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A study of using the Living Well with Dementia for Couples and Families approach in the NHS

Submission date 02/12/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/12/2025	**Overall study status** Ongoing	
Last Edited 12/05/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Around 982,000 people in the UK have dementia. Getting this diagnosis can be upsetting for both the person and their family. Living Well with Dementia (LivDem) groups help people adjust by talking together in a group setting.
Some people prefer talking with their family instead of in a group. LivDem-Families was created for this purpose: the person with dementia and their family meet with a trained facilitator to discuss how dementia affects them. So far, we have tried out LivDem-Families with six families, and their feedback was positive. This study will explore whether other families might find the LivDem-Families approach helpful and whether it could be offered in the NHS.

Who can participate?
To take part people must have received a diagnosis of dementia in the last 2 years, be over the age of 60 years and not in paid employment.

What does the study involve?
Families will join five meetings with a facilitator to talk about:
1. How things have changed for the whole family
2. Coping together
3. Understanding dementia
4. Living well and planning ahead
5. Other sources of support
Participants will complete questionnaires and may be interviewed to share feedback.

What are the possible benefits and risks of participating?
LivDem-Families gives couples and families time to talk together about dementia. This can be upsetting, therefore facilitators are trained to support participants. People living with dementia have told us that although it can be hard to talk about dementia, they still wanted the opportunity to talk openly together with their family or other supporters.

Where is the study run from?
University of the West of England (UK)

When is the study starting and how long is it expected to run for?
December 2025 to December 2026

Who is funding the study?
NIHR ARC West (Dementia Capacity Building fellowship scheme) (UK)

Who is the main contact?
Prof. Richard Cheston, Richard.Cheston@uwe.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
356199

Study information

Scientific Title
Supporting families to adjust to a diagnosis of dementia: a feasibility study of the adapted LivDem intervention

Acronym
LivDem-Families Feasibility

Study objectives
To date we have created the adapted LivDem-Families manual and training package. We then conducted a small study in which the manual was used by a trained and experienced Clinical Psychologist with four couples or families and a second small study where health care workers were trained and delivered the intervention to two couples. Thus, we now need to see whether this intervention and the associated training package is feasible and acceptable in an NHS setting. If this research suggests LivDem-Families is indeed feasible and acceptable in the NHS, it

has the potential to improve the health and wellbeing of people living with dementia and their families, as they are supported to come to terms with the diagnosis and find ways to cope now and in the future.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 23/09/2025, HRA Seasonal REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; seasonal.rec@hra.nhs.uk), ref: 25/LO/0616

2. approved 31/10/2025, College of Health Science and Society Research Ethics Committee (University of the West of England, Frenchay Campus, Coldharbour Lane, Bristol, BS16 1QY, United Kingdom; +44 (0)11732 88528; julie.tonks@uwe.ac.uk), ref: 13919660

Study design
Interventional feasibility study at two NHS sites

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

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

Interventions
LivDem-Families is a psychosocial intervention where a person recently diagnosed with dementia and their partner and/or family members meet with a facilitator to talk about their diagnosis, its impact on them all and how to live well with dementia now and in the future. It is made up of five 90-minute sessions, where the person diagnosed with dementia and those who support them can talk together about what is happening with a trained facilitator. The aim of LivDem-Families is to support adjustment to the diagnosis so that whole family can cope better now and plan for the future.

As this is a feasibility study to test acceptability, participants will not be randomised but will be identified as eligible by the NHS dementia services who already support them.

In addition to taking part in the intervention, all family members will be asked to complete a series of outcome measures before and after taking part in the LivDem-Families. They will also be invited to take part in a follow-up research interview to explore whether they found LivDem-Families to be acceptable and feasible.

NHS staff who are delivering LivDem-Families will also be consented into the study as participants and will complete an outcome measure before and after delivering the intervention regarding how LivDem families impacts their work. They will also be invited to a focus group to explore whether they found it to be acceptable and feasible to deliver LivDem-Families in their NHS service.

Intervention Type

Behavioural

Primary outcome(s)
Feasibility and acceptability of the LivDem-Families intervention is measured using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure during the follow-up research interview (up to 1 month after the final intervention session)

Key secondary outcome(s))
1. Awareness of dementia diagnosis and symptoms is measured using Section 1 of the RADIX completed at baseline and during the final intervention session by the person living with dementia.
2. Hope and resilience are measured using the Positive Psychology Outcome Measure completed at baseline and during the final intervention session by the person living with dementia.
3. Self-compassion is measured using the Self-compassion Scale Short Form completed at baseline and during the final intervention session by both the person living with dementia and their family members.
4. The quality of social relationships within the family is measured using The EVOS questionnaire completed at baseline and during the final intervention session by both the person living with dementia and their family members.
5. Caregiver's competence in dealing with caregiving is measured using the Short Sense of Competence Questionnaire completed at baseline and during the final intervention session by the family members of the person living with dementia.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Person with dementia:
1. They must have a diagnosis of one of the following:
1.1. Alzheimer's disease
1.2. Vascular dementia
1.3. Lewy Bodies dementia
1.4. Mixed dementia
2. This diagnosis was received between 3 months and 2 years ago.
3. They must be currently receiving dementia support from Bristol Dementia Wellbeing Service or Somerset Foundation Trust.
4.They must be over the age of 60 years when they are referred for the LivDem-Families intervention and not in paid employment.
5. They must have a mild to moderate level of cognitive impairment and be, to some extent, able to reflect on and communicate their experiences.
6. They must be judged by a member of the clinical team to have achieved some degree of adjustment to their dementia as evidenced, for instance, by a score of at least one on the RADIX screening instrument or by an ability to acknowledge, at least at times, that their cognitive problems are more than those caused by old age.
7. As this is an intervention which relies heavily on verbal communication and clinicians in this trial are English speaking, participants must be fluent in English. We recognise this means certain groups of people will be excluded from this research study. To rectify this, once the intervention is established in English we will explore options for how this service can be provided equitably (e.

g. by community organisations being trained in and delivering LivDem-Families).
8. They must have the capacity to provide informed consent and willing take part in the study. This will be reviewed at each contact.
9. They must want to talk about dementia with their partner or family members.

Family member:
1. Has a family member(s) who is living with dementia who wishes to take part in the study and meets the inclusion criteria. If the person with dementia is regularly supported by a close friend with whom they have a good relationship, the intervention could then be delivered with the person and their friend.
2. They want to talk about dementia with their partner, family member or friend who has a diagnosis of dementia.
3. They are to some extent able to empathise with the person living with dementia. For example, they show some understanding of the impact of what they say on the person with dementia.

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Person with dementia:
1.They do not want to talk about dementia at all or become extremely upset when this topic of memory problems or dementia is raised.
2. They do not wish to talk about dementia with their partner or family members.
3. They have severe pre-existing mental health problems. For example, extremely high levels of anxiety, very low mood/severe depression, severe agitation or psychosis. In this case other sources of support will be explored e.g. other interventions offered by the service.
4. They have a significant history of trauma (e.g. abusive relationships).
5. There are risks of harm to self or others. This assessment of this criteria will be supported by standardised measures, such as the Patient Health Questionnaire (PHQ-9) which has a question regarding thoughts of harming oneself over the last two weeks. Also, clinicians will have access to care notes and risk assessments for their service users and can check if there have been previous risk concerns. If there are concerns about safeguarding, clinicians will follow their local procedures with support from the research team.

6. There are significant pre-existing relationship problems within the couple or family. If there are safeguarding issues, clinicians will follow their local procedures. If not, we will consider referral to local relationship support services.
7. They are currently receiving another psychosocial intervention such as counselling or psychotherapy.
8. They must have some ability to take the perspective of others and to empathise with their position.
9. The person has neurological impairment which affects their ability to understand the point of view of somebody else and empathise with their position. NB while we will assess this on a case-by-case basis, we recognise that people who have been diagnosed with Behavioural-Variant Frontotemporal dementia (BV-FTD) (which is associated with executive deficits and thus difficulties with empathy and perspective taking) are likely to be excluded from this this research.
10. The person has a diagnosis of mild cognitive impairment, stroke (without vascular dementia) or is awaiting diagnosis. This intervention is aimed at people who have a confirmed diagnosis of dementia.

Family member:
1. They become extremely upset when this topic of dementia is raised.
2. They have severe pre-existing mental health problems. For example, extremely high levels of anxiety, very low mood/severe depression, severe agitation or psychosis. In this case clinicians will consider alternative avenues for support in consultation with the research team.
3. They have a significant history of trauma (e.g. abusive relationships).
4. There are risks of harm to self or others. This assessment of this criteria will be supported by the Patient Health Questionnaire (PHQ-9) which has a question regarding thoughts of harming oneself over the last two weeks. If there are concerns about safeguarding, clinicians will follow their local procedures and consider alternative avenues for support such as community mental health services.
5. They are currently receiving another psychological intervention such as counselling or psychotherapy.

Date of first enrolment
01/12/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter

England
EX2 5AF

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
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TA1 5DA

Sponsor information

Organisation
University of the West of England

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health Research Applied Research Collaboration West

Alternative Name(s)
NIHR Applied Research Collaboration West, NIHR ARC West, NIHR Applied Research Collaboration West Midlands, ARC West, Applied Research Collaboration West

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (UWE Bristol Research Repository, https://www.uwe.ac.uk/study/library/research-support/research-repository).

The data will include pre and post outcome measures, some limited transcripts of research interviews and focus groups, and acceptability and feasibility scores. Also some participant demographics such as gender, age and diagnosis.

Data will be available at the end of the study with no expected end date to access. There are no access criteria and consent has been gained from participants to share anonymised data. Data is anonymised using participant codes and there are no ethical or legal restrictions.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	17/06/2025	12/05/2026	No	No
Study website			03/12/2025	No	No