data **This protocol has regard for the HRA guidance and order of content.**

FULL/LONG TITLE OF THE STUDY: Supporting families to adjust to a diagnosis of dementia: a feasibility study of the adapted LivDem intervention.

SHORT STUDY TITLE / ACRONYM: LivDem-Families Feasibility

PROTOCOL VERSION NUMBER AND DATE: v2 (17.06.25)

RESEARCH REFERENCE NUMBERS

IRAS ID Number: 356199

SPONSORS Number: 13919660

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STUDY SUMMARY

Study Title	Supporting families to adjust to a diagnosis of dementia: a feasibility study of the LivDem-Families intervention
Internal ref. no. (or short title)	LivDem-Families: A Feasibility Study
Study Design	Mixed methods
Study Participants	• Clinicians working at NHS sites • Managers working at NHS sites • People living with dementia and their families

Planned Size of Sample (if applicable)	Three post-diagnostic dementia clinicians at Bristol Dementia Wellbeing Service and three Clinical Psychologists at Somerset NHS Foundation Trust. Up to 16 couples or families where one person is living with dementia (up to 10 families at Bristol Dementia Wellbeing Service and 6 families at Somerset NHS Foundation Trust).
Follow up duration (if applicable)	N/A
Planned Study Period	13 months
Research Question/Aim(s)	**Primary research question** Is the LivDem-Families intervention acceptable to couples and families as a way to help them talk more openly about and adjust to their dementia? Is the preliminary data supportive of LivDem-Families improving health and wellbeing outcomes for people living with dementia and their family members? **Secondary research questions** Is the LivDem-Families intervention feasible and acceptable in an NHS setting? Is the proposed process for assessing whether a family is eligible for LivDem-Families acceptable and feasible? Is the preliminary data supportive of the intervention reducing levels of distress for people living with dementia and their families? Does the preliminary data indicate that participating in the intervention could lead to increased levels of distress for some individuals? Is the LivDem-Families training package, including direct teaching and ongoing clinical supervision, acceptable and feasible in an NHS setting to both clinicians and managers? Are the selected methods of evaluation an acceptable and feasible way of measuring the outcomes of the LivDem-Families intervention? Are there any revisions to the facilitator manual or training package that could improve the intervention being offered?

FUNDING AND SUPPORT

FUNDER(S)	National Institute for Health and Care Research (via NIHR ARC West), Floor 9 Whitefriars Lewins Mead Bristol BS1 2NT
FINANCIAL AND NON FINANCIALSUPPORT GIVEN	Grant ref: The funding for this fellowship is part of the overarching ARC award, reference NIHR200181 Dementia funding total amount: £788,042

ROLE OF STUDY SPONSOR AND FUNDER

The University of the West of England Bristol (UWE) is the Sponsor for this study. UWE Bristol takes responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. UWE Bristol will ensure that all necessary approvals from an NHS research ethics committee are obtained before undertaking the study. Signed ethically approved informed consent and acknowledgement forms from any participants who will be involved in the project will be obtained.

The study is funded by the National Institute for Health and Care Research via NIHR ARC West. The funder has not had any influence over the study design or analysis.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The project does not have a formal Project Management Group.

For work package 1 (training), Dr Natasha Woodstoke, Prof Richard Cheston and Dr Karin Buschenfeld will deliver the facilitator training and make practical arrangements in conjunction with NHS clinicians.

For work package 2 (intervention delivery), delivery of the intervention will be by NHS clinicians who will meet Dr Woodstoke and Prof Cheston on a regular basis to discuss issues arising from the intervention and research. NW and RC will have honorary contracts with BDWS and SFT to enable this support and allow access to relevant clinical notes.

For work package 3 (evaluation), the LivDem research team at UWE will liaise with NHS clinicians to visit participating families. A focus group of NHS clinicians and their managers will be facilitated by the research team. All interviews and focus groups will be carried out by LivDem team members.

STUDY GANTT CHART

	2025							2026				
	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May
Preliminary work Ethics applications and other governance requirements												
Work Package 1: training												
RC and NW provide training to facilitators and makes practical arrangements for the intervention												
Work Package 2: preliminary study												
Facilitators work with families to deliver the intervention												
Regular supervision with RC & NW												
Work package 3: evaluation												
Follow up and acceptability interviews												

STUDY PROTOCOL

1 BACKGROUND

1.1. What is the problem being addressed? Each year in the UK, approximately 200,000 people are diagnosed with dementia. While people may receive medication and some practical help, they are rarely offered support to help them to adjust to the diagnosis and to adapt to their new impairments.

1.2. How does the existing literature support this research? The Living Well with Dementia (LivDem) course is an eight-week group intervention that aims to support people recently diagnosed with dementia to adjust to their condition (Cheston & Marshall, 2019). Sessions last for 90 minutes and are attended only by people living with dementia. Carers and other family members are invited to attend an introductory session before the course commences and a final session at the end. LivDem courses are led by two facilitators, typically community nurses, occupational therapists or psychology assistants often under the supervision of clinical psychologists in NHS settings. LivDem is currently delivered across over 50 sites in the NHS and voluntary, community, faith and social enterprise (VCFSE) services in the UK, as well as in Ireland, Italy and Japan and is supported by a website (https://www.livdem.co.uk).

In order to help participants to feel safe enough to explore their experiences of their diagnosis (Cheston, 2022), the course takes a deliberately slow pace, initially focussing on the symptoms of cognitive impairment, then the emotional impact of this and ways in which participants cope with their feelings. Only in the middle sessions, when the group has formed and is ready to discuss more emotionally problematic material, will course facilitators initiate a discussion on how to talk about the diagnosis to others before looking in detail at the diagnosis, its treatment and prognosis. Finally, the LivDem course looks at ways of living well with dementia, including making decisions about the future, and the importance of staying as active as possible (Cheston & Marshall, 2019).

Two qualitative studies have suggested that over the course of the eight weeks, some participants were able to make changes in how they talked about their dementia indicating a potential process of adjusting to their dementia. Thus, in the initial sessions, participants tended to refer to their dementia indirectly, talking about "it" or "that thing that I have". By the end of the course, however, most participants were able to openly acknowledge their dementia, referred directly to their diagnosis and explored different aspects of their illness (Cheston, Gatting, Marshall, Spreadbury & Coleman, 2017).

Currently carers of people living with dementia do not attend the eight-week LivDem course but are instead invited to sessions that take place before and at the end of course. However, informal feedback from people living with dementia has highlighted that some potential participants are reluctant to engage with the group-based nature of the course. Instead, some people living with dementia tell us that they would prefer to discuss their illness within their family, rather than with strangers. However, any more active involvement of carers in the LivDem course might impact on the internal dynamics of the course as well as presenting logistical challenges for services.

In order to explore the best way to involve carers more actively in the LivDem we have conducted four pieces of research: first we consulted 26 stakeholders (Woodstoke, Winter, Dodd, & Cheston, 2024); second, we conducted an online survey of 28 current LivDem facilitators (Cheston, Reilly, Topalova, Woodstoke, & Dodd, 2024); third we developed an adapted version of LivDem (known as LivDem-Families) and this was trialled with four families, facilitated by an experienced clinical

psychologist; fourth we trained five research psychologists in LivDem-Families and they delivered the intervention to two couples.

Stakeholder consultation

We conducted a scoping exercise of the options around adapting LivDem with 26 stakeholders made up of four different groups: people living with dementia; family members; LivDem group facilitators; and psychologists or psychotherapists who either worked clinically with families or who were carrying out research in this area.

All interviews were conducted online using a mixture of semi-structured interviews and focus groups, with the transcripts of the recordings being analysed using Reflexive Thematic Analysis. Stakeholders felt that it would be possible to adapt the LivDem model for couples and families so long as a number of conditions were met. First it was important to be clear about who might and especially who might not benefit from the intervention. Second, it was important to create conditions where everyone can share thoughts. Third, although helping families to talk about the dementia together would require empathic facilitation, it was important to distinguish this from psychotherapy aimed at resolving more complex dynamics. Finally, while there were potential gains from integrating families into the current, group-based model, there were also significant challenges to doing this and on balance there was a preference towards creating a new, standalone intervention.

Online survey of LivDem facilitators.

We used Qualtrics to generate an online survey which was distributed during March and April 2023 to health and social care professionals who had completed the LivDem course facilitator training programme and given their permission to be contacted by the team with research opportunities. Facilitators were asked for their opinions as to how families could be more actively involved in the current LivDem intervention and what potential advantages and disadvantages this might bring. Survey questions allowed a mix of free text replies and ordinal responses (typically across a four-point Likert scale: strongly agree, agree, disagree and strongly disagree). Twenty-eight participants with a mean age of 43.7 took part in the study.

Respondents tended to agree or strongly agree (21) that carers should be more actively involved although seven disagreed or strongly disagreed with this statement. Most agreed (22) that carers would benefit from this involvement (six disagreed). However, a majority of facilitators expressed concerns at the impact of this on participants with dementia: thus, more facilitators disagreed or strongly disagreed (15) with the statement that involving carers would improve engagement than agreed with the it (12). Similarly, facilitators were equivocal as to whether having carers more actively involved might improve the adjustment of participants with dementia, with 17 being unsure what the effect would be, six believing it might help adjustment and five being concerned that it might make adjustment harder. These results suggest that whilst most facilitators believe that family carers should be more involved, there were mixed responses as to whether them being included in the group intervention would be helpful.

We explored facilitators' concerns around the impact of involving carers might be through a series of questions allowing open text responses. The response to these suggested that facilitators were worried that participants with dementia in a LivDem group might be over-shadowed by having their carers present:

Having the people with dementia attend on their own has certainly allowed space for honest conversations about the changes and challenges within relationships, which has seemed to be supportive. We have also found that in the sessions where the carer attends, they can sometimes tend to speak for the person with dementia. In the sessions where the carer isn't there, given time and space, the person with dementia has almost always found their own way of expressing what they're trying to say, and this has felt really important.

52-year-old female working in a VCFSE

I feel that participants may feel unable to share their true thoughts with carers at every session and I often find that carers will speak on behalf of the participant. I believe there is a place for carer support and attendance within the sessions but not at the detriment of the positive effect the course has on the confidence of the participant.

49-year-old female working in NHS

We asked facilitators to rank four different service responses that might allow carers to be more actively involved. Facilitators' preferred option was for a parallel group for carers running alongside the LivDem course (average rating 1.12, where 1 = best and 5 = worst). A female facilitator working in the NHS wrote: "*We have now set up a carers support group in the same building at the same time which Alzheimer's Society facilitate and this is working REALLY well".*

While the clear preference of facilitators was for parallel groups for carers, facilitators also identified potential barriers to this. Importantly, the labour-intensive nature of running an additional group means that it might be challenging for services to prioritise this additional time commitment for their staff especially if their service was not directly commissioned to do so. As one participant commented "*managers don't see family as warranting a service only the person*".

Overall, most facilitators thought families should be more involved but it was not felt they should be invited to LivDem groups and creating stand-alone carers' groups was often not feasible. We therefore created an adapted version for couples and families.

Preliminary trial of an adapted version of LivDem

From these two consultations we decided to create an adapted version of the LivDem approach that could be specifically delivered directly to couples or families where one person was diagnosed with dementia. We revised the LivDem group manual and presented early versions of this to our public involvement group, amending this on the basis of their feedback. This new version is LivDem-Families. It consists of five sessions that are intended to be facilitated by non-psychologists in a range of settings, and consists of the following elements:

- Initiation: establish participants meet inclusion criteria (e.g. quality of relationship, level of distress), explore timing and suitability of intervention, take consent and complete outcome measures.
- Session 1: How have things changed?
- Session 2: How does it feel to have dementia?
- Session 3: The dementia journey.
- Session 4: Living well now and in the future.

- Session 5: Follow up: How are things now?

Initially, we conducted a preliminary study of LivDem-families, with four couples and families all of whom were recruited through the Join Dementia Research register. Participants consisted of: two married couples, a couple and their adult son and a daughter providing care for her mother. The intervention was carried out by a qualified clinical psychologist, with acceptability interviews at the end of this conducted by a different member of the research team. All participants rated LivDem families as highly acceptable (total mean score 19.8 out of 20 where a higher score indicates greater acceptability), highly appropriate (19.6) and highly feasible (19.3).

Participants in the preliminary trial have described how talking about the dementia together during the course has enhanced their relationship – as one daughter told us:

> *I understand a bit more what you feel (and) you understand a bit more what I feel … it's a journey together, because the person who has it and the person who hasn't got it, you're in it together and you have to look forward together and I feel that's helped us.*

Her mother also felt that talking had been important:

> *I suppose talking about it and thinking about it and the chat that's just gone, realising that it's quite a common thing and anything you can do to help, just do it …. yeah, I know its long winded, but I can't see any better way of helping people than coming and sitting and talking … accepting it, not being frightened of it, accepting it and being fine with it.*

Pilot trial of LivDem-Families

Following on from the preliminary trial, we developed and delivered training in how to facilitate LivDem-Families to five research psychologists at ReMindUK (a NHS commissioned dementia service in Bath). To date they have delivered the intervention to two couples where one person has dementia. As part of this trial, we have continued to refine eligibility criteria and make changes to the LivDem-Families facilitator manual in light of feedback from facilitators.

2 RATIONALE.

2.1 Why is this research important in improving the health and wellbeing of patients and health and care services?

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.

2.2. What do we anticipate the outcomes and impact of the research programme will be? We anticipate that training and supporting NHS clinicians to deliver LivDem-Families will enable us to find out whether this intervention is feasible and acceptable to families and health care workers in NHS settings.

3 RESEARCH QUESTION/AIM(S)

3.1 Research Questions.

Our central research questions are whether the LivDem-Families intervention is a feasible and acceptable way to help couples and families to talk more openly about and adjust to their dementia? Furthermore, does preliminary data suggest LivDem-Families leads to improved health and wellbeing outcomes for people living with dementia and their family members?

This can be broken down into a number of subsidiary questions, including:

- Is the LivDem-Families intervention feasible and acceptable in an NHS setting?
- Is the proposed process for assessing whether a family is eligible for LivDem-Families acceptable and feasible?
- Is the preliminary data supportive of the intervention reducing levels of distress for people living with dementia and their families?
- Does the preliminary data indicate that participating in the intervention could lead to increased levels of distress for some individuals?
- Is the LivDem-Families training package, including direct teaching and ongoing clinical supervision, acceptable and feasible in the NHS?
- Are the selected methods of evaluation an acceptable and feasible way of measuring the outcomes of the LivDem-Families intervention?
- Are there any revisions to the facilitator manual or training package that could improve the intervention being offered?

3.2 Research Objectives. In order to answer these questions, we propose to:

- Deliver a training and support package to 3 or 4 post-diagnostic dementia clinicians in Bristol Dementia Wellbeing Service and three Clinical Psychologists in the Somerset Foundation Trust .
- Support those clinicians to deliver LivDem-Families to up to 16 people living with dementia and their partners or families.
- Carry out acceptability interviews with the people living with dementia and their families who have taken part in the study.
- Carry out a focus group with NHS clinicians who have facilitated the intervention and their managers to explore adherence to protocol and whether LivDem-Families was feasible for these clinicians in the NHS setting.
- Complete outcome measures with people living with dementia, their family members and clinicians.
- Collect and analyse data relating to the staff training and support package as well as the intervention.

4 STUDY DESIGN and METHODS of DATA COLLECTION and DATA ANALYSIS

This is a program of work with three packages:

4.1 Work package 1: Training health care workers to deliver LivDem Families. Training on LivDem-Families will be delivered to three clinicians working at Bristol Dementia Wellbeing Service (BDWS) and three Clinical Psychologists in Somerset NHS Foundation Trust (SFT). The training

sessions will be delivered by Dr Natasha Woodstoke (NW), Dr Karin Buschenfeld (KB) and Prof Richard Cheston (RC) who will then meet the clinicians to provide supervision and where necessary further training.

The clinicians at both sites all routinely work with people living with dementia and their carers but have a range of professional experience/qualifications. AT BDWS the clinicians are not psychological therapists; one is an Occupational Therapist and two are Dementia Support Workers. At SFT the clinicians are all Clinical Psychologists and thus trained psychological therapists. As such this group are typical of the diverse range of health care workers who we anticipate will be delivering LivDem-Families across the NHS when, and if, it is rolled out.

The clinicians will evaluate how helpful the training has been and the extent to which it prepared them to deliver the intervention using the NoMAD evaluation (Finch et al., 2016).

4.2 Work package 2: Intervention delivery. Having attended the training sessions, each clinician will then deliver the LivDem-Families intervention to either one, two or three families or couples, one of whom is living with dementia. The total number of participating couples and families will be up to 6 in Somerset NHS Foundation Trust and up to 10 at Bristol Dementia Wellbeing Service (up to 16 families in total).

Evaluation questionnaires will be administered to all members of the families receiving the intervention at two time points: during the initiation meeting preceding the intervention and at the follow-up meeting. The following measures will be used:

4.2.1 Measures to be completed by the person living with dementia.

1. the Self-compassion Scale Short Form (Raes, Pommier, Neff & Van Gucht, 2011),
2. the Positive Psychology Outcome Measure (Stoner, Orrell & Spector, 2018)
3. section 1 of the RADIX (Quinn, Morris & Clare 2018),
4. The EVOS questionnaire (Aguilar-Raab, Grevenstein & Schweitzer 2015).

4.2.2 Measures to be completed by family members.

1. the Self-compassion Scale Short Form- (Raes et al., 2011),
2. the Short Sense of Competence Questionnaire (Vernooij-Dassen et al., 1999),
3. The EVOS questionnaire (Anguilar-Raab et al., 2015).

4.2.3 Risk assessment

As participants, both those living with dementia, and their family members, will be receiving a health intervention, we will take the following steps to ensure there is support in place if concerns regarding risk to self or others are disclosed at any point in the research process:

- GP details for the person living with dementia will be held by Bristol Dementia Wellbeing Service (BDWS) and Somerset NHS Foundation Trust (SFT) as they will already be a service user of this NHS service. BDWS and SFT will also collect and store securely the GP details of their family members for the duration of this research study.
- We will seek permission from those taking part to inform their GP they are taking part in the LivDem-Families intervention. Also, to contact their GP if we are concerned for their wellbeing

or that of others (e.g. they disclose thoughts to hurt themselves or others) during the course of the intervention. This is clearly stated in the Participant Information Sheet (PIS) and Family Participant Information Sheet.

- An eligibility requirement for this study is that the person must not be currently experiencing severe mental health problems and/or emotional distress. Therefore, as part of the initiation process into the study we will assess levels of distress for all participants. In this assessment we will be guided be guided by structured measures of mental health (e.g. the Patient Health Questionnaire (PHQ-9, Kroenke, Spitzer & Williams, 1999)). If it is assessed that the person does not meet eligibility owing to the levels of distress they are currently experiencing, the clinician would support the individual, signpost to relevant mental health support and inform their GP. This step aims to reduce the risk of this intervention exacerbating preexisting distress and mental health problems.
- For those who are eligible, we will send a standard letter to the GP of each individual taking part in LivDem-Families informing them they are taking part and a brief overview of the intervention. We will also include a copy of the signed consent form and the Participant Information Sheet so the GP is aware of what the research entails and their participation is recorded on their medical health records.
- If during the course of the intervention we are concerned for the wellbeing of any participant we will follow the Distress Protocol 170625 v1 and Adverse Event Protocol 070525 v1, including informing the relevant healthcare provider/GP to provide further support. We will consider whether their participation in the research needs to stop or recommence with their wellbeing as the priority.

Commented [NW1]: Updated as per 'Ethical review number 3A'

Commented [NW2]: Added in response to 'Ethical review number 7'

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3 Work package 3: Acceptability and feasibility evaluation of LivDem-Families

4.3.1 Acceptability interviews. Either NW or RC will meet all participants living with dementia and their families up to four weeks after they have completed the follow up intervention to establish how acceptable the intervention has been, and to identify any potential improvements to the intervention that are required.

If we are unable due to resourcing to meet with all participants, we will use purposive sampling to select families to interview. This sampling will identify families who (i) appear to have particularly benefitted from the intervention, (ii) families who have dropped out for any reason and (iii) families with demographic characteristics which differ to the majority of other participants (e.g. in terms of ethnicity, sexual orientation).

The acceptability interviews will be recorded and transcribed and analysed using reflexive thematic analysis (Braun and Clarke, 2021). Data will be collected face-to-face where possible, or online via Microsoft Teams and will include completion of the Acceptability Intervention Measure or AIM (Weiner et al., 2017) with families. Data will then be used to amend the LivDem-families intervention.

4.3.2 Feasibility focus groups. NW and/or RC will facilitate two online focus groups with clinicians and managers from the two sites to establish how feasible it has been to deliver the intervention in NHS services, and to identify any potential improvements to the intervention and how it is delivered. These focus groups will also be recorded and transcribed and analysed using reflexive thematic analysis (Braun & Clarke, 2021). Data will be collected online via Microsoft Teams. Participants will also be asked to complete the AIM measure.

4.3.2 Feasibility evaluation

From the data collected in WP1 and WP3 we will assess the following feasibility outcomes:

1. *Adherence.* We will develop a questionnaire to measure each element of LivDem-families as the proportion of the facilitators reporting good understanding and regular use of that element.
2. *Fidelity.* Using a five-step process (Hoffman et al., 2014), we will develop a checklist to measure the fidelity of, and engagement with, each element of the LivDem-families intervention.
3. *Sustainability* will be measured through the responses of facilitators on Section C3 of NoMAD (Finch et al., 2016).
4. *Acceptability of the intervention* will be measured: (i) by the proportion of families who rate the intervention as acceptable on AIM, and (ii) through the responses of facilitators to Section C2 of NoMAD.

5.1 Inclusion, Exclusion and Stop Criteria

5.1.1 Inclusion and exclusion criteria for LivDem-Families facilitators (WP1, WP2 and WP3)

- Must be employed at the BDWS or SFT, have capacity to give consent and are willing to take part in the study.
- Must have experience supporting people with dementia and their families following diagnosis.

To ensure staff do not feel obliged to participate, we will highlight to staff and managers that they can attend the LivDem-Families facilitator training and deliver the intervention and research (which may be an expectation from their managers) without being participants in the research themselves. This will mean they can complete their workplace obligations of attending relevant training and delivering the intervention without feeling obliged to consent to be a participant in the research. This is detailed in the staff PIS (LivDem-Families Feasibility Staff PIS 260825 v2).

Commented [NW3]: Added in response to 'Ethical review number 1'

5.1.2a Inclusion criteria for people living with dementia (WP2 and WP3)

- They must have a diagnosis of one of the following:
  - Alzheimer's Disease
  - Vascular Dementia
  - Lewy Bodies Dementia
  - Mixed dementia
- This diagnosis was received between 3 months and 2 years ago.
- They must be currently receiving dementia support from BDWS or SFT.
- They must be over the age of 60 when they are referred for the LivDem-Families intervention and not in paid employment.
- They must have a mild to moderate level of cognitive impairment and is, to some extent, able to reflect on and communicate their experiences. For example, a score of from about 60 to 87 on the ACE-III may indicate mild/moderate impairment (Hseih, Schubert, Hoon, Mioshi, & Hodges, 2013). Scores can be combined with information from the initiation session to inform a decision about whether to offer the intervention.

- They must be judged by a member of the clinical team at BDWS or SFT 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.
- 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).
- They must have the capacity to provide informed consent and willing take part in the study. This will be reviewed at each contact.
- The must want to talk about dementia with their partner or family members.

5.1.2.b Exclusion Criteria for people living with dementia (WP2 and WP3)

- They do not want to talk about dementia at all or become extremely upset when this topic of memory problems or dementia is raised.
- They do not wish to talk about dementia *with their partner or family members.*
- 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.
- They have a significant history of trauma (e.g. abusive relationships).
- There are risks of harm to self or others. This assessment of this criteria will be supported by structured measures such as the Patient Health Questionnaire (PHQ-9) which has a question regarding thoughts of harming oneself over the last two weeks. Also, BDWS/SFT 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.
- 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.
- They are currently receiving another psychosocial intervention such as counselling or psychotherapy.
- They must have some ability to take the perspective of others and to empathise with their position.
- They have a 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.

- 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.

5.1.3a Inclusion criteria for family members of people living with dementia (WP2 and WP3)

- 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.
- They want to talk about dementia with their partner, family member or friend who has a diagnosis of dementia.
- 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.

5.1.3.b Exclusion criteria for family members of people living with dementia (WP2 and WP3)

- They become extremely upset when this topic of dementia is raised.
- 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. For example, referral to community mental health services.
- They have a significant history of trauma (e.g. abusive relationships).
- There are risks of harm to self or others. This assessment of this criteria will be supported by structures measures such as 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, BDWS/SFT clinicians will follow their local procedures and consider alternative avenues for support such as community mental health services.
- They are currently receiving another psychological intervention such as counselling or psychotherapy.

5.1.4 Stop or Pause Criteria for the LivDem-Families Intervention

If during the intervention any of these criteria are met this will be discussed with a member of the research team and we will consider pausing or stopping the intervention:

1. The person living with dementia and/or their family member(s) become extremely upset when this topic of memory problems or dementia is raised.
2. The person living with dementia or their family members have expressed not wanting to continue with the intervention or there is concern they are do not want to continue from their behaviour (even if it has not been said explicitly).
3. There is concern the nature of the conversations within the intervention are unhelpful to the person living with dementia or family members (e.g. if family members are extremely critical of the person with dementia within sessions).

4. It emerges that any the person living with dementia or their family member has severe pre-existing or current mental health problems. For example, extremely high levels of anxiety, very low mood/severe depression, severe agitation or psychosis. In this case we will consider alternative support, such as community mental health services.
5. There are pre-existing relationship problems and sessions are focused on these rather than on living well with dementia. We will consider referral to other services if appropriate.
6. There are safeguarding concerns or risks to self or others for any member of the family. In this case clinicians will follow the distress protocol and local procedures with support from the UWE research team.

5.2 Recruitment

5.2.1 Recruitment route. Participants living with dementia and their family members will be recruited through the BDWS or SFT and will have already given their consent to be approached to be part of a research project. Each clinician who is facilitating LivDem-Families will work with either 2 or 3 couples or families where one person has a form of dementia. The clinicians who facilitate LivDem-Families and their managers will also be participants in the research.

Staff participants will be approached by their managers where this research and the LivDem-Families fits with their existing clinical job role and skill set. They will be invited to attend training on the LivDem-Families intervention. If after this, they wish to be staff participants in the research they can provide consent to the research team. The research team will make it clear that this will have no bearing on whether they can deliver the research to NHS patients as part of their clinical role.

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5.2.2 Capacity. All participants will have capacity to give informed consent using the following criteria for capacity: ability to understand the information provided; ability to retain the information for long enough to be able to make a decision; ability to process the information; and ability to communicate their decision. Although no specific limits on a cognitive screening test can provide a definitive guide, we expect that participants with dementia would score between 60 and 87 on the ACE III, which has been recognised as a reliable indicator of a mild level of dementia.

Where participants have a diagnosis of a form of dementia, we will also assess capacity informally during our initial conversations with them and a member of their family. All members of the project team are experienced clinicians and researchers and are used to assessing capacity in this way. We will continually review at every meeting that the person retains capacity. In the event that somebody loses capacity during the research process, we will withdraw them from the study. Any identifiable data collected with consent would be retained and used in the study, but no further data will be collected or any other research procedures carried out on or in relation to the participant.

5.2.3 Consent. All participants will be sent the consent form and PIS before the study commences. Then at the initiation meeting, they will be asked to confirm they have read and understood the PIS and given the opportunity to ask questions about the study. Spare copies of the PIS and consent form will be available. They will be asked to read and sign the consent form to confirm that they consent to take part in the study.

5.2.4 Withdrawal from the study. We will emphasise to participants that taking part in the study is completely voluntary. After giving their consent, a participant is still free to withdraw at any time, and without giving a reason. We will regularly check in with participants that they wish to continue and

reiterate their right to withdraw during the study. Once the study is completed participants will be given 2 weeks to withdraw their data from the study.

If participants withdraw during the course of the study, they can choose whether they want the data they have provided so far to be deleted. If they choose this, all their data will be deleted from OneDrive and their data will not be included in the analysis or results.

6 ETHICAL AND REGULATORY CONSIDERATIONS

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

Health Research Authority approvals to conduct the research with clinicians working in NHS services (WP1) and people living with dementia and their families (WP2 and WP3) will be applied for using the Integrated Research Application System (IRAS).

6.1.1 Regulatory Review & Compliance. Appropriate site-specific approvals will be in place prior to any recruitment to the study. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

6.1.2 Amendments. Amendments will be decided amongst the project management team (RC, NW, KB and ED). The IRAS system will be used to notify any amendments relating to participating NHS sites. HRA processes will be followed to ensure that all sites work to the most recent version of the protocol.

6.1.3 Other ethical issues. It is possible that people living with dementia and their families may become distressed during discussions about dementia and its impact on their lives. For example, when engaging in the intervention, the content of sessions may contain emotive topics, such as the impact of dementia on their family. It is possible that people living with dementia and their families may become distressed during discussions about dementia and its impact on their lives. For example, when engaging in the intervention, the content of sessions may contain emotive topics, such as the impact of dementia on their family. We will address this risk in three ways:

a) Our recruitment criteria will specify that participants with dementia must be judged by a clinician to have achieved some degree of adjustment to their dementia.
b) The clinicians at BDWS and SFT are experienced in working with people with dementia and their families. They are all trained to deliver the LivDem group course before and will receive training from the LivDem team in delivering LivDem-Families. During the research project they will be supervised by Dr Natasha Woodstoke and Prof Richard Cheston who are both experienced Clinical Psychologists. Prof Cheston has an international reputation for working psychotherapeutically with people living with dementia and their families and has extensive experience of containing and resolving distress.
c) If a participant become distressed during the research process, then clinicians will follow the procedure set out in the Distress Protocol 170625 v2. They will be given the option to stop the meeting and asked if they wish to continue before restarting.

Commented [NW5]: Updated version uploaded to IRAS in response to Ethical review number 7

d) It is possible that during the research process participants may reveal information about their past which is of concern and which, if it had been known about prior to the research commencing would have meant that the person would not have met the criteria for inclusion in the study. This might include information about self-harm or suicide, or significant pre-morbid trauma. We outline the pause, stop and recommencing procedure that we will follow in this case in the Distress Protocol 170625 v2, including our procedures for communication around risk with health and social care workers. If the intervention needs to be stopped, we would highlight to BDWS or SFT that there is an unmet mental health need in case they are able to offer further support to the family.

e) Participants are able to withdraw from the study at any time and this will be reiterated during the course of the study as part of continuing informed consent.

7.1 Patient & Public Involvement.

The LivDem team have an active public involvement team which has contributed to the development of LivDem-Families. A group of five people who have all provided care to a relative living with dementia have met six times to advise on adapting the LivDem intervention and have reviewed the adapted manual for LivDem families. We have also consulted with a person living with dementia who has suggested changes to the LivDem-Families manual and who has agreed to work with us through the study. We will continue to work with our experts by experience through the course of this study.

8.1 Data protection and patient confidentiality.

Participants are provided with information on the PIS, Family PIS and Staff PIS ((LivDem-Families Feasibility PIS 180625 v2; LivDem-Families Feasibility Family PIS 270825 v1; LivDem-Families Feasibility Staff PIS 180625 v2), about how we intend to use and store their data and that their data will be used for the stated purposes of the study. Only members of the research team will have access to the data. Data minimisation will be achieved by collecting minimal personal data. Personal data collected (including participants names and addresses) will only be used to maintain contact with participants. Where GP details are not already held (e.g. for family members of people living with dementia), BDWS and SFT will collect and store these in order to inform GPs that participants are taking part in the research and to contact GPs if any risk issues arise during the course of the intervention. These details will not be held by the research team.

Any sensitive data such as ethnicity, medical information such as dementia diagnosis will be collected as research data and stored separately from personal details which could be used to identify them. These data will only be reported as summary statistics in reports and published papers to describe the sample and therefore will not be able to be linked to any individual.

9.1 Home working.

We anticipate that members of the research team will work from their University offices and store electronic data on a University OneDrive. Should it become necessary to work from home, then we will store electronic data using a University OneDrive, following the relevant university guidelines for home working. Electronic data will not be stored using home computers. Hard (paper) copies of personal data will not be kept at home.

10.1 Storage and sharing of data.

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10.1 Data storage and sharing. For WP2 all families will be seen in their own homes. Following meetings with clinicians or the UWE study team a clinical note will be made on the participants clinical notes on the RIO system where relevant and appropriate.

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A participant log will be maintained at the BDWS or SFT which will include personal details of participants (both people living with dementia and their families). Participants will then be assigned an anonymised code, which will be recorded on the participant log and used to refer to all participants on data forms and in the demographic log.

All questionnaires will be completed on site, with paper copies stored securely on site. A member of the LivDem research team will visit BDWS and SFT regularly to access these paper copies and will store anonymised digital records of them on a secure, networked drive (UWE Bristol OneDrive). Once uploaded to OneDrive the paper copy will be shredded and disposed of in confidential waste.

For WP3 meetings can either be in person or online. In person meetings will be recorded on a UWE owned voice-recorder. At the end of the meeting, recordings will be uploaded from the voice-recorder onto OneDrive and the recording on the voice-recorder deleted. Recordings will then be manually transcribed by a member of the study team.

Online meetings using Microsoft teams will be recorded using the facilities provided on Teams. This includes the automatic transcription option. Following the meeting, the transcript will be checked for accuracy.

All transcripts will be anonymised through the removal of people's names and other personal information. Where necessary non-identifiable terms, participant ID codes or pseudonyms will be used instead. Following checking, the data recording will be deleted.

Transcripts will be stored electronically on a secure, networked drive (UWE Bristol OneDrive). Access will be controlled via passwords and permissions to dedicated study folders. Where it is necessary to create hard copies of transcripts or other data, then these will be securely stored in locked filing cabinets that are accessible only to research staff. Access to data will be limited to quality control, audit, and analyses. Data shared between sponsor and coinvestigators will be de-identified to minimise breach of confidentiality.

The 2018 Data Protection Act applies to this research. Participants will be provided with a data privacy notice which outlines how we intend to use and store their data and that their data will be used for the stated purposes of the study. Only members of the research team will have access to the data.

Data minimisation will be achieved by collecting minimal personal data. Personal data collected (including participants names and addresses) will only be used to maintain contact with participants and will be stored separately from research data and will be kept in a password protected separate file on OneDrive. Where GP details are not already held for family members of people with dementia, these will be collected by BDWS and SFT to inform the GP that participants are taking part in the research and to contact the GP if any concerns about risk arise. These details will be stored securely either in a locked filing cabinet or on a secure computer drive.

Any sensitive demographic data such as ethnicity, medical information such as dementia diagnosis will be collected as research data and stored separately from personal details which could be used to identify them. These data will only be reported as summary statistics in reports and published papers to describe the sample and therefore will not be able to be linked to any individual.

We will ensure that the research methodology does not facilitate unintentional re-identification of individuals as could occur, for example, by using a very small sample of participants from a cohort where individuals would be easily identifiable.

Disclosure of significant risk of harm. During the research, should information relating to harm to the person or to another be disclosed that represents a significant risk of harm, then senior clinicians in BDWS or SFT will create and follow a care plan to provide appropriate support. They will inform the participant that they have a duty of care to share this information and will do so if necessary, for example with their GP. This process is outlined in the Participant Information Sheet and included in the consent form. RC and NW will have honorary contracts and research passport with BDWS and SFT to enable them to support this process and allow access to relevant clinical information as required.

These discussions will also identify whether the research process should be recommenced or whether it should be stopped. At all times, the paramount concern will be the couple or families' well-being.

10.2 Data processing. The Participant Log (including names, contact details, dates and times of contact, GP details) will initially be saved at the pilot sites. At the end of the data collection phase for WP3 this will then be transferred by a study team member to the UWE OneDrive with a secure password and will only be accessible by the research team. The version stored at the pilot sites will be destroyed. There will be no printed version of the Participant Log. At the pilot sites this will be processed by the team in order to make contact with the participants and arrange research appointments. At UWE if the participant consents, then we will store personal data in order to contact participants in the future to let them know the outcome of the research.

All data collected from meetings and interviews will be anonymised so that participants are not recognisable. The Demographics Log including diagnosis, ethnicity, living situation (e.g. living alone), marital status, year of birth, gender and sexual orientation will also be anonymised so that participants are not recognisable.

10.3 Reporting of data. In reports of the work, where excerpts are quoted from interviews, any information that might lead to the identity of participants, other people or organisations being inferred will be disguised.

10.4 Data disposal. We plan to hold personal data for less than 3 months after study end and research data for 6 years from study end. Recordings of interviews will be deleted once a transcription of the meeting has been checked and agreed. Personal details will be securely deleted at the end of the study. We will upload anonymised research data into the UWE data repository. We will be happy to share anonymised research data with other researchers who contact directly to request the data.

11. Ending the study

Commented [NW7]: Section 11 added in response to 'Assessment number 11'

11.1 Definition of ending and final report

This study will be defined as ended when the last visit to the last participant is complete. This will be when all data required to answer the research questions in this protocol has been collected. When the study ends we will notify the Research Ethics Committee (REC) that gave our favourable opinion within 90 days of the study ending. Following this formal declaration final analysis of the data will take place. A final report will be submitted to the REC within 12 months of the end of the study.

11.2 Dissemination of results

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For participants who asked to be informed of the results of the study, we will contact them to share what the research found out, including a plain language summary of the research. Their names and contact details will then be destroyed.

Research findings from this study will be made accessible through publication in an academic journal, at conferences and sharing with NHS dementia services.

11.3 Post-research care

The Participant Information Sheets all state that once the study ends they will not have further support from the research team. However, they will be able to access treatment as usual in the NHS. The research team will also endeavour to ensure participants are aware of other local sources of support e.g. community organisations, charities and carer support.

12. Indemnity

The University of the West of England, Bristol ("UWE") insurance arrangement for employees and for students working under the supervision of a UWE employee and where the project is included on an authorised UWE research register.

For research which is not deemed a clinical trial (i.e. not on UWE's clinical trials register) UWE's Professional Indemnity policy provides insurance cover for indemnity against legal liability for damages and claimant's costs and expenses arising out of any act, neglect, error or omission (i.e. wrongful advice given in good faith).

UWE's Employers Liability Insurance is in place to protect UWE's employees if they are harmed whilst engaged on UWE business, should UWE be held legally liable.

UWE's Public Liability insurance policy covers legal liability for third party personal injury, death, disease or illness to any person or loss or damage to third party property. Details of the Employers / Public and Professional Indemnity policy covers are attached.

13. DISSEMINIATION POLICY

8.1.1 Background IP. The LivDem approach was published as a manual in 2019, and background IP is owned by Richard Cheston and Ann Marshall and their relevant employing organisations (UWE Bristol for RC, Southern Health Partnership Trust for AM)

8.1.2 Foreground IP. The research data and research materials (e.g., digital recordings, transcripts) will be owned by the University of the West of England, Bristol (UWE). UWE Bristol will own these materials to ensure and enable their management of data archiving in line with their obligations as Sponsor to the research.

8.1.3 Study reporting. On completion of the study, the data will be analysed and tabulated, and a paper prepared for publication in a peer review journal. Data from the study will also be presented at academic conferences. The funder will be acknowledged in the study report. Participants will be informed of the findings through a newsletter summary of the final report.

8.2 *Authorship eligibility guidelines and any intended use of professional writers.* There is no intention to use professional writers to write the final study report or the published papers arising from this project. It is envisaged that all researchers and any other parties involved in the creation of that data will be involved in the authorship of at least one paper arising from the project. The International

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Committee of Medical Journal Editors criteria for defining authorship will be followed when submitting manuscripts to journals.

14. REFERENCES

Aguilar-Raab, C., Grevenstein, D., & Schweitzer, J. (2015). Measuring social relationships in different social systems: the construction and validation of the evaluation of social systems (EVOS) scale. *PLoS One*, *10*(7), e0133442.

Braun, V., & Clarke, V. (2021). Thematic analysis: A practical guide. SAGE.

Cheston, R., Gatting, L., Marshall, A., Spreadbury, J. H., & Coleman, P. (2017). Markers of assimilation of problematic experiences in dementia within the LivDem project. *Dementia*, *16*(4), 443–460. https://doi.org/10.1177/1471301215602473

Cheston, R., & Marshall, A. (2019). *The Living Well with Dementia Course*. Routledge.

Cheston, R. (2022). Dementia and Psychotherapy Reconsidered.

Cheston, R., Reilly, F., Topalova, N., Woodstoke, N.S., & Dodd, E. (2024) The LivDem 2023 survey: Facilitator views on benefits and the more active involvement of carers in the Living well with Dementia (LivDem) course, *The FPOP Bulletin*, 166 (April), 48-55, https://doi.org/10.53841/bpsfpop.2024.1.166.48

Finch, T. L., et al. (2016). NoMAD: implementation measure based on Normalization Process Theory. 2015. Available at: http://www.normalizationprocess.org/

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A.-W. ., & Michie, S. (2014). Better Reporting of interventions: Template for Intervention Description and Replication (TIDieR) Checklist and Guide. *BMJ*, *348*(348), g1687–g1687. https://doi.org/10.1136/bmj.g1687

Hsieh, S., Schubert, S., Hoon, C., Mioshi, E., & Hodges, J. R. (2013). Validation of the Addenbrooke's Cognitive Examination III in Frontotemporal Dementia and Alzheimer's Disease. *Dementia and Geriatric Cognitive Disorders*, *36*(3-4), 242–250. https://doi.org/10.1159/000351671

Kroenke, ., Spitzer, R.L., & Williams, J.B.W. (1999). Patient Health Questionnaire-9 (PHQ-9) [Database record]. APA PsycTests. https://doi.org/10.1037/t06165-000

Quinn, C., Morris, R. G., & Clare, L. (2018). Beliefs about Dementia: Development and validation of the Representations and Adjustment to Dementia Index (RADIX). *The American Journal of Geriatric Psychiatry, 26*(6), 680-689. doi:10.1016/j.jagp.2018.02.004

Raes, F., Pommier, E., Neff, K. D., & Van Gucht, D. (2011). Construction and factorial validation of a short form of the Self-Compassion Scale. *Clinical Psychology & Psychotherapy*, *18*(3), 250–255. https://doi.org/10.1002/cpp.702

Stoner, C. R., Orrell, M. & Spector, A. (2018). The Positive Psychology Outcome Measure (PPOM) for people with dementia: Psychometric properties and factor structure. *Archives of Gerontology and Geriatrics*, 76, 182-187.

Vernooij-Dassen, A. Felling, E. Brummelkamp, M. Dautzenberg, G. van den Bosch, R. Grol. A (1999) The short sense of competence questionnaire (SSCQ): measuring the caregiver's sense of competence. *J Am Geriatr Soc* , 47: 256-7.

Weiner, B. J., Lewis, C. C., Stanick, C., Powell, B. J., Dorsey, C. N., Clary, A. S., Boynton, M. H., & Halko, H. (2017). Psychometric assessment of three newly developed implementation outcome measures. *Implementation Science*, *12*(1). https://doi.org/10.1186/s13012-017-0635-3

Woodstoke, N. S., Winter, B., Dodd, E., & Cheston, R. (2024). "How can you think about losing your mind?": A reflexive thematic analysis of adapting the LivDem group intervention for couples and families living with dementia. *Dementia*. https://doi.org/10.1177/14713012241272805