a) mechanisms that improve inclusivity and b) acceptability and 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.

2.3 Study outcome

The table below details the feasibility outcome measures and details of data collection can be found in section 5.

Feasibility Outcome	Measure
Conversion rates (from eligible sample approached to consent to contact to informed consent)	Screening log (study-specific) records and consent records
Overall recruitment rates and barriers to recruitment	Screening logs (including reasons for declining at a) initial approach and b) after giving consent to contact)
Proportion of people with dementia completing the intervention (at least 4/6 GL course sessions)	Research data and attendance records
Proportion of recruited people with dementia completing each round of measures at 3 time points, baseline, course completion and 6 months post-baseline (or at GL sessions, for the 'in the moment' measure)	Research data
Acceptability of the trial processes to site staff, carers and people with dementia.	Qualitative interviews
Acceptability and accessibility of outcome measures to people with dementia.	Research data, Qualitative interviews
Views and experiences of delivery partners to GL implementation, barriers and facilitators	Qualitative interviews
Attrition (including both the proportion of participants not completing the trial protocol and loss to follow up).	Research data and withdrawal records

Outcomes data from participants with dementia will be collected at baseline (one month before the commencement of the course), on course completion and at 6 months post baseline. Demographics information will only be collected at baseline. This covers all measures except the Canterbury Wellbeing Scale, which is an 'in the moment' measure to be used at each session for those randomised into the intervention arm. The table below details the measures that will be tested for feasibility and further details of data collection can be found in section 5.

People with dementia outcome	Measure
Demographics, usual care	General demographics and background information Usual care information based on CSRI
Capability wellbeing	ICECAP-O

Living well with dementia	My Life Questionnaire (MLQ)
Health-related Quality of life	EQ-5D-5L
Depression measure	Geriatric Depression Scale
Loneliness measure	De Jong Gierveld Loneliness Scale
Wellbeing measure (in the moment)	Canterbury Wellbeing Scale

3 STUDY DESIGN AND METHODS

3.1 Study design summary

The study has three phases, phases 1 and 2 will run concurrently.

Phase 1: Collaborative development of the Good Life manual and facilitator-training, with stakeholder informed review and revision (June – Dec 2025: 7 months)

Phase 2: Feasibility site set-up with NHS and community providers in 3 sites **(**June – Dec 2025: 7 months)

Phase 3: Feasibility trial across 3 sites and embedded qualitative study (January 2026 – August 2027:20 months)

3.2 Projected timetable and duration of participation

This study starts on 1st June 2025 with a duration of 27 months to August 2027. 54 people with dementia will be recruited to the trial over a seven-month period. The duration of their involvement in the trial will be from the time they give informed consent until 6 months post-baseline (unless they are purposively sampled to take part in a qualitative interview). A sub-set of participants with dementia (n=15) and carers (n=15) will be purposively sampled to take part in qualitative interviews or focus groups for the embedded qualitative study. The peer tutors (n=6) will be invited to take part in a qualitative interview and delivery site staff (n=6) will be invited to take part in a focus group. A sub-set of recruitment staff (n=6) will be invited to take part in qualitative interviews. These will take place up to eight months post baseline.

3.3 Study Methods

Phases 1 and 2 will involve consultation and collaborative development of the Good Life manual and facilitator-training, as well as inclusive research processes for Phase 3.

Phase 3 is a parallel group randomised feasibility study (Good life course + usual care vs usual care) with an unequal ratio 2:1. There is also an embedded qualitative study. The trial will be conducted in three locations across England. Each locality will have a variety of

recruitment pathways, including memory services, primary care and potentially community organisations (see 3.4.1 for further details).

3.3.1 Phase 1: Manualisation and training development (months 1-9)

Phase 1 will be the collaborative development of the GL manual, which will be advanced through a series of workshops (involving a wide range of stakeholders) alongside a task and finish group comprised of co-applicants and key stakeholders (including experts by experience). Manualisation will be guided by Galinsky et al.'s [17] three stages 1) Formulation; 2) Revision; and 3) Differentiation. No research data will be collected at this stage.

We will run 3 development workshops:

Workshop 1 (Formulation): This will be held in person and involve the research team and a core group of stakeholders setting out key principles and activities for inclusion in the manual. There will then be a period of review through the three-strand stakeholder network. This will support the development of the manual.

Workshop 2 (Revision and Differentiation): The second workshop will be held online to accommodate a wider range of stakeholders (who may be geographically spread) including people from the intervention sites and the network groups.

Workshop 3 (Training development): The third workshop will be a small, task focussed meeting to cross-check the training plans against the manual and finalise training documents.

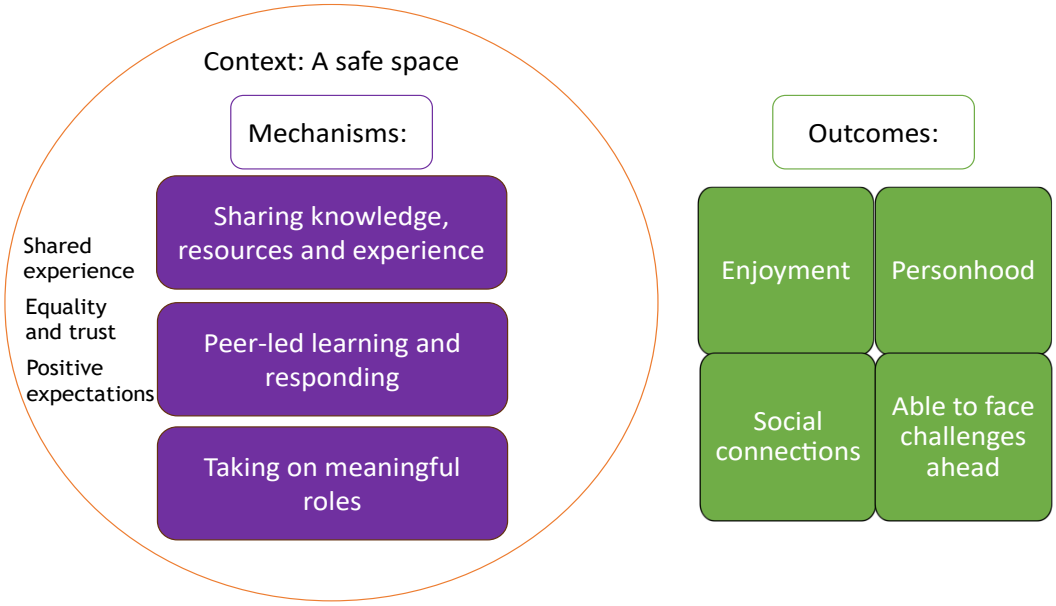
The stakeholder advisory network and project management group will feed in throughout via a variety of mechanisms including workshop attendance, email and telephone conversation. See 8.3 for further information on the stakeholder advisory network.

The formulation stage of Galinsky et al. started when the approach was first co-produced and continued in the development of the initial theory of change [14]. The previous realist informed evaluation developed a programme theory which will provide the core constructs for the manual.

The first two workshops will be used to develop, review and revise the course manual and ensure that it can be used with different populations. The development of the manual is the first step to developing facilitator training. The aim of the third workshop will be to ensure the training is built around the core constructs of GL and is complimentary to the manual. An active learning approach will be the premise on which the training is built to enable trainees

to develop the adaptive skills needed to run the GL course in different contexts. Engaging with our wider stakeholder network will ensure the training is culturally inclusive and adaptable for different communities (differentiation) whilst keeping to the core constructs.

Figure 1: Core constructs of the Good Life with Dementia Programme



3.3.2 Phase 2: Feasibility site set up (months 1-9)

The intervention will be delivered in three locations: Sheffield, Manchester and Bristol.

1. **Manchester:** LMCP (a research experienced community development organisation) are committed to providing the South Asian focused GL course and supporting NHS partners to undertake inclusive recruitment.
2. **Bristol:** The Bristol Dementia Wellbeing Service (part of Devon Partnership NHS Trust) keen to both recruit to the study and deliver GL. This service integrates a psychology team with psychiatrists and dementia practitioners (social workers, OTs, dementia navigators) and is in a good position to facilitate cross sector working throughout.
3. **Sheffield:** The People Keeping Well (PKW) Community Partnership has a network of community-based dementia advisers who are keen to train as GL facilitators, and consultants in both the young onset and older aged memory services are supportive.

Ongoing discussions will continue with the three delivery organisations as well as NHS recruitment partners to feed into the development of inclusive recruitment processes, HRA ethics, and excess treatment costs (Schedule of events cost attribution tool, SoECAT)

completion, to ensure all processes are considered feasible by recruiting and delivery partners and all site costs are covered.

3.3.3 Phase 3: Feasibility trial (month 8-27)

Phase 3 will include the training of professional facilitators working for delivery partners in each of the three localities, support of local people living with dementia to become peer-tutors, recruitment of eligible participants to the trial through sites and participant identification centres (PICs), and delivery of the Good Life course to participants randomised to the intervention group.

54 participants will be recruited across 3 sites (18 per site) and informed consent collected. Baseline data collection will take place prior to randomisation on a 2:1 ratio (intervention or usual care). For those randomised into the intervention group they will attend a 6-week Good Life course in their local area. Upon course completion both arms of the trial (intervention or usual care) will have a researcher visit them to collect follow up data. The final data collection point will be at 6-months post baseline apart from a sub-set of participants with dementia who will be invited to a qualitative interview about their experiences of taking part in the research.

Facilitator training will be delivered by Innovations in Dementia (IiD) alongside people with lived experience of dementia. The trainee facilitators will receive a copy of the manual and be supported throughout the set up and running of the course via online monthly supervisions by IiD. Couse set up includes the identification and support of peer tutors (people with dementia who are *not* trial participants) and co-production sessions to tailor the course to the local context. It also includes a home visit or equivalent contact with each participant in the intervention group in advance of the course to answer questions and build trust. The course runs for six sessions, meeting as a group in-person, co-facilitated by trained facilitators and peer-tutors living with dementia. Fidelity of the course will be assessed by IiD against agreed criteria aligned with the core constructs in the manual, and by course observation by the research team (at least one session to be observed in each location). For detailed information on the intervention see 4.1

3.3.4 Embedded qualitative study

The qualitative element of the study will involve all subgroups of this project, participants with dementia; carers; peer tutors; delivery staff and recruitment staff. It will enable us to hear the views and experiences of a cross section of people involved in the study with regards to

intervention implementation, acceptability and inclusivity of processes. The embedded qualitative study will provide further valuable insights into:

- The mechanisms that might improve acceptability and inclusivity
- The role of carers and the potential for aligned benefits or harms to this group

See section 5.6 for a detailed description.

3.4 Participant selection

The study will recruit 54 trial participants, 18 per locality over a seven-month period. As this is a small feasibility study a statistical sample size calculation is not appropriate. Instead, sample size was a pragmatic decision, informed by guidance on feasibility trials [18,19]. Teresi et al. (2022) [19] state that sample sizes in feasibility studies should consider budget constraints; participant flow and numbers needed to answer the feasibility questions. Our primary objective for the trial is to assess the feasibility of the methods and processes for use in a larger study therefore a sample size of 54 was deemed achievable and would provide enough data to evaluate trial design including recruitment, retention, adherence, and acceptability of outcome measures.

3.4.1 Recruitment process

Recruitment strategies will be co-developed with our network of lived experience advisers, local NHS and community providers and LMCP to ensure they are inclusive. From initial discussions with people with lived experience, including those from South Asian communities, it is likely that a written invitation to take part is necessary but not sufficient, even for some people with English as a first language. Trust is a significant factor influencing whether people from minoritized communities respond positively to invitations to join research [20] and we have been advised that a personal approach, either by telephone or face to face (e.g. during a routine appointment) will be most effective. With this in mind, we plan two main routes to recruitment, but we will not limit our recruitment strategies to these should ongoing discussions with stakeholders highlight other potential recruitment strategies. Recruitment will take place over a 7-month period from month 8. The routes will be staggered, starting with Route A (NHS) as our primary recruitment strategy as this is most systematic and could be the route through which people newly diagnosed with dementia are routinely signposted to the Good Life course if it is found to be effective in a future trial. Recruiting through the NHS also has the benefit that those doing the initial screening and

approach have access to health records and therefore ease of checking the inclusion criterion of dementia diagnosis.

In order to recruit eligible 18 people newly diagnosed with dementia in each site by August 2026, we anticipate having to obtaining consent to contact from twice that number (36 potential participants per locality) over the 7-month recruitment period. Considering recruitment strategies can be slower in the initial months of recruitment and improve over time (as processes become refined and staff become more familiar with the study) we will aim to build up to our recruitment target as follows:

- Month 1 (Jan): Two people per site give consent to contact (cumulative site total 2)
- Month 2 (Feb): Four people per site give consent to contact (cumulative site total 6)
- Month 3 (March): Six people per site give consent to contact (cumulative site total 12)
- Month 4-7 (April to July): Six people per site per month give consent to contact (cumulative site total by end of July 2026 12+[4x6] = 36)

The need to initiate Route B will be judged on a site-by-site basis rather than overall recruitment numbers, as some sites may have more barriers to recruitment than others. If by the end of March 2026, consent to contact has not been received from 12 potential participants in a particular site, this will trigger Route B (community recruitment alongside Route A) in that site.

Route A

(i)Recruitment through memory service PICs. Memory services staff will identify patients meeting the inclusion criteria (with support from the RDN where required) and invite them in person (for example at 6-or 12-week follow-up appointments) to give permission to be contacted by a researcher. This could be through database searches for patients meeting the eligibility criteria and/or at routine appointments. The research team and memory services staff (where relevant) will receive dedicated support and training in culturally appropriate ways of approaching and informing SA patients about the study.

(ii) Primary care PICs. We will work with the RDN who have primary care networks and a primary care lead in each area. This could include GP surgeries screening current patient lists, followed by personalised approaches. The research team (with support from the RDN where required) will work with practice staff to review patient notes, identify potentially eligible people and devise appropriate ways to approach them to introduce the study. The research team and practice staff (where relevant) will receive dedicated support and training in culturally appropriate ways of approaching and informing SA patients about the study.

iii) NHS recruitment sites: NHS sites with capacity to complete consent processes in full (providing information, answering questions, assessing capacity, receiving informed consent and recording this in patient records) will be able to do this, as an alternative to obtaining consent to contact and passing details on to the research team to follow up.

Route B: Recruitment through community organisations. Route B will trigger as described above. We have indications that this might be particularly relevant in the South Asian community site where diagnosis rates appear to be lower. If Route B is triggered in any site, this will run in parallel with Route A. In Route B, community organisations will publicise the study at relevant community events and meetings. They may also screen client lists as per Route A and introduce the study to potentially eligible participants through trusted community workers. Staff will complete consent to contact forms as per Route A and pass these securely to the research team. Community organisations will not receive consent themselves.

Potentially eligible participants via either route will be informed about the study by either health care professionals or the community organisation in person (face to face or over telephone) using information provided on a plain English and/or Urdu summary of the research (written or video). If the person expresses an interest in finding out more about the study the recruiter will either:

- complete a consent to contact form (with preferred contact details and information about communication needs) and pass these via a secure means to the research team. A member of the research team will then contact the potential participant to discuss the study further (with or without interpretation support as required).
- contact them directly (recruiting NHS sites only) to arrange a time to go through the study information in full, assess capacity according to MCA guidance (where there is reason to believe capacity to give informed consent is compromised) and receive consent or record that the person did not choose to join the study. Sites receiving consent directly must give potential participants at least 1 week to consider the information and make a decision, and must inform the university research team immediately if someone does consent to minimise the risk of over-recruitment.

For participants identified through the NHS Route A, part of the consent to contact information will require the site staff to confirm potential participants meet the eligibility criteria of a diagnosis of dementia and record the level of dementia they assess the potential participant to currently have (mild/moderate/advanced). For potential participants coming through Route B, the consent to contact will not contain this information as potential

participants can self-identify as having a dementia diagnosis. Instead, potential participants identified through Route B will be asked where they were diagnosed and when. Not being able to answer these questions would not exclude someone from taking part, the aim is to understand how feasible it is to collect this information.

There is not the potential in this study to actively overrecruit, as in order for the Good Life course to run optimally the maximum number of attendees is 12. We will monitor the recruitment levels through an ongoing dialogue with the sites to ensure we do not over recruit – when the recruitment target of 18 participants with dementia per locality is reached, we will pause recruitment in that locality. If a potential participant has given consent to contact but is yet to be contacted or has not yet made a decision when recruitment is paused, they will be sent a letter explaining that the study is at capacity and they have been added to a waiting list for all those expressing an interest in taking part in the study. Those still not consented onto the trial when it begins will be offered the opportunity to be part of the wider stakeholder network instead.

As the recruitment phase is up to 7 months long (to allow the maximum chance of reaching our recruitment targets) there will likely be a wait for all participants between giving consent and the study commencing, during which time they may have a change of circumstances and either no longer meet the inclusion criteria or change their mind about taking part. The study team will write to all participants explaining the reason for any wait and giving an expected start date, followed by regular updates. We will keep in contact with potential participants via a means of their choice (email, telephone, letter) and make it clear how they can contact the research team if they change their minds about taking part or their circumstance change.

To mitigate against attrition during waiting phases we will stagger the intervention start dates on an individual locality basis. When a site has 18 recruited participants we will liaise with delivery partners to arrange the soonest date to commence the intervention in that area. If the delivery partner is ready to go, we will commence baseline data collection and randomisation in that area. Using staggered start dates has a twofold benefit, it alleviates data collection pinch points and participants are not waiting for the intervention for lengthy periods of time unnecessarily. Interventions in all three localities will start ahead of or in line with the project timeline.

3.4.2 Inclusion criteria

The following broad inclusion criteria apply for participants in this study

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

For dedicated South Asian Group

- Self-identify as a member of a South Asian Community

3.4.3 Exclusion criteria

The following are the exclusion criteria for the study

- People without the mental capacity to give informed consent at baseline
- People with dementia living in care homes
- People diagnosed more than 12 months ago (from consent to contact)
- 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.
- 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)

The inclusion criteria of a recorded diagnosis of dementia from a medical professional only applies to potential participants recruited through the NHS where this can be clarified by the healthcare professional introducing the study to them. For sites where we move to community recruitment, we will be using the inclusion criteria of self-identifying as having a dementia diagnosis.

3.4.4 Participant withdrawal or declining to take part

Participants can withdraw from the study at any time without giving a reason, either from the intervention (GL course) or data collection, or both. We are using an intention-to-treat approach, meaning that if someone chooses to withdraw from the course, we will continue to collect data from them with their ongoing consent. Equally, anyone withdrawing from the data collection may choose to continue the course.

Any data collected up to the point of withdrawal would continue to be used in the study unless there was something specific the participant requested removing. If a participant would like us to remove some of their data, they can ask us to do so up to two weeks after it was provided. After that, it might not be possible, as their responses may already be included in the overall study findings. This is clearly detailed in the information sheets for the study.

It is important to understand any reasons for withdrawal as these will enable possible adaptations to be made for future studies which may support future research participation for people with dementia. Equally it is important to understand the reasons why eligible participants decline to take part in the study. Therefore, all people with dementia who either decline to take part or withdraw from the study at any point will be invited to complete a brief questionnaire indicating their reasons and any adaptations that would make it possible for them to take part in future studies. For those people who decline to take part in the study this will be completed at a site level by recruitment staff using an online secure anonymous questionnaire. For participants choosing to withdraw at any point after informed consent the questionnaires will be available in a range of formats (online, on paper, by telephone/digital platform or face-to-face) with translated versions and interpretation available.

3.4.5 Adaptations for South Asian recruitment

We are working collaboratively with LMCP and the wider stakeholder network to develop inclusive recruitment strategies and research materials, this is an ongoing piece of work but after initial conversations is likely to include:

Route A: Developing a short video that can be shown at clinic appointments by clinicians to introduce the research. There will be an English version and an Urdu version. Urdu is a language that is understood (written or verbal) by a wide range of members of the SA communities. Written information sheets will also be available in Urdu.

Consent to contact information will include details of communication preferences and needs. The recruiting site staff or a member of the university research team will contact potential participants via phone or email initially, with the option of an in-person visit if required. LMCP can provide support at this stage in the form of joint phone calls or visits and interpretation.

Route B: Community organisation staff (LMCP) will facilitate initial conversations by providing interpretation and support in overcoming cultural barriers.

The support of LMCP with recruitment will ensure that the research team are approaching conversations in a culturally appropriate way and thus enabling potential participants to feel safe to take part in the study.

3.5 Consent

Informed consent will be obtained and documented by research trained staff at recruitment sites or members of the research team (hereafter both are referred to as 'researcher'). Processes are detailed below.

3.5.1 People with dementia (feasibility study)

The participants recruited to the feasibility study will be people with dementia who have the capacity to give informed consent when recruited. Capacity to give informed consent to take part in this research will be assessed (using MCA guidance) by a researcher in person or online before consent is received and reassessed by a researcher at each data collection time point, face to face (with or without a carer present), at home or in another setting they choose (e.g. where there is interpretation available through trusted workers). If the participant has a clear preference for remote data collection (such as Zoom or telephone) this will be possible, with remote consent being obtained. Participants may choose to give written or verbal consent (witnessed by a researcher). In the case of remote online consent this will be audio recorded.

Verbal consent- the researcher will read out the consent form to the participant and witness them agreeing or disagreeing to each statement. If the participant understands and agrees to each statement, the researcher will initial the consent boxes on behalf of the participant and sign the consent form to witness the fact they have given informed consent to participate in the research.

Audio recorded consent- the researcher will use an encrypted voice recorder to record the participant verbally agreeing to each read out statement and stating their full name and that they agree to taking part in the research.

The participants will be provided with a copy of the participant information sheet and a copy of the consent form for their future reference regardless of the method with which the participant gives consent.

Participants with dementia will be given at least a week after receiving study information to consent (written or verbal) or decline to take part in the study. The participant information sheet will clearly set out what their involvement in the trial will involve (attending 6-week intervention if randomised to this group, usual care, and 3 data collection visits), and it will note that one or more of the Good Life sessions will be observed by a researcher to assess fidelity of the intervention (see 5.7 for further details). The information sheet will also detail that we would like permission to inform both their GP and a family member or friend (who

could be contacted in an emergency) about their participation in the study, and someone who could act as a consultee if required (this could be the same or a different person). Giving these contacts is optional and there are separate bullet points on the consent form to agree or disagree with. If the participant agrees then the appropriate parties will be sent a letter and copy of the participant information sheet informing them of the person with dementia's involvement in the study. The information sheet will also include information about the qualitative interviews for the study and explain that involvement in this part of the study is optional. Participants will opt in or out of being considered for a qualitative interview via a separate bullet point on the consent form (interview participants will be purposively samples from the pool of participants who opt in). Consent is an ongoing process and as such informed consent (willingness to continue in the study) and mental capacity to give informed consent, will be checked at each data collection time point.

3.5.2 Loss of capacity part way through study

An inclusion criterion for this study is the capacity to give informed consent at baseline. However, the study has a 6 month follow up and therefore capacity may fluctuate, or people may lose capacity part way through the study.

We are taking an intention to treat approach, so if a person loses capacity part way through the study they can remain in the study on the advice of a consultee. The research team will contact a consultee (typically carer/family member but not always) if/when notified (for example, by a carer or the GL course facilitator) that a person has lost capacity, or if a researcher visits to collect follow-up data and considers a person not to have capacity to give continued informed consent. Consultees will be provided with a consultee information sheet and asked to sign a consultee declaration form if they feel the person they support would want to continue in the study. If the consultee agrees, we will still attempt to collect follow-up data but will be mindful of the participant's comfort and capacities and stop data collection is the person does not assent or appears in any discomfort. Advice of the consultee would be sought at each subsequent data collection point to reconfirm their views on the person's wishes. Part of the background information collected at baseline asks for details of someone to act as a consultee in case of emergency.

The right to withdraw remains the same and the consultee can withdraw a person without capacity to give informed consent from the study at any time if they believe that is what they would want or think continued involvement is causing any distress. Data collected up to that point would be retained. Reasons for withdrawal would be collected by the withdrawal questionnaire, if possible, which can be completed by a person with dementia or consultee.

Participants without capacity would not be included in the embedded qualitative element of the study.

The premise of the Good Life course is inclusivity and peer support, therefore if during the course itself (6 sessions) someone loses capacity they would be supported (by facilitators and peer tutors) to continue participating in the course if they wish (or if their consultee thinks this would be their preference). One of the measures being tested for feasibility is an 'in the moment' wellbeing scale used to collect data before and after each session. If a facilitator has concerns about a person's capacity, they would not collect this 'in the moment' data that week and would notify the research team, who would seek consultee advice.

3.5.3 Embedded qualitative study

A sub-section of people with dementia, carers, delivery staff, recruitment staff and peer tutors will be invited to be interviewed or take part in focus groups as part of the qualitative element of the study. The research staff will be responsible for providing information about this part of the study and obtaining consent. For a detailed overview of the consent processes for all five groups of qualitative participants see section 5.6.

3.6 Randomisation

Once enough participants have been recruited in an area (18 per locality) and informed consent has confirmed, the baseline data will be collected. Upon completion of all the baseline data for that site randomisation will take place. Only participants who have given informed consent and completed the baseline data collection will be randomised. Participants for each site will be randomised individually once the recruitment target (18) has been reached. This will allow for staggered starts of the intervention.

Randomisation will be undertaken to a ratio of 2:1, with 12 people randomised to the intervention and 6 to usual care in each study site. An unequal ratio is being used to allow greater numbers to the intervention arm to help incentivise recruitment. Sealed Envelope software [21] will be used to carry out the randomisation.

The researcher will enter brief participant details (study ID, study site, and date of informed consent) into the online randomisation site. The online tool will indicate which participants have been allocated to which group (intervention or usual care). The researcher will then inform the participants personally rather than an automated email being sent.

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.

3.7 Screening logs

We will use an online platform to collect data from the sites on the number of people approached who meet the inclusion criteria. The screening logs will also document the number of people assessed for eligibility, the number of people approached, number of people giving consent to contact and achievement of targets. The screening log will document the preferred contact and communication details of the people who gave consent to be contacted by a researcher with further information about the study. For people who decline to be contacted with further information about the research the sites will ask for a reason from a short list and document this. This way we can use the information gathered to inform our practice moving forward as to reasons for not wanting to take part in a study like this. We will record the flow of participants through the study in line with recommended Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines [22].

4 TRIAL STRATEGIES

4.1 Intervention

Participants randomised to the intervention group will attend a 6-week GL course in their local area co-delivered by professional facilitators and peer-tutors living with dementia. Professional facilitators will be staff working for one of the delivery partners listed under Phase 2, following the manual and facilitator training developed in Phase 1.

Two professional facilitators for each site will attend a 2-day training workshop run by IiD. They will receive the Good Life manual and be supported throughout the set up and delivery of the course in their local area by IiD through online supervision meetings. Peer-tutors (2 per site) will be people living with dementia already known to services who will be supported to tailor the course to local needs and co-deliver sessions alongside professional facilitators. Peer-tutors will be invited to participate in the embedded qualitative study looking at the feasibility of intervention delivery but will not be participants in the trial and thus do not need to meet the inclusion criterion of having been diagnosed in the previous 12 months. It will be

the responsibility of delivery sites to recruit and support peer-tutors, not recruitment sites or the research team.

Tailoring of the course will be done through 3 in person co-production sessions between the facilitators and peer-tutors. Across these meetings, priorities are agreed and a plan for content over the six sessions of the course is devised. Throughout this time, the tutors have the opportunity to ask questions and discuss concerns with the facilitators, either in the group meetings or individually after. They also plan how they would like to be involved in delivery of the course. This could involve introducing speakers, sharing their own experiences and/or fielding participants' questions. In all these activities they will be supported by the professional facilitators. A member of the research team may attend one or more of these co-production meetings to assess fidelity. After each co-production meeting a summary of what was discussed is mailed out to peer-tutors for reference/to support recall. Between and after co-production sessions, facilitators invite experts and local services to speak on the course and answer participants' questions.

Prior to the course starting each participant randomised to the intervention arm will be contacted by the professional facilitators and a pre-course visit (or equivalent contact) arranged. This allows facilitators to introduce themselves and the course and to answer participants' queries about how the course works and check on travel needs and any accessibility requirements. This is an essential part of the model, supporting building of rapport, alleviating anxiety thereby promoting course attendance.

Each session will involve a pre-planning element with peer-tutors to write scripts and support peer-tutors in preparation for the session. During the course sessions the non-judgemental ethos of the course and equal value of everyone's knowledge and experience is emphasised. Peer-tutors are not expected to have all the answers, rather the course is an opportunity to learn and share together. A key part of the preparatory sessions is discussing how the tutors might feel if a participant on the course becomes upset or raises a sensitive issue. Whilst lived experience positions peer-tutors well to respond with empathy to the challenges faced by peers, it is not peer-tutors' responsibility to manage safeguarding or the emotional wellbeing of participants, this is the role of the professional facilitators and the wider service they work for, and established safeguarding procedures of individual organisation will be followed.

After each of the six sessions there will be an opportunity for peer-tutors to debrief with the professional facilitator and input into the session summary letter which will be sent out to all participants (including peer-tutors). This provides ongoing support for peer tutors and a

record of what was discussed for the participants. An end of course resource pack is produced for all attendees.

After the course, facilitators will work with learners and tutors to plan ‘next steps’. Options will be different in different areas, but one possibility is that learners from the initial course become tutors on a future course. We will capture ‘next steps’ qualitatively, measuring outcomes of these additional opportunities for study participants will be tested for feasibility at 6-months.

Delivery in the South Asian site will be undertaken by LMCP with translated materials and tailored language support.

The GL model advocates reimbursing peer-tutors for their time attending co-production sessions and co-facilitating the course sessions. We will be adopting this policy for the trial, using INVOLVE rated (£25 per hour).

Fidelity of the intervention is an important consideration when planning for a larger trial. IiD will assess fidelity against the manual checklist and researchers will observe at least one co-production meeting and one course session in each locality, recording details of delivery and tailoring to produce the TIDieR checklist. The course will run weekly for 2 hours (with a break) at an accessible venue. Carers will not be invited to take part in the training, but a buddy or personal assistant can accompany the person if required, and there will be a separate space for carers to congregate and socialise during each session

4.2 Control

Individuals randomised to usual care will not receive any additional services and will be asked not to attend an official GL course until 6-month data collection is complete. We will ask both groups to report on all services and groups attended over the 6-month period to improve our understanding of usual care, using a bespoke tool informed by the CSRI. Learning about usual care will be interpreted in light of learning from the wider DeNPRU-QM study to reduce duplication of effort.

5 DATA COLLECTION

5.1 Schedule of data collection

Data collection will focus on feasibility of administration of the outcome measures detailed in section 2.3, together with demographics and service use data collection. Members of the research team will collect demographic and baseline outcomes data prior to randomisation. The data will be collected with a flexible approach dependent upon the request of the

participant. This could be face to face or remote via an online platform or telephone. The first session is likely to be face-to-face (to build trust and enable communication), but if a person has a clear preference for remote communication from the outset this will be possible. All questionnaires will be administered by a member of the research team. The questions will be asked by the researcher (with visual aids showing scales where appropriate) and the participant's answer inputted into online questionnaires on a tablet.

Adaptations for reduced capacity: If a participant loses the capacity to give informed consent but still assents to attempting the measures (and a consultee advises that they would wish to remain in the study) the researcher will proceed but be particularly alert to signs of fatigue, distress or confusion. Whilst in general we will approach data collection in a standardised way (administering the same measures in the same way) for people with reduced capacity there will be the flexibility to amend the questionnaire order and use short versions. For example, we would start with the most dementia friendly measure (My Life Questionnaire) and we could replace the full Geriatric Depression Scale (GDS) with the 4 item GDS screening tool. Finding ways to make participation possible for as a broad a group as possible it a key aim of this inclusive feasibility study and so rather than rule out flexibility we will allow this where warranted and note the consequences (for feasibility, data quality and participant experience).

Adaptation for SA participants: If required for interpretation, LMCP will support at the consent and baseline data collection point. If further support is required for the subsequent data collection, then a professional interpreter will be employed. Baseline data collection happens pre randomisation and therefore LMCP can support with this and support building of relationships between participants and researcher. Once allocation takes place LMCP's role is intervention delivery only.

Two subsequent data collection points will be on completion of the GL course and 6 months post baseline.

Participants randomised to the intervention arm will complete an 'in the moment' short wellbeing questionnaire (the Canterbury Wellbeing Scale) before and after each course session, facilitated by the professional facilitators.

5.1.1 Baseline data

Prior to randomisation baseline data will be collected by a member of the research team. Demographic information collected will include:

- Contact details of emergency contact who could act as consultee (if consented to)
- GP details (if consented to)
- Date of birth
- Gender
- Living situation (with others, living on own)
- Type of dementia
- Co-morbidities
- Ethnicity
- Details of usual residence (own home, supported living)
- Time since diagnosis (if known)
- Time since first noticed difficulties
- Time since initial help seeking (e.g. contacted GP about potential dementia symptoms)

The baseline questionnaires will contain the following:

- Demographics
- Usual care
- ICECAP-O
- My Life Questionnaire (MLQ)
- EQ-5D-5L
- Geriatric Depression Scale
- De Jong Gierveld Loneliness Scale

The questionnaires will be administered in the order above (to assess acceptability with the primary outcome measure ICECAP-O being asked first) unless there is justification for adaptation (for example because of fatigue or reduced capacity – see above) in which case these reasons and any action take will be noted. .

5.1.2 Intervention period

Participants randomised to the intervention arm will be contacted by the course facilitators in their locality and then supported to attend a 6-week course, for 2 hours with a break each week. Each week the Canterbury wellbeing scale will be administered at the start and end of each session by the course facilitators. Training in how to administer this scale will form part of the 2-day facilitator training package. The facilitators will support the participants to complete the scale, reading out the questions to the group and the participants individually

completing a paper version of the scale. The group facilitators will collect these at the end of the sessions and store them securely until a member of the research team collects them at a site visit.

Attendance figures will also be collected during the course, along with any reasons given for non-attendance.

5.1.3 Course completion data collection

At course completion a researcher will visit each participant (both arms of trial) or make other arrangements to collect follow up data. The questionnaires used at baseline (except demographic information) will be repeated in the same order. A sub-set of participants will be purposively sampled and invited to take part in qualitative interviews, see 5.5 for further details.

5.1.4 Six month follow up

The 6 month follow up will be 6 months from baseline data collection and will include the same questionnaires as at course completion for both arms of the trial.

5.2 Feasibility of implementation

As part of assessing the feasibility of implementation we will invite professional facilitators and peer-tutors to take part in qualitative interviews on completion of the intervention delivery. At this point we will also collect some demographic and context information from the professional facilitators and peer tutors (with their consent). During the two-day training the professional facilitators will be made aware that some of the sessions will be observed to assess fidelity of the intervention. When recruiting peer tutors the professional facilitators will clearly explain that this iteration of the Good Life course is part of a research project and a researcher may be present at some course sessions to see how it is being delivered, but they will not be collecting any data from peer-tutors (unless they consent to take part in a qualitative interview after the course).

5.3 Embedded qualitative study

The qualitative part of the study will include in-depth interviews with people with dementia and carers. For participants with dementia who consented to a family member or friend who

supports them being informed of the study and interviews we will send out a summary of the interview, what is involved and a consent to contact form for them to return if they are interested in finding out more. We will purposively sample both groups to ensure a range of diverse participant experience is included such as ethnicity, and living situation (living alone or with carer, for instance). Interpreters will support qualitative interviews where needed.

The interviews will be flexible in approach. Those with people with dementia will most likely will be face to face, unless telephone or online is requested.

We will invite all delivery partners (professional facilitators and any other staff involved in delivery) to take part in an online focus group. Peer tutors will be invited to take part in individual interviews most likely face to face.

A sub-set of recruitment staff will be invited to take part in an online interview.

All interviews will last 30-45 mins and the focus group 60-90 minutes. They will be audio recorded using an encrypted voice recorder. Audio recordings will be transcribed by a University of York approved transcription service. Topic guides will be used for the differing groups of participants and informed by the study aims developed with input from the project management group and advisors with lived experience.

5.3.1 Qualitative focus group with delivery partners

Professional facilitators (n=6) from the 3 sites will take part in an online focus group. Topics for delivery partners will include barriers and facilitators to GL implementation, study processes and inclusiveness. The delivery partner focus group will take place after course completion.

5.3.2 Qualitative interviews with peer tutors

Peer tutors (n=6) will be invited to take part in a one-off individual interview. Topics covered in the interviews will include becoming a peer tutor, co-producing their local course and jointly delivering the course sessions with professional facilitators. The peer tutors will be invited for interview at the end of the Good Life course.

5.3.3 Qualitative interviews with carers

Family members or others identified as ‘carers’ will be invited to be interviewed about their role in supporting recruitment, retention, adherence to GL and any knock-on benefits or

harms, recognizing that people with dementia live interdependent lives [23]. Carers can be interviewed in a dyad with the person with dementia that they support if this is requested. Carers will be sent a summary of the interviews and can express interest by returning a consent to contact form when they are informed of the person, they support participation in the research.

We will interview n=15 carers across both arms of the trial, the intervention arm and UC arm.

It is important to interview carers from both arms of the trial to gain a picture of how supporting recruitment and study retention is affected by the randomisation process. Carers will be invited for interview after course completion data collection.

5.3.4 Qualitative interviews with participants with dementia

Participants with dementia will be interviewed about their views and experiences of the study including initial contact, processes of recruitment, randomisation, experiences of providing data (including measure acceptability and applicability), attending the intervention (where applicable) and the inclusiveness of all study processes.

Participants will be interviewed from both trial arms n=15 and can be interviewed in a dyad with their carer if requested. Participants with dementia who do not have a named carer will be purposively selected to understand any implications of not having this support.

For the embedded qualitative element separate participant information sheets detailing what is involved in this part of the study will be provided to potential participants and separate informed consent will be obtained for this part of the study. We will only invite people for interview who agreed on their trial consent form that they were happy to be contacted about this part of the study.

5.3.5 Qualitative interviews with recruitment staff

The recruitment staff will provide ongoing information about the success or otherwise of recruitment strategies through the site-specific screening log. Data will also be gathered through ongoing check in conversations, email conversations, any site visits or attending team meetings to discuss trial processes. Information on recruitment will be collated onto a simple framework on excel. We will also invite a subset of staff to take part in a qualitative interview or focus group. Topics covered in the interviews/focus group will include reasons for success or otherwise of recruitment strategies, inclusiveness and suggestions for improvements required for a full trial.

5.3.6 Informed consent for the qualitative study

The people with dementia will be informed about the interviews in the feasibility study PIS and if they are happy to be contacted about the interviews, they can indicate this on the feasibility study consent form. Carers will be informed of the opportunity to take part in an interview via letter or email. If they have consented to be contacted with further information about taking part in an interview, we will send them the information sheet. The delivery partners and peer-tutors will be approached by the research team towards the end of intervention delivery with information about the qualitative study and asked if they would be willing to take part.

The peer tutors will be provided with a separate participant information sheet to the professional facilitators for the interviews. This will provide information about what is involved in taking part in a qualitative interview, including audio recording and transcription of the interviews. Agreeing to be a peer-tutor does not imply they will take part in a qualitative interview, we will make clear throughout that this would be voluntary. Full information will be given at least a week before the interview to give time to make a decision, and informed consent will be sought immediately before the qualitative interview.

Potential participants across all groups who are selected to be invited for an interview will be contacted by a researcher and details about what is involved explained along with receiving the PIS. Informed consent will be flexible as per the processes used for the feasibility study (section 3.5) dependent upon the request of the participant. For members of the SA community (people with dementia and carers) we are developing inclusive research materials as part of phase 2 of the research, this is an ongoing piece of work.

There is more likelihood to have remote data collection in this qualitative part of the study. Both carers and recruitment staff may prefer to have either a telephone or online interview due to other commitments. The focus groups with staff will be online due to the dispersed geography of staff. The consent processes for remote interviews/focus groups will vary based on preference and digital skills. If the potential participant has an email address and is confident to complete a consent form electronically returning it to the researcher, then informed consent can be completed electronically. In this instance both the returned completed consent form and a copy of the accompanying email will be stored securely to produce an audit trail. If the potential participant is not confident in using email, then informed consent can be obtained verbally and audio recorded. The consent form would be read out by the researcher and the participant would verbally agree or disagree with each statement, completing the consent process by stating verbally their full name and whether

they consent to take part in the research or not. This would then be stored securely on the University of York server separate to any data.

5.4 Assessing the fidelity of the intervention

One of the research questions for this trial is whether the Good Life course can be manualised and delivered consistently across differing community settings. The fidelity of the courses will be assessed in the following ways.

Throughout the set up and delivery of the course the professional facilitators will have monthly online supervision sessions with IiD, these will give the opportunity for any difficulties arising from adhering to the core constructs or deviations from the manual to be documented and addressed. A fidelity self-report checklist will be used to check adherence to the core constructs and manual for the course, this will be devised after Phase 1 (manualisation and training development) with input from the PMG. This checklist will be completed after each course session by the professional facilitators and will be written into the sub-contracts for each site.

At least one pre-course coproduction meeting and one course session per site will be observed by a member of the research team and the same checklist completed by the researcher for that session for comparison. The observation of the session will be to assess fidelity of the intervention to the manual and core constructs only. Information that some sessions may be observed for fidelity will be included in the participant information sheet for the trial. The observations will not be audio or video recorded; the researcher will be assessing fidelity only, not collecting data.

The researcher will provide a reminder on the day of the observation explaining what it is for. For clarity it is the facilitators who are being observed to see how they deliver the course and whether it is consistent across all settings and with the manual.

The qualitative interviews with delivery partners and peer tutors will provide further insight into the fidelity of the intervention.

6 DATA ANALYSIS

6.1 Quantitative data

The quantitative data will be analysed using descriptive statistics. Mean and standard deviations for key outcomes will be calculated to support subsequent power calculations for

the full trial. Whilst any difference between intervention and control groups might support our case for the 'promise' of the intervention, it will not be used as a basis for estimating required sample sizes.

Data will be reported in line with CONSORT guidance extension to feasibility studies. We will assess the feasibility and acceptability of the trial design by calculating proportion of participants:

- Consenting from those eligible/approached
- completing baseline and follow up measures
- completing the intervention - i.e. attending at least 4 out of the 6 sessions.
- completing in the moment wellbeing questionnaires

In line with CONSORT guidance, we will additionally report the proportion of complete data at each timepoint for each measure.

6.1.1 Criteria for progression to full RCT

Descriptive data on recruitment, retention, response rates and adherence to the course will be framed against the below, traffic-lit progression criteria:

	Participants	**Action**
Go (Green)	**a) Recruitment:** ≥45 participants with dementia recruited in 7-month period (equates to >83% of desired sample of 54) **b) Retention:** ≥75% of recruited participants remain in the study (excluding deaths) **c) Data collection:** ≥75% provide data at each time point **d) Adherence:** ≥75% of intervention group adhere to the intervention	Continue to full trial
Amend (Amber)	**a) Recruitment:** 30 to 44 participants recruited **b) Retention:** 50-74% remain in the study (excluding deaths) **c) Data collection**: 50-74% provide data at each time point **d) Adherence:** 50-74% adhere to the intervention	Proceed with adaptations
Stop (Red)	**a) Recruitment:** <27 participants (<50% of expected sample) **b) Retention:** <50% remain in the study (excluding deaths) **c) Data collection**: <50% provide data at each time point **d) Adherence:** <50% adhere to the intervention	Consider not proceeding

6.2 Qualitative data

Transcripts will be analysed inductively using Framework [24] to facilitate reflexive thematic analysis [25] grounded in lived experience. The 2-day residential analysis workshop will enable the research team to draw on the expertise of experts by experience and other study partners. The research associate will lead the initial coding and discuss initial interpretations with other members of the team to reduce the influence of any one person. This will begin the process of theme development which will be further developed in the analysis workshop. Analysis will be an iterative ongoing process throughout the interview/focus group period, with qualitative data collection and initial analysis occurring simultaneously. Findings will be considered alongside the quantitative data analysis to consider the acceptability and feasibility of the study processes.

7 END OF STUDY PROCEDURES

The end of the study is defined as the point when the last participant has completed their 6 months post baseline follow up or the last qualitative interview for the embedded qualitative element of the study is completed, whichever is the latter.

The CI will notify the REC of the end of the trial or if the trial ends prematurely (with reasons).

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Research Ethics Committee (REC) and other Regulatory review & reports

The study will be subject to appropriate REC and HRA approvals as it involves NHS sites. The trial will be conducted in accordance with the protocol and GCP guidance where applicable.

Amendments will be reviewed by the Sponsor to assess whether they are substantial or non-substantial. Amendments will be submitted to the HRA for consideration. Participating NHS sites will be notified of all amendments. An amendment history will be kept within the study master file.

8.2 Peer review

The proposal for this feasibility trial has been peer-reviewed through the NIHR peer review process including both expert and lay reviewers.

8.3 Patient & Public Involvement (PPI)

The project has a dedicated PPI lead who has a background as a mental health social worker and extensive experience in PPI work and already has established networks with SA community groups having worked with them on the previous research of the Good Life course. The PPI involvement includes the following elements: a three-strand stakeholder advisory network, public members with lived experience on the study steering committee, advisors with lived experience on the project management group, and co-produced analysis residential. We will report on our PPI activity and outcomes guided by GRIPP2 [26]. Public members on the project management group, and study steering committee will be reimbursed for their attendance at meetings in line with NIHR guidance. Public members contributing to the three-strand stakeholder network will be given vouchers for their contributions and the community organisations supporting them can also be reimbursed for their efforts in supporting involvement.

8.3.1 Three strand stakeholder advisory network

We will establish a flexible, multi-modal stakeholder advisory network combining meetings with other forms of communication including email, telephone, discussion at existing groups and digital platforms. Ongoing PPIE will run across three strands:

1. Practitioner: statutory, voluntary and private sector practitioners who work in dementia care or support in some context, recruited through our existing extensive networks and ongoing networking activities. Meetings will be three times a year but can change in line with need. There will additionally be a wider practitioner network of interested practitioners who would like to be kept updated of progress of research and opportunities for involvement.

2. Lived experience: will consist of a core group of people with lived experience of dementia who would like regular and ongoing involvement in the research. They will be recruited through networks such as DEEP, Curious Minds and Involvement at York as well as service contacts at feasibility trial sites. Target membership will be 8-12, recognising that involvement may be fluid and influenced by members' health and wellbeing. Meetings will be 3 times a year. Additionally, there will be a wider lived experience group comprising of

people with experience of dementia (either personally, family member, friend) who will be kept updated on the progress of the research but can drop in and out.

There will also be a separate unpaid carers sub-group with options for regular meetings or more informal involvement. Any meetings would be separate to the core lived experience group unless both groups requested partnership working.

3. A subgroup specifically designed to engage people from SA communities: made up of South Asian people with dementia, family carers and the community workers who support them, recruited through the groups we built relationships with for the initial study. Work with this sub-group will take place through existing structures (groups which are already meeting) within a framework of wider activities. Opportunities for more informal ad-hoc contributions as requested/desired in a variety of formats will be available. Network members can join the wider lived experience or practice networks, and a SA member of this network will attend the study's steering committee as an expert by experience. Additionally, there will be an optional SA practitioner group comprising of practitioners with specific knowledge/expertise in working with SA communities.

The network will be facilitated by our dedicated PPIE lead, ensuring the insights of each strand inform the others. The schedule for involvement will be responsive to the needs of the project but is expected to include: 1) input into manual and training development; 2) recruitment approaches; 3) data collection; 4) implications of findings.

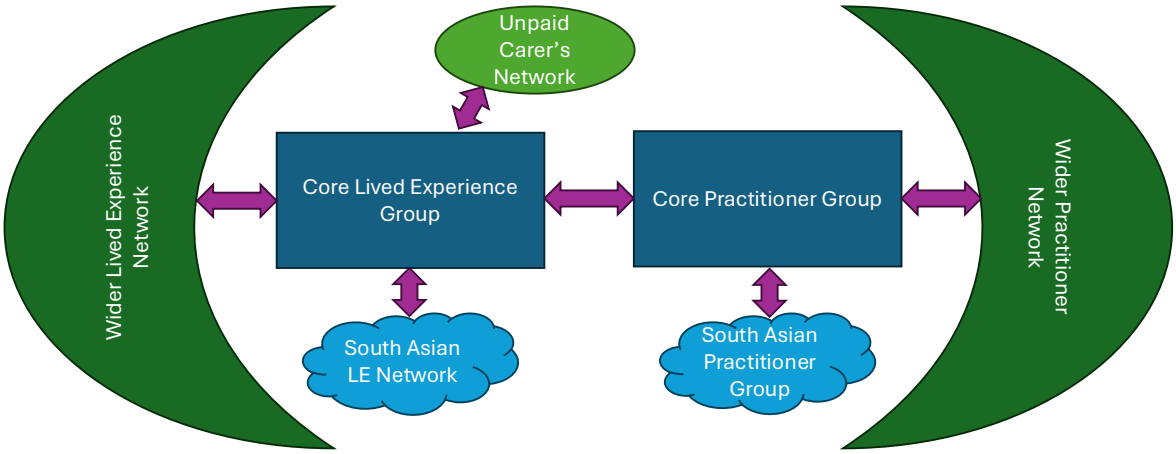


Figure 2 Representation of interconnected network

8.3.2 Study steering committee

The study steering committee will consist of a range of members with a mix of skills and knowledge from backgrounds such as the Department for Health and Social Care, dementia advocacy organisations and members with lived experience. This group will have an independent chair and independent PPIE members and will meet twice a year for independent oversight and to support study impact.

8.3.3 Project management group

This group includes a range of stakeholders including co-applicants, delivery partners and site staff from the three recruitment sites as well as the core research team. Two members of this group are experts by experience and have been closely involved with this project from the start. They were team members on the co-produced GL realist evaluation, and they worked on the development of the proposal for the feasibility study. This group meets quarterly, with responsibility for overall study management and to ensure a collaborative approach throughout.

8.3.4 Analysis residential

There will be a two-day residential analysis workshop that will include the experts by experience on the project, co-applicants and other study partners. The research team have experience of having run a similar workshop for the previous project.

Data management and some initial analysis will take place prior to the residential to ensure that the information presented is in an accessible format to enable an inclusive analysis workshop.

8.4 Data protection, patient confidentiality and research data management

Personal data (names, contact details) will be stored securely on University of York's secure server and only members of the research team and research administration staff will have access to it. This data will be stored separately to any research data and will only be used to contact participants about the research, follow up visits, and dissemination of findings. The recruiting sites will provide the research team with consent to contact information for potential participants via a secure online platform. Personal information for participants who

decide not to take part or do not meet the inclusion criteria will be destroyed. All paper consent forms will be scanned and stored electronically away from any research data. The paper version will then be securely destroyed. Any paper documentation containing identifiable information waiting to be scanned and stored electronically will be stored in a locked cabinet in the CI's office behind a door only members of the research team have access to.

Information containing personal identifiable information will not be removed from the sites apart from when securely transferring data to the research team. Participant details will be anonymised in any publications or reports resulting from the study.

At the point of informed consent all participants will be given a unique study ID which will then be used on all study documentation.

Exception- Canterbury wellbeing scales completed during course sessions will initially be identifiable using participants' first names (with a family name initial if there are duplicate first names on a course). The Canterbury wellbeing scale does not ask for any personal information, other than how the person is feeling 'in the moment' (engaged, interested etc.) Completed measures will be securely stored in a locked cupboard by the professional facilitators during the intervention period. A member of the research team will collect them as soon as possible after the intervention has finished and transfer them to Qualtrics with the participants' unique study IDs. Paper copies will them be shredded.

8.4.1 For all other quantitative data

The online platform Qualtrics will be used to complete the demographics, service use and outcomes questionnaires with participants. Each participant will be given a unique identifier and only the research team will have access to the 'key' to unlock which ID belongs to which participant. The researchers will use a University of York encrypted iPad to collect questionnaire responses. In the event of this been lost or stolen the University of York has the ability to remotely lock or wipe the iPad and questionnaires can be completed offline where connectivity is a problem.

Qualtrics can be accessed securely via the internet to manage the questionnaires.

8.4.2 For qualitative data

The qualitative interviews will be voice recorded using a University of York encrypted voice recorder and transferred as soon as possible onto the secure server. The recording will then be deleted from the voice recorder. Audio recordings will be transcribed by a University of York approved transcription service that has the necessary confidentiality agreements

signed. Audio recordings and transcripts will be labelled with a study ID number and stored securely in line with the University of York's data storage policies.

Anonymised quotes may be used in publications and presentations and anonymised data may be made available for secondary data analysis by the research team or other researcher researching a relevant topic upon request. This will only be for participants who have indicated their agreement to the ongoing use of their anonymous data on their consent forms.

At the end of the study, study data will be archived for 10 years in accordance with the University of York Research Data Management Policy https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/research-data-management-policy/

Access to study data will be limited to relevant individuals of the research team and the CI will act as data custodian.

The University of York will be the owner of the copyrights and associated intellectual rights in the study data.

8.4.3 Informing GP

Participants with dementia taking part in the feasibility study will be asked to give permission for their GP to be informed of their participation in the research. This will form part of the informed consent process. GP details will be collected via a secure online platform as part of the baseline background questions. GP's will be sent a letter and copy of the participant information sheet informing them of their patient's participation in the research for their records.

8.4.4 Informing carer

Participants with dementia taking part in the study will be asked to give permission for a member of their family or close friend (who could be contacted in an emergency or act as a consultee if required) to be informed of their participation in the research. This will form part of the informed consent process. Carer details will be collected via a secure online platform as part of the baseline background questions. Carers will be sent a letter and copy of the participant information sheet informing them of the person they support's participation in the research.

8.5 Indemnity

The University of York will act as Sponsor for the study and provided legal liability insurance. Contained within the PIS's is a statement regarding indemnity.

8.6 Trial conduct

The protocol will be adhered to throughout the study period, any deviations from the protocol will be documented and reported to the CI and sponsor if required.

A serious breach of the protocol will be reported to the sponsor immediately who will determine the seriousness of the breach and whether the REC need informing.

The research team will maintain regular contact with the recruitment sites to address any issues as they arise. The delivery sites will have ongoing supervision throughout the set up and delivery of the intervention to support with any issues relating to the intervention.

The Trial Master File will document all processes and management of the feasibility study including any deviations from the protocol.

8.6.1 Trial monitoring, audit and inspection

The trial will be monitored in agreement with the sponsors policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial documentation will be made available upon request for monitoring or auditing purposes by the sponsor, and authorising REC.

A Trial Monitoring Plan will be developed by the sponsor and agreed by the PMG and CI. Typically monitoring is delegated to the research team and is likely to include:

- Consent processes (taken by appropriate person and documented correctly)
- Data collection is consistent and adheres to protocol
- Adverse events, protocol deviations procedures are being followed and documented correctly
- No key data missing
- Data is valid
- Review of recruitment rates, withdrawals and loss to follow ups.

8.7 Adverse events

Safety reporting is an integral part of research and should be built into any participant contact and research activities, it is therefore important to record adverse events. Adverse

events can either be because of study conduct (deviation from study documents or processes such as consent), intervention or they could be completely unrelated to the study (missing a course session through physical ill health). These events vary in severity dependent upon the nature of the deviation. It is important to report adverse events particularly those which may have serious or unintended consequences as patterns may be detected on reviewing the records. Adverse events may be reported by the participants, observed or identified by site teams or by researchers when data collecting.

Any serious or other adverse events will be reported according to GCP guidelines see figure 3 (NIHR Decision Tree for Adverse Events Reporting non-CTIMPS) as to whether it is an adverse event that needs documenting at a site level or whether it is a serious event which needs reporting to the CI. We will provide an Adverse Event (AE) log and Serious Adverse Event (SAE) reporting form to all the sites. If an adverse event is detected by a local team, then they will report it to the site PI or delegated person with responsibility, who will log it on the appropriate form and monthly updates will be provided to the research team of any AEs. Serious adverse events must be reported immediately to the Sponsor; it is important to gather as much information about the event as possible. Anyone can report a serious event, and best practice is to err on the side of caution if unsure of whether an adverse event needs reporting.

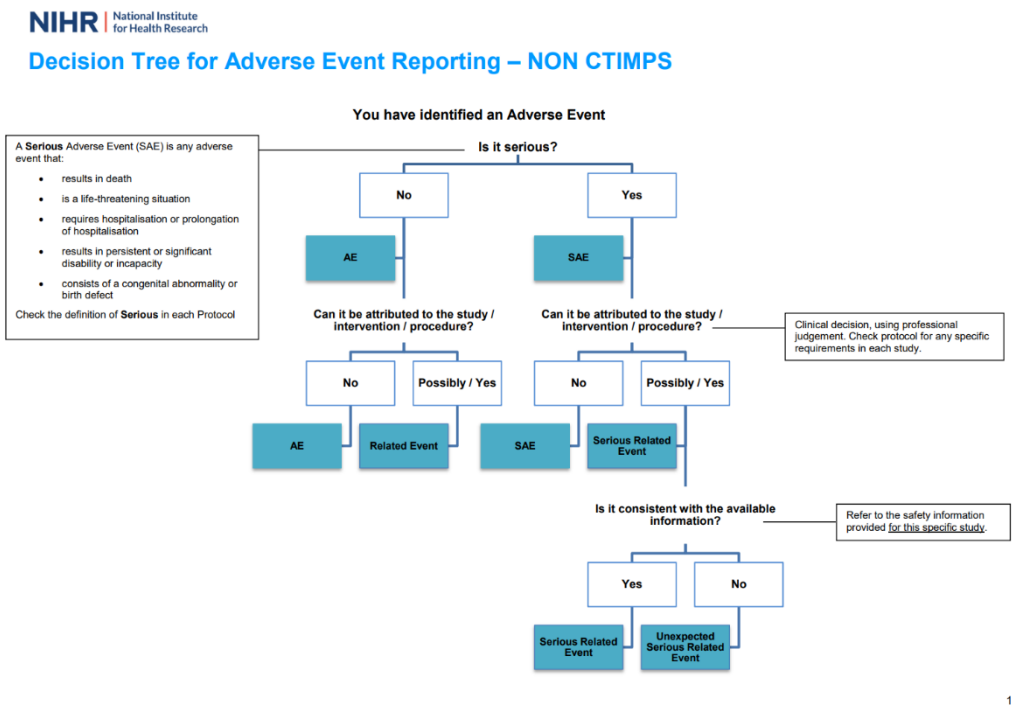


Figure 3. NIHR Decision Tree for Adverse Events Reporting non-CTIMPS

9 TRIAL MANAGEMENT

The CI of the project will have overall responsibility for the project and have oversight of the different components of the study. The project will be managed from the University of York.

9.1 Project management group (PGM)

The Project Management Group consists of all the co-applicants on the project alongside delivery partners and staff from the 3 recruitment sites. The group consists of a mix of experts by experience, dementia care practitioners and university research staff. It numbers 14 members and meets quarterly online. The group inputs into all aspects of the ongoing set up and delivery of the project, including development of study documentation, monitoring progress, discussing any issues as they arise and inputting into reports and dissemination.

9.2 Study steering committee

The study steering committee is likely to total 8-10 members in total with a mix of skills and knowledge from backgrounds such as the Department for Health and Social Care, dementia advocacy organisations and members with lived experience. This group will have an independent chair and will meet twice a year online. Its remit will be to inform the trial and maximise impact and dissemination of knowledge.

9.3 Sponsor and funding

University of York are the sponsors for this feasibility trial and National Institute for Health and Care Research (NIHR) Three Schools: Dementia Research Programme the funding body (Reference NIHR 356285).

10 DISSEMINATION

The research will produce new knowledge on the inclusive implementation of a manualised version of GL and the feasibility of a trial including diverse populations. Pathways to impact will be targeted at operational and strategic levels, with a view to both informing current use of the intervention and developing plans for further research. A strategic impact plan will be developed co-productively with our advisers and collaborators, but is likely to include:

1. Three in-person knowledge exchange events in the delivery sites, with one additional online event to maximise opportunities for impact nationally. These will be advertised using

existing university platforms and the applicant team's wider networks, including through the Study Steering Committee, three-strand advisory network and site-based research partners. These events will share findings and seek views on potential effects, challenges and next steps.

2. Production of targeted resources to support effective and consistent delivery of GL, including dissemination of the manual and training pack to ensure best practice.

3. A suite of wider strategic, practice and public facing resources to share research findings across the health and social care landscape, with a consideration of relevance for service provision at local and national policy levels. These resources will be developed in partnership with our Study Steering Committee and three-strand advisory network to ensure relevance and inclusivity. They could include commissioner briefings, practice guidance, summaries for DHSC/NHS England and written, infographic or audio-visual resources for people with lived experience and family carers. Resources will be hosted online by the University of York for ongoing accessibility and publicised by university media teams and dementia networks.

4. Presentations to maximise impact through practice and commissioning networks including ICB E&E committees, Communities of Practice, MSNAP, NHS England, Journal of Dementia Care, Future NHS and research dissemination initiatives such as Making Research Count and the Curiosity Partnership. The research team has extensive contacts within these networks.

10.1 Authorship eligibility guidelines

Data arising from the study will be owned by the Sponsor, The University of York. The researchers will aim to publish a research article in a peer-reviewed academic journal.

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12 SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

For and on behalf of the Trial Sponsor:

Signature: Date:

.....

...

Name (please print):

.....

...

Position:

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...

Chief Investigator: Date:

Signature 1: 31/07/2025

Name: (please print):

1 Kate Gridley