Improving the Quality of Life for People Living with Dementia and Carers: The Design and Development of a Dementia Specific Online Narrative-Based Intervention with a Feasibility Study

Lived Experience Narratives in Dementia (LEND)
LEND Protocol Work Packages 1-3.

Version 1.0 22nd September 2025

Sponsor: Nottinghamshire Healthcare NHS Foundation Trust
Sponsor Number: 146158/2024
REC/ IRAS Ref: IRAS 351969
CPMS ID: 66864
ISRCTN number: (to be added once registered)
Chief Investigator: Prof. Martin Orrell
Funder: NIHR Programme Grants for Applied Research - NIHR206255

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HRA Protocol Compliance Declaration:

- **This protocol has regard for the HRA guidance**

SIGNATURE PAGE

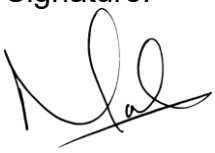
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:



Date:
22 September 2025

Name (please print): Mark Howells

Position: Head of Research and Evidence

Chief Investigator:

Signature:



Date:
22 September 2025

Name: (please print): Martin Orrell

.....

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LEND
Lived Experience
Narratives in Dementia

Nottinghamshire Healthcare NHS
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KEY STUDY CONTACTS

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Sponsor	Nottinghamshire Healthcare NHS Foundation Trust Highbury Hospital Highbury Road Nottingham NG6 9DR researchsponsor@nottshc.nhs.uk
Funder(s)	National Institute for Health and Care Research (NIHR) NIHR Central Commissioning Facility Grange House 15 Church Street, Twickenham TW1 3NL +44 (0) 208 8438056 programme.grants@nihr.ac.uk
Key Protocol Contributors	Chief Investigator (CI): The Chief Investigator (CI) provides overall leadership and responsibility for the LEND Programme, ensuring the study is conducted in accordance with ethical, regulatory, and sponsor requirements. The CI is accountable for the scientific integrity, governance, and delivery of all work packages, and serves as the primary point of contact for the sponsor and regulatory bodies. Programme Manager (PM): The Programme Manager oversees the day-to-day delivery of the LEND Programme, ensuring compliance

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	with regulatory, ethical, and sponsor requirements. They coordinate activities across work packages, manage timelines, support data governance, and serve as a central point of communication between the research team, sponsor, and collaborators. Programme Steering Committee (PSC): The PSC provides independent oversight of the LEND Programme, offering expert guidance to ensure the research meets its scientific, ethical, and strategic objectives. It monitors progress, advises on risks, and ensures accountability to the funder and sponsor. Programme Management Board (PMB): The PMB oversees the operational coordination of the LEND Programme, supporting the CI and PM in delivering milestones. It facilitates integration across work packages, advises and deliberates on resource management, and addresses emerging challenges. Data Monitoring and Ethics Committee (DMEC): The DMEC provides independent review of participant safety, data integrity, and ethical conduct throughout the programme. It monitors emerging findings and adverse events and advises on study modifications and amendments or whether continuation is warranted. Please note, the PSC will decide when to convene and the DMEC will report to the PSC. Lived Experience Advisory Panel (LEAP) Members: The LEAP comprises expert collaborators with lived experience of dementia, either personally or as carers. They provide critical insight to ensure the LEND Programme remains inclusive, relevant, and ethically grounded. LEAP members contribute to study design, data interpretation, and dissemination, ensuring the research reflects the priorities and values of those most affected. LEND Researchers: LEND researchers will organise, design and deliver LEAP groups in collaboration with LEAP group members. They will support recruitment, obtain informed consent, and conduct data collection and

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	analysis. They ensure ethical, inclusive engagement with participants and contribute to the delivery and refinement of the programme across all phases. LEND Administrators: LEND administrators provide logistical and operational support across the programme. They assist with scheduling, documentation, data management, and communication to ensure the smooth running of research activities.

STUDY SUMMARY

Study Title	Improving the quality of life for people living with dementia and their carers: The development and evaluation of a dementia specific online narrative-based intervention
Internal ref. no. (or short title)	Lived Experience Narratives in Dementia (LEND)
Study Design	Primary Research A user-centred design approach will be employed, utilizing mixed methods to explore and develop the LEND intervention and the corresponding methodology necessary for the feasibility randomized controlled trial design outlined in WP3. This process will incorporate semi-structured interviews, rating scales, focus groups (including input from a Lived Experiences Advisory Panel), choice-based experimental tasks, and the adaptation of existing tools to facilitate the creation of new ones, such as utilizing the INCRESE inventory to develop INCRESE-D.
Study Participants	People with Dementia Carers (as defined in protocol) Members of the Public
Planned Size of Sample (if applicable)	All participants are individual recruits (repeated measures are not used; dyads are not used). WP1.1 Online (WP1.1O) or Paper Copy (WP1.1P) questionnaire / survey (a minimum of n=300 per year, a minimum of n=1,500 continuously over 5 years) WP1.2 (Semi-structured interviews) People with Dementia (n=15) Carers (n=15)

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	WP1.3a&b (Narrative impact validation) People with Dementia (n=20) Carers (n=20) WP1.4 (Focus Group Work 4 x n=10) People with Dementia and Carers (mix) (n=40) WP1.5 (Discrete choice experiment) People with Dementia (n=10) Carers (n=10) Members of the Public (n=10) WP2.1 (INCRESE-D Inventory) LEAP members (N/A) Nottinghamshire's Dementia PPI Group, Queens Medical Centre (N/A) WP2.2 (The LEND Collection) N/A WP2.3 (The LEND Intervention Development) Phase 1: Development Workshops using LEAP members (N/A) Phase 2: First working version: People with Dementia (n=10) Carers (n=10) Phase 3: Refinement, 2nd working version People with Dementia (n=10) Carers (n=10) Phase 4: Refinement, 3rd working version People with Dementia (n=10) Carers (n=10) WP3.1 (feasibility n=60) People with Dementia (n=30) Carers (n=30) WP3.2 (long term impact of the Online LEND Intervention n=20) People with Dementia (n=10) Carers (n=10)
Follow up duration (if applicable)	WP3.1 Feasibility 6-month follow-up WP3.2 Long Term Impact 12-month follow up 18-month follow up
Planned Study Period	It is planned that the duration of the study period over the following 3 years are, with the exception of WP1.1, which will run over 5 years, approximately, as detailed below:

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	WP1: Development of Theory (ongoing - evolving) • WP1.1: Online (WP1.1O) or Paper Copy (WP1.1P) questionnaire / survey (over 5 years) • WP1.2: Semi-structures interviews (between months 4-9) • WP1.3a&b: Validation of narrative (between months 4-9) • WP1.4 Focus Group Work (between 10-12 months) & LEAP members (throughout the duration of the LEND programme). • WP1.5: Discrete choice experiment (between months 6-18) WP2: Development of the LEND intervention (between months 0-36) • WP2.1: (INCRESE-D Inventory) (between 6-20 months) • WP2.2: The LEND Collection: (this will be ongoing for the duration of the project) • WP2.3: The LEND Intervention Development) (between months 10-36) ○ Phase 1: Development: Workshops using LEAP members (between months 10-12) ○ Phase 2: First working version (between months 12-14) ○ Phase 3: Refinement, 2nd working version: (between months 14-18) ○ Phase 4: Refinement, 3rd working version (between months 18-36) WP3: An Explorative Feasibility Study • WP3.1: Feasibility Study: (between months 20-32) • WP3.2: Exploration of Long-term Impact (between months 30-36) (The entire LEND programme will be 5 years, including WP4 and WP5. WP4 and WP5 are not included in this protocol).
Research Question/Aim(s)	Work Package 1: Main Aims The aim of work package 1 is to develop LEND programme theory by using interviews and a discrete choice experiment study • Work Package 1: Activity 1: Online survey (WP1.1O) or paper copy (WP1.1P). The primary objective: is to develop an

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	understanding of how people living with dementia use social media over time. • Work Package 1: Activity 2: Interviews Primary objective: to develop a theoretical understanding of how narratives in dementia can benefit to people living with dementia. Secondary objectives: 1. To understand the barriers (for example, digital poverty) and facilitators (for example, user friendliness) when using technology with the research groups 2. To collect a set of recovery narratives to inform work on later phases of the LEND project, if participants choose to donate their narrative to the study. • Work Package 1: Activity 3a: Narrative Impact Validation Primary objective is to engage people living with a diagnosis of dementia and carers with online narratives. (See Study Design for Work Package 1: Activity 3a). • Work Package 1: Activity 3b: Narrative Rating Primary objective: To explore the categorisation of narratives based on a rating scale and feedback. • Work Package 1: Activity 4: Focus Group Work Primary objective: To Collaborate with The Centre for Ethnic Health Research, prioritising the inclusion of under-served groups of people with dementia and carers by ensuring adequate representation within the local community. • Work Package 1: Activity 5: Discrete Choice Experiment Primary objective: Using the Discrete Choice Experiment to explore the similarities and differences in the rating given to narratives from people with dementia, carers and the general public.

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	Work Package 2: Main Aims The aims of Work Package 2 are threefold: 1. To design, develop and use the INCRESE-D inventory for characterising lived experience dementia narratives 2. To produce The LEND Collection of narratives 3. To design, develop and produce the preliminary version of the LEND intervention (for refinement prior to Work Package 3). • Work Package 2: Activity 1: INCRESE-D Inventory Primary objective: Modify the existing version of the NEON 77-item INCRESE for dementia narrative categorisation (cf. Rennick-Egglestone et al., 2022). • Work Package 2: Activity 2: The LEND Collection Primary objective: Using the narrative of 500 plus existing lived experience narratives from people with dementia or carers, the LEND Collection will be developed, having been filtered for exclusion (for example, hate speech) and categorised using INCRESE-D. • Work Package 2: Activity 3: LEND Intervention Development Primary objective: To develop the LEND intervention and, using in-vivo testing, assess the usability of the LEND Intervention and acceptability of this testing. Work Package 3: Main Aims Overall, WP3.1 will determine whether the LEND Programme is suitable for a future larger-scale trial and explore the long-term impact of the Online LEND Intervention. • Work Package 3: Activity 1: Outcome Measures and the LEND Intervention Objective: To a) establish optimal approaches to recruitment, data collection and which data to collect and b) how LEND-P participants (people with dementia) and LEND-C (carers for people with dementia) engaged and interacted with the LEND intervention (e.g. assessment of use in

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	terms of time (frequency and length), and what narratives accessed). • Work Package 3: Activity 2: Exploration of Impact of the Online LEND Intervention Objective: To assess the long-term impact of the online LEND intervention for people with dementia and their carers from LEND-C and LEND-P groups using an interview approach.

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
National Institute for Health and Care Research Programme Grant for Applied Research NIHR Programme Grants NIHR Central Commissioning Facility (CCF) Grange House 15 Church Street Twickenham TW1 3NL	**£2,622,137.76 over 5 years** **The project figure covers the entire programme (including Work Package 4 and Work Package 5).** **The current protocol only covers Work Packages 1, 2 and 3 (not Work Package 4 or 5).**

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ROLE OF STUDY SPONSOR AND FUNDER

The funder is the National Institute for Health and Care Research (NIHR). This study is funded by the NIHR Programme Grants for Applied research (ref no NIHR206255). The study sponsor is Nottinghamshire Healthcare NHS Foundation Trust.

The Sponsor will provide guidance and direction regarding the conduct of all aspects of the study.

The sponsor and funder have no role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The sponsor or funder do not control the final decision regarding any of these aspects of the study.

The sponsor and funder reserve the right to discontinue the study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The sponsor and funder shall take advice from the Programme Steering Committee (PSC) as appropriate in making such decisions. Any decision to terminate the trial will be taken on the advice of the PSC, in conjunction with the sponsor and funder.

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ROLES AND RESPONSIBILITIES

The CI will be responsible for the overall conduct of the research working closely with the programme manager, who will oversee the day to day running of the programme team. Overall, management will be by monthly meetings of a Programme Management Board (PMB) chaired by the CI and will comprise the investigators, the programme manager, two LEAP members, researchers and a sponsor representative. Each work package will have 1-2 nominated leads. They will convene groups of individuals working on their work package and meet regularly as required, reporting to the PMB. This model has worked well in the NIHR PrAISED programme. By choosing and measuring early indicators of success or early identification of problems, a good risk identification and management procedure and having an effective and accountable management system, we will anticipate and avoid or mitigate problems. The programme will be overseen by a Programme Steering Committee (PSC). Two members of the LEAP and two further independent members (including a statistician and clinician), and a sponsor representative. The PSC will decide when to convene a Data Monitoring and Ethics Committee (DMEC), which will report to the PSC. The DMEC will be responsible for safeguarding the interests of the trial participants, assessing the safety and efficacy of the interventions during the trial, reviewing external evidence with an impact on risk/benefit and for monitoring the overall conduct of the LEND programme.

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Study Steering Groups

1. **Programme Steering Committee (PSC)**
   PSC Independent Chair: Professor Claudia Cooper, Lead for Centre for Psychiatry and Mental Health QMUL. The PSC will meet quarterly or more when required. The role of the Steering Committee is to provide overall supervision for the LEND programme on behalf of the Sponsor and Funder and to ensure that it is conducted to the rigorous standards set out in HRA.

2. **Programme Management Board (PMB)**
   Chaired by: CI. Membership includes co-investigators, the programme manager, two representatives from the Lived Experience Advisory Panel (LEAP), site principal investigators, research staff, and a representative of the Sponsor. The PMB holds operational responsibility for the delivery of the programme, facilitating communication between all sites and stakeholder groups and ensuring the study progresses in accordance with Good Clinical Practice and contractual obligations. Safety reporting and recruitment would be reviewed at each meeting.

3. **Established Patient and Public Involvement (PPI) Group**
   This group, focused on dementia, frailty, and palliative care, is facilitated by the School of Health Sciences at the University of Nottingham. It will be formally engaged biannually to review study materials and advise on recruitment, dissemination, and inclusivity. The first scheduled consultation took place on 20th September 2024.

4. **Lived Experience Advisory Panel (LEAP)**
   Comprising at approximately ten individuals with lived experience of dementia (either living with the condition or as carers), this panel ensures that the study is informed by experiential knowledge. The LEAP will meet four times annually. It receives facilitation support from the Centre for Ethnic Health Research and LGBT+ advocacy organisations to promote inclusivity and ensure representation of diverse voices.

5. **Community and Third Sector Engagement**
   The programme will maintain ongoing collaboration with community organisations, voluntary sector bodies, and charities that support individuals living with dementia and their carer's. These partners will contribute to dissemination, co-production of study materials, and community outreach, as evidenced through formal letters of support.

Please note, wherever possible, minutes will be made available and filed accordingly for all meetings, ensuring information transparency and good working practice. All members of meetings have the right to use meeting minutes to reflect on what has been learned through the study, including through publishing their reflections.

In addition to the responsibilities and roles outlined above, the sponsor will issue a green light when appropriate in keeping with the Standard Operating Procedures outlined by

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Nottinghamshire Healthcare NHS Foundation Trust. The sponsor will also be invited to all Steering Group Meetings and be made fully aware of all activities involved with the LEND programme.

PROTOCOL CONTRIBUTORS:
Professor Martin Orrell (Chief Investigator and Programme Lead & WP3 Lead)
Dr Linda O'Raw (LEND Programme Manager)
Dr Orri McDermott: PPI and EDI Lead, qualitative research
Professor Katie Featherstone (WP1 Lead)
Dr Fiona Ng (WP1 Lead and Training)
Dr Stefan Rennick-Egglestone (WP2 Co-Lead)
Professor Praminda Caleb-Solly (WP2 Co-Lead)
Professor George Christopher Fox (WP3 Lead)
Dr Tom Lodge (LEND Research Fellow)
Briony Harden (LEND Research Fellow)

Co-Applicants and Leads on WP1
Dr Fiona Ng: University of Nottingham, ORCID iD: 0000-0002-8656-8830; Web Page. ORCID Web Link https://orcid.org/0000-0002-8656-8830; Expertise in mental health, behaviour change, qualitative methods, developing programme theory. Lead of programme theory work package 1. Named Point of Contact for Training with success in 3 fellowship awards.

Professor Katie Featherstone: The University of West London, ORCID ID: 0000-0003-4999-8425; Web: https://www.uwl.ac.uk/staff/katiefeatherstone; Senior academic nurse with expertise in quality of life in dementia and large studies and complex interventions for people with dementia, work with family carers.

Co-Applicants and Leads on WP2
Professor Praminda Caleb-Solly: University of Nottingham, ORCID iD 0000-0001-8821-0464; Web Page. ORCID Web Link https://orcid.org/0000-0001-8821-0464; Computer science, machine learning, technologies to assist people with age related disabilities and long-term conditions. Joint lead of LEND Intervention work package 2.

Dr Stefan Rennick-Egglestone: University of Nottingham, ORCID iD 0000-0003-4187-011X; Web Page. https://scholar.google.com/citations?user=-0hCAhQWP1.4AJ; ORCID Web Link https://orcid.org/0000-0003-4187-011X; Experience of digital intervention development, the use of lived experience narratives in health research and practice, trial management, systematic reviewing, human computer interaction research, research data management practice, lived experience in dementia care.

Co-Applicants and Leads on WP3
Professor George Christopher Fox: University of Exeter, ORCID iD 0000-0001-9480-5704, Web Page;

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https://medicine.exeter.ac.uk/people/profile/index.php?web_id=Christopher_Fox+https://people.uea.ac.uk/chris_fox; ORCID Web Link: https://orcid.org/0000-0001-9480-5704

Professor Martin Orrell: Director of the Institute of Mental Health, University of Nottingham. The nature of this research demands a high level of interaction with people with dementia and their carers. Therefore, the protocol has been designed in such a way to maximise on advice provided to us from participants with lived experience of living with dementia.

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KEY WORDS: Dementia, Carers, Narrative, Quality of Life, Story-Telling.

List of Abbreviations

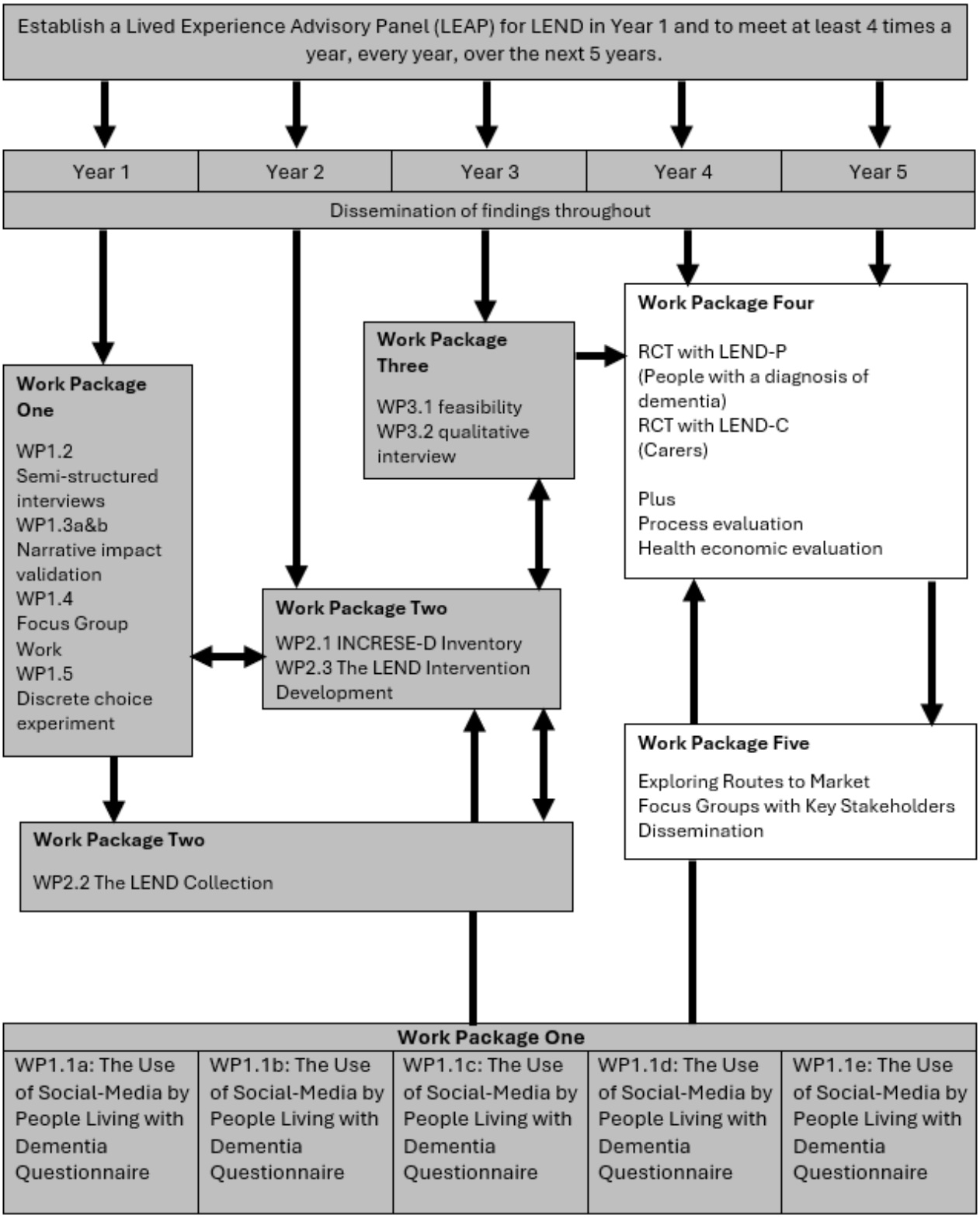
AHS	Adult Hope Scale (measure)
APR	Annual Progress Report
CEHR	The Centre for Ethnic Health Research
CSES	Caregiver Self-Efficacy Scale (measure)
CSRI	Client Service Receipt Inventory (measure)
DCE	Discrete Choice Experiments
EID-Q	Engagement and Independence in Dementia Questionnaire (measure)
EQ-5D-5L	EuroQol 5-Dimension 5-Level (carer impact assessment) (measure)
ESRC	Economic and Social Research Council (UKRI)
GCP	Good Clinical Practice
GSES	General Self-Efficacy Scale (measure)
HRA	Health Research Authority
ICECAP-O	ICEpop CAPability measure for Older people (measure)
INCRESE	Inventory of Characteristics of Recovery Stories
INCRESE-D	Inventory of Characteristics of Recovery Stories for Dementia
IT	Information Technology
LEAP	Lived Experience Advisory Panel
LEND	Lived Experience Narratives in Dementia
LEND-C	Lived Experience Narrative in Dementia – Carer group
LEND-P	Lived Experience Narrative in Dementia - People with Dementia group
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, Asexual, Plus other gender identifications
MHA	Mental Health Act
MRC	Medical Research Council
MRS	Marginal Rate Substitution
NEON	Narratives Experiences Online
NHS	National Health Service

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NIHR	National Institute for Health and Care Research
NICE	National Institute for Health and Care Excellent
NPI	Neuropsychiatric Inventory
PPI	Patient and Public Involvement
PwD	People with Dementia
QoL-AD	Quality of Life in Alzheimer's Disease (Measure)
QoL	Quality of Life
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RSES	Rosenberg Self-Esteem Scale (Brief version) (measure)
TAU	Treatment As Usual
SWEMWBS	Short Warwick Edinburgh Mental Wellbeing Scale (measure)
WP	Work Package

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Figure 1: LEND Study Flow Diagram



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STUDY PROTOCOL
Improving quality of life for people living with dementia and their care partners: the development, intervention and evaluation of a dementia specific narrative-based intervention: LEND (lived experience narratives in dementia)

1. BACKGROUND

This protocol document is for work on “Improving the quality of life for people living with dementia and their care partners: the development, intervention and evaluation of a dementia specific narrative-based intervention” (NIHR206255), an NIHR Programme Grant for Applied Research, referred to as LEND throughout this document. LEND has been funded as a five-year study.

A dementia diagnosis can adversely affect an individual's identity, including self-esteem, optimism, self-efficacy, social engagement, self-stigma, positive affect, and relationship quality (Low et al., 2018; Bunn et al., 2012), thereby impairing quality of life (QoL) and the ability to live well (Bunn et al., 2012; Lamont et al., 2020; Wolverson et al., 2016; Kitwood et al., 1997; Dos Santos et al., 2018). Self-stigma post-diagnosis is linked to reduced empowerment and hope (Bhatt et al., 2021), contributing to excess disability (the gap between potential and actual function) (Specter & Orrell, 2021), which increases care needs and associated costs. Individuals with dementia and their caregivers require support, psychological resources, and a sense of connectedness (McCabe et al., 2016; Parkinson et al., 2017) to comprehend their symptoms and devise management strategies. This study addresses the urgent need identified in the '2023 WHO Report on Rehabilitation Interventions', recommending services provide relevant information to people living with dementia and their family carers, tailored to their circumstances and disease stage (Lee, McDermott & Orrell, 2023). The Lived Experience Narratives in Dementia (LEND) intervention will offer tailored narratives, enhancing access to personal stories for a diverse range of disadvantaged and minority groups.

The term 'recovery' can be interpreted in two ways (Handley et al., 2024). The conventional clinical and lay definition implies curing a disorder and/or returning to previous levels of functioning. The second definition, used in LEND, pertains to the personal recovery process, involving changes in attitudes, hope, values, and goals to live better with dementia symptoms, acknowledging that there is no cure and the overall trajectory is one of decline. These two papers (Daley et al., 2013; Daley et al., 2020) informed the national briefing document 'Continuing to be me' from ImROC (Perkins et al., 2026), which discusses 'Recovering a life with a Diagnosis of Dementia'. Key aspects identified by individuals with dementia include maintaining a positive outlook, self-care, social, physical, and mental activity, interest in surroundings, peer support, and coping strategies for frustration and memory problems. LEND could support several of these aspects.

Over 850,000 individuals in the UK live with dementia, supported by 700,000 informal carers. The annual cost of dementia to the UK economy is £34.7 billion, with healthcare accounting for 14% (£4.9 billion), publicly and privately funded social care for 45% (£15.7 billion), and

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unpaid care for 40% (£13.9 billion). Enhancing post-diagnostic support and wellbeing through technology is a priority for the NHS, service users, and globally (Shah et al., 2016; NHS England, 2016; James Lind Alliance, 2021; Alzheimer's Society, 2018; NICE, 2018), particularly for under-served communities with limited research inclusion, high healthcare burden, and difficulties in accessing and engaging with healthcare (Whitham et al., 2023). The NICE reference case for economic evaluation recommends an NHS and societal perspective to consider costs and benefits to informal carers, which is crucial in dementia due to the high proportion of carer-attributable costs (NICE, 2013).

Sharing lived experience narratives (Clifford et al., 2016; Sommer, 2013) among peers can enhance QoL and has proven beneficial for individuals with long-term conditions, including mental health (Slade et al., 2021), chronic pain (Ressler et al., 2012), and cancer (Chou et al., 2011). Platforms like healthtalk.org demonstrate ongoing demand for health-related narratives across various conditions. The NIHR-funded Narrative Experiences Online (NEON) program includes three nationwide trials in England (n=1,830) of a web-based narrative intervention to improve QoL in individuals with mental health issues and informal carers (Sommer, 2013), utilizing a filtering system and machine learning for narrative retrieval.

The NEON-O Trial, with 1,023 participants with non-psychosis mental health issues, showed improvement in quality of life ($p = 0.041$) and meaning in life ($p = 0.014$). The intervention yielded a mean quality-adjusted life-year gain of 0.0142 per user over one-year, reduced NHS costs by £170 per user, and was cost-effective per NICE standards. Low-cost, accessible lived experience narratives can empower individuals with dementia (Clare et al., 2022). Carers and those with dementia value learning from similar experiences (Bamford et al., 2021; Sbaffi & Hargreaves, 2022). This study adapts narrative principles for i) early-stage dementia patients and ii) carers of individuals at any dementia stage.

An important focus of our approach is to ensure people can access narratives that reflect the inequalities and diversity of experiences of living with dementia or being a carer. We will include strategies to engage people identifying as:
i) Black and South Asian ethnicities, who may have higher dementia prevalence but reduced awareness (Bothongo et al., 2022). In this context, "reduced awareness" indicates lower levels of understanding about dementia symptoms, progression, and available support within certain communities. This may result from cultural perceptions, limited access to tailored information, and language barriers that affect information dissemination and service utilization.
The knowledge of dementia and available services, along with experiences of racism, stigma, and culturally preferred coping strategies, shape how individuals from different backgrounds understand and manage dementia (Bunn et al., 2012; Giebel et al., 2014).
ii) LGBT+ where stigma about sexuality impedes help seeking behaviour, increases fear of discrimination, and discourages disclosure of identity which means support is often from friends rather than family (Di Lorito et al., 2021). People with young onset and/or rarer dementias are also likely to find access to relevant narratives particularly helpful.

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People with dementia and carers can access and use the LEND web-based intervention on their home devices, with support from family or others if needed. Eighty percent of households with an adult aged 65+ have an internet connection, and internet use among over-75s doubled to 54% from 2013 to 2020 (ONS, 2020).

The internet is the most used and desired information source for people with dementia and carers (Soong et al., 2021). COVID-19 restrictions have accelerated older people's use of technology. Established design guidelines exist for web-based resources for people with dementia, with evidence of use (Suijkerbuijk et al., 2019; Niedderer et al., 2020).
The anticipated outputs, outcomes, benefits, and impact of the proposed research is that the LEND programme theory developed in WP1 will underpin how the LEND Intervention will impact the person with dementia and carers QoL. The LEND programme theory will be developed by the research team in coproduction with the LEND lived experience advisory panel (LEAP) interviews with people with dementia and carers and a discrete choice experiment to understand the decisions participants make about the relevance of narratives. This work will benefit people with dementia and carers by ensuring the LEND Intervention includes all necessary components to achieve the expected outcomes.

The LEND Intervention is developed in WP2, working in co-production with the LEAP we will develop a categorisation inventory, collect lived experience narratives, and curate the collection using the inventory, and design and develop the LEND web application. We will ensure the LEND end-user website within the web application is of benefit to people with dementia and carers through extensive usability testing. The feasibility of a definitive trial will be established in WP3, this will benefit people with dementia and carers by ensuring that trial processes work for participants and are not overly burdensome. Ethical amendments will be made periodically.

Ethics approval for WP4 and WP5 will be sought at a later stage. The effectiveness in improving quality of life (QoL) at six months and the cost-effectiveness of the LEND Intervention will be evaluated in WP4 and WP5 through two randomized controlled trials (RCTs): i) LEND-P for individuals with dementia and ii) LEND-C for carers of people with dementia. All participant-facing materials will be co-produced with the LEAP. Establishing effectiveness is crucial before implementation, and an implementation plan will be developed in WP5 to ensure impact.

2. RATIONALE

The primary outcome of LEND is to enhance QoL and wellbeing for people with dementia and carers by developing the LEND intervention, an online tool that utilises the narratives of people with dementia and carers to support others. This will be demonstrated by definitive evidence from the LEND-P and LEND-C trials (feasibility in WP3, trials in WP4), supporting low-cost implementation into policy and practice (guided by WP5).

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3. THEORETICAL FRAMEWORK

The innovation of the LEND program lies in adapting a mental health concept (asynchronous peer support through recorded recovery narratives) to dementia, creating a novel intervention based on program theory to improve QoL for people with dementia and carers. Our website design research will generate new insights into best practice web applications for people with dementia, including the use of machine learning to help participants find suitable narratives. Our health economics work package is innovative in considering three perspectives: NHS, societal, and household. We also include a discrete choice experiment (DCE) to identify the most valued attributes of the LEND online therapeutic platform (Ryan et al., 2007).
The LEND Intervention will be available immediately upon program completion, with additional benefits expected over the next 3-5 years through widespread implementation. The LEND Intervention will be widely disseminated via NHS services, including Memory Assessment Services, community mental health teams, the Alzheimer's Society, community groups, and networks supporting the research during the program.

4. RESEARCH QUESTIONS/AIMS

The overall aim is to improve quality of life for i) people with dementia, and ii) carers by developing and evaluating the online LEND Intervention.

4.1.0. Aims and Objectives

4.1.1. Work Package 1: Main Aims

The aim of work package 1 is to develop LEND programme theory by analysing interview data, providing impact validation of narratives, rating narratives and the completion of a discrete choice experiment study.

4.1.2. Work Package 1: Activity 1: Online (WP1.1O) or Paper Copy (WP1.1P) survey

Primary objective: The Work Package 1: Activity 1 is to develop a theoretical understanding of how people living with dementia use social media technology.

4.1.3. Work Package 1: Activity 2: Interview

Primary objective: The Work Package 1: Activity 2 is to develop a theoretical understanding of how narratives in dementia can benefit to people living with dementia.

4.1.4. Secondary Objectives:

1) To understand the barriers (for example, digital poverty) and facilitators (for example, user friendliness) when using technology with people with dementia and carers of people with dementia.
2) To collect a set of recovery narratives to inform work on later phases of the LEND project, if participants choose to donate their narrative to the study.

4.1.5. Work Package 1: Activity 3a: Narrative Impact Validation

Primary objective: To engage with people living with a diagnosis of dementia and carers and give them up to 5 lived experience narratives from a pool of 30 narratives, including those

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from diverse and under-represented groups, from existing collections (see Study Design for 6.1.2 Work Package 1: Activity 3a).

4.1.6. Work Package 1: Activity 3b: Narrative Rating
Primary objective: The aim of Work Package 1: Activity 3b is explore the categorisation of narratives based on a rating scale and feedback.

4.1.7. Work Package 1: Activity 4: Focus Group Work
Primary objective: To Collaborate with The Centre for Ethnic Health Research (CEHR), prioritising the inclusion of under-served groups of people with dementia and carers by ensuring adequate representation within the local community.

4.1.8. Work Package 1: Activity 5: Discrete Choice Experiment
Primary objective: Using the Discrete Choice Experiment to explore the similarities and differences in the rating given to narratives from people with dementia, carers and the general public.

4.2.0. Work Package 2: Main Aims
The aims of Work Package 2 are threefold:

1) To design, develop and use the INCRESE-D inventory for characterising lived experience dementia narratives
2) To produce The LEND Collection of narratives
3) To design, develop and produce the preliminary version of the LEND Portal and the Online LEND intervention (for refinement prior to Work Package 3).

4.2.1. Work Package 2: Activity 1: INCRESE-D Inventory
Primary objective: Modify the version of the NEON 77-item INCRESE for dementia narrative categorisation (cf. Rennick-Egglestone et al., 2022).

4.2.2. Work Package 2: Activity 2: The LEND Collection
Primary objective: Using the narrative of 500 plus lived experience narratives from people with dementia or carers, the LEND Collection will be developed, having been filtered for exclusion (for example, hate speech) and categorised using INCRESE-D.

4.2.3. Work Package 2: Activity 3: LEND Intervention Development
Primary objective: To develop the LEND Portal and the Online LEND intervention and, using in-vivo testing, assess the usability of the LEND Intervention and acceptability of this testing.

4.3.0. Work Package 3: Activity 1: Feasibility: The Online LEND Intervention
Objective: WP3.1 aims to a) establish optimal approaches to recruitment and data collection for the standardised quantitative outcome measures (online via the LEND Portal), as well as the identification of which outcome measures are best to use. Additional, b) LEND will assess the acceptability and suitability of the LEND Intervention to LEND-P participants (people with dementia) and LEND-C (carers for people with dementia) using length of interaction (time) of

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LEND-P and LEND-C participants using the online LEND intervention and which narratives were accessed.

4.3.1. Work Package 3: Activity 2: Exploration of Long-term impact
The aim is to assess the long-term impact of the Online LEND Intervention on LEND-P and LEND-C groups that took part in WP3.1.

4.4.0. Overriding Aim and Outcome of the LEND Programme
Aim: Improve the quality of life for i) people with dementia and ii) carers by developing and evaluating the Online LEND Intervention that uses lived experience narratives.

5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

5.1.0. Capacity and Consent
All participants will be required to provide written informed consent prior to enrolment in the study (see Section **7.3.1. Informed Consent**). In accordance with the Mental Capacity Act 2005, the UK Policy Framework for Health and Social Care Research, and the principles outlined in the Declaration of Helsinki, capacity to consent will be viewed as a dynamic and situation-specific attribute.

For participants living with dementia, capacity will be assessed on an ongoing basis to ensure individuals continue to understand the nature, purpose, and requirements of the study, and that their willingness to participate is maintained throughout. This includes assessing capacity by digital means as discussed in **5.4.0. Work Package 3: Activity 1: Feasibility of the Online LEND Intervention**.

Researchers involved in the recruitment and follow-up of individuals with dementia will have prior experience in dementia research and will undertake specific training on ethical engagement with individuals who may lack capacity. All researchers will also hold a valid Good Clinical Practice (GCP) certificate to ensure compliance with ethical and legal standards.

Should a participant be assessed as having lost the capacity to provide informed consent during the course of the study, they will be withdrawn from further active participation. However, in line with ethical and regulatory guidance, including the Declaration of Helsinki, data collected prior to the loss of capacity will be retained for analysis and continued use, as approved during the original consent process. This practice respects participants' autonomy at the time of consent and ensures that their contributions to the research are preserved for the benefit of others.

This approach maintains the ethical integrity of the study and ensures that the rights, dignity, and welfare of all participants are prioritised throughout.

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5.1.1. Methods

5.1.2. Work Package 1: Activity 1: Online (WP1.1O) or Paper Copy (WP1.1P) Survey
This is a mixed methods exploratory survey that will employ an online survey design using MS Forms, with both closed and open-ended questions to gather quantitative and qualitative data on the views and experiences of people with dementia and their carers on creating and engaging with online peer narratives on social media platforms, identifying which technological features are important to them.

Qualitative surveys are particularly suitable when exploring people's views, opinions and lived experiences. Open questions encourage people to respond in their own words and leaves freedom to share what they think is important (Braun, Clarke & Gray, 2017). However, through Patient and Public Involvement (PPI) consultations with people with dementia in previous survey development (Gerritzen, McDermott & Orrell, 2023), we found that it can be difficult for people with dementia to respond to open questions only. They suggested that including multiple-choice questions as well can guide people and prompt ideas for the open questions, suggesting that a mixed-methods approach would be most appropriate for this survey. The questionnaire style survey will be available online continuous for the duration of the LEND programme. To promote accessibility and inclusivity, a paper-based version of the questionnaire style survey will also be made available upon request. This option ensures participation is not limited by digital access, literacy, or preference, in line with the NIHR's commitment to reducing health research inequalities.

The online survey will be administered using Microsoft Forms. The landing page will contain key information drawn from the Participant Information Sheet (PIS), informing participants that no personally identifiable information is required. Survey questions will be carefully worded to minimise the risk of inadvertent disclosure of personal data.

Participants will be advised that by submitting the survey, they are providing consent for their responses to be used in this research, including their demographic details. As survey responses will be anonymous, it will be made clear that, due to the nature of the survey, it will not be possible to withdraw their responses once the 'submit' button has been clicked as we will be unable to identify the data as theirs.

To proceed to the survey questions, participants will be required to click a 'continue' button at the bottom of the landing page, confirming their understanding. To allow individuals to express interest in taking part in future phases of the research without compromising survey anonymity, a second Microsoft Forms link will be made available upon completion of the survey. This separate form will include an information page explaining how personal data will be collected, stored, and processed. Individuals will be asked to confirm their understanding and consent by ticking a series of statements before being presented with a form to enter their name and contact details.

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Expressions of interest submitted via this second form will be directed to a secure, generic email account managed by the Sponsor. Access to this account will be limited to authorised members of the research team. A member of the team will manually transfer contact details into a secure spreadsheet stored within the Sponsor's protected IT environment. This spreadsheet will include multiple tabs to record referral sources, enabling evaluation of recruitment strategies (e.g., one tab for expressions of interest via Microsoft Forms). Once the contact information has been securely transferred to a file located in the Sponsor's protected IT environment, participant details will be permanently deleted from the Microsoft Forms account.

Survey responses will be downloaded by a member of the research team into a password-protected Excel file. This dataset will contain no identifiable information but will contain demographic data. It will be stored securely within the Sponsor's IT environment. Access will be restricted to authorised research personnel. Anonymised survey data will be shared periodically with research partners and collaborators at the University of Nottingham and Bournemouth University, dependent on the purpose of analysis.

To ensure access to the survey and the option to register an interest in participating in later phases of the research project isn't limited only to respondents with access to the digital survey, a paper version of the survey will also be made available. Paper copies of the PIS and survey questions will be issued to potential participants via post or by hand (for example, provided by recruitment partners in Dementia Cafes). A separate form will be included to allow respondents to express their interest in participating in later phases of the project by sharing their name and contact details. All paper documents will be accompanied by two pre-addressed envelopes to allow participants the option of posting back their survey responses and the contact details separately, to the research team, thereby preserving the anonymity style of paper survey responses. On receipt of a paper survey questionnaire, a member of the research team will scan the document into a secure folder within the Sponsor's IT environment, access to which will be restricted to the research team only, before manually adding the responses to the same spreadsheet used to collect responses from the digital survey. Once the responses have been scanned, the paper document will be securely destroyed. On receipt of contact details in paper form, an authorised member of the research team will add the information to the same spreadsheet used to collate contact details submitted via MS Forms. The paper document will be securely destroyed once the contact details have been added to the spreadsheet.

If participants elect to return paper documents in person, directly to a member of the research team (for example, at an event), the documents will be securely transported to the Institute of Mental Health (IMH) in a lockable wallet and processed (as above) as soon as is reasonably practicable.

To recruit participants, LEND Posters, containing contact details for the research team, will be put into GP surgery waiting rooms, providing an overriding aim and a QR code. The QR code will link straight to participant information, digital consent questions and eventually, to the

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online survey. For individuals that may not have access to technology, a paper version will be available upon request.

Participants will be explicitly informed, both in the Participant Information Sheet (PIS) and at the end of the questionnaire style survey, that providing personal contact information is entirely voluntary, will not affect their current participation, and that their survey responses, including their demographic data (which will be collected for the purposes of subgroup analysis) will remain anonymous.

The consent process aligns with the principles of the UK GDPR, ensuring lawful basis for contact regarding future research, and supports the ethical obligation to respect participants' autonomy, as set out in the Declaration of Helsinki.

Survey responses and contact details will be stored in separate password protected files in a secure location within the Sponsor's IT environment, separate from all other data, in accordance with sponsor's data protection policies and SOPs. Restricted access will be granted only by way of the delegation log for purposes outlined in this protocol. Hence, LEND researchers will ensure that individuals understand the distinction between participating in the current study and opting into future contact.

For all participants, capacity to consent to future work packages in the LEND programme will be assessed independently of their capacity to complete the questionnaire style survey, as per the Mental Capacity Act 2005, recognising that different decisions may require different thresholds of understanding, and that consent is continuous. This process ensures compliance with current UK legal and ethical standards, safeguards participants' privacy, and facilitates ongoing public involvement in dementia research in a respectful and ethically appropriate manner.

Corresponding documents: WP1.1O Participant Information, WP1.1O Consent, WP1.1O Online Survey, WP1.1P Paper Survey, WP1.1P Participant Information Sheet, WP1.1P Consent Form.

5.2.0. Work Package 1: Activity 2: Interview

This work package involves conducting up to 30 semi-structured interviews to validate version 1 of the LEND programme theory. The interviews will explore how individuals living with dementia (n=15) and carers (n=15) are impacted by dementia narratives and demographic data will alsobe collected to ensure the LEND programme can track diversity within the sample and to support appropriate contextualisation of the findings.

Participants will be identified through a combination of established networks, including Dementia Café groups, community organisations, social prescribers, carer support groups and partner third-sector organisations (such as Alzheimer's Society UK). Public-facing advertisements and PPI channels will also be used to promote the study. To enhance inclusivity and equality of access, recruitment will be targeted to ensure representation across

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under-served communities, supported by the Centre for Ethnic Health Research and relevant community-based organisations, (please see **7.3.0. Recruitment Strategy**).

Initial expressions of interest will be followed up by a member of the research team who will provide the Participant Information Sheet (PIS) and Consent Form in advance, either by post or electronically, depending on participant preference. Where appropriate, carers may assist in reading or discussing study materials, but the autonomy and understanding of the person with dementia will be prioritised at all times. If a completed consent form hasn't been returned within six weeks of the date of issue, the individual's name and contact details will be deleted from the contact details spreadsheet.

On receipt of a completed consent form, each participant will be allocated a unique ID number (UID) by the research team. This will allow data shared during the interviews to be linked to any additional information shared by the participants during the follow up calls. A spreadsheet including the UIDs and participants' personal data will be stored securely within the sponsor's IT environment and access to it will be restricted to the Programme Manager and CI only. The key will be stored separately from any pseudonymised data.

The key to allow reidentification of participants will be destroyed once the follow-up call has been completed. This will render the interview transcripts and any additional data collected during the follow-up call anonymous.

In accordance with the Mental Capacity Act 2005, the UK Policy Framework for Health and Social Care Research, HRA guidance, the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and the ethical principles outlined in the Declaration of Helsinki, all participants will be provided with full information about the study, including its purpose, what participation entails, the voluntary nature of involvement, the right to withdraw, and how data will be used, stored, and shared. Sufficient time will be given for participants to consider the information and ask questions. Written consent will be obtained prior to the interview, either in person or electronically. Consent will be reaffirmed immediately prior to commencing the interview to ensure participants remain willing and able to continue.

The interview will either be in-person or via Teams on a secure laptop, depending on participant preference and accessibility needs. They will be recorded via Teams or using an Olympus DS9000 recording device approved by the sponsor for this purpose and in accordance with Nottinghamshire Healthcare NHS Foundation Trust SOPs.

Interviews recorded via MS Teams will be saved within the researcher's secure NHS Teams account and will be transcribed using the 'speech to text' function. MS Teams recordings will be securely destroyed once the transcripts have been checked for accuracy and any directly identifiable information has been removed; the participants' UIDs will be included in the transcripts to allow data linkage (if applicable) after the follow-up call. The transcripts will also be stored securely within the sponsor's IT environment and access to them will be restricted to the research team only. Recordings made using a recording device will be uploaded to a

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secure area within the sponsor's IT environment and access to them will be restricted to the research team only. Recordings will be deleted from the device post-successful upload. Transcripts will be produced manually by an authorised member of the research team. Transcripts won't include any directly identifiable data however, the UIDs allocated on receipt of the consent forms will be included. The audio recordings will be securely destroyed once the transcripts have been checked for accuracy. The transcripts will be stored in a secure area of the sponsor's IT environment separately from the pseudo key, access to which will be restricted to the research team only.

Capacity to provide informed consent will be assessed on a case-by-case basis by trained researchers, recognising that capacity is ongoing and is both decision and time specific. Researchers will be experienced in dementia research and will have completed training in Good Clinical Practice (GCP), with specific preparation for working ethically and sensitively with individuals who live with dementia. If a participant is deemed to lack capacity at the time of consent, they will be excluded from the LEND programme.

During the interview, participants will be asked to provide some demographic information. They will then be introduced to a selection of peer-led narratives, shared either physically, via screen share, or through postal delivery in advance. Participants will be asked not to engage with the narratives prior to the interview, where possible, to allow for real-time responses. The researcher will guide the discussion around the perceived relevance, emotional impact, and resonance of the narratives, particularly in the context of lived experiences. Following the interview, participants will be offered a structured debrief to support emotional wellbeing and provide space for initial reflections.

Recognising that narrative impact may unfold over time, participants will also be offered a follow-up telephone call approximately one week later, providing an opportunity to share any additional insights or delayed emotional responses. If there is no answer, then other contact opportunities will be tried (such as email). To respect the right to privacy, follow-up phone calls will be done no more frequently than once a week and for no longer than six weeks. Follow-up calls won't be recorded however, notes, which will include the UIDs, will be made.

When a follow-up call has been answered, as outlined above, a vignette will be completed by the researcher to ensure reflective consideration has been given to the research delivery process. Further, this phased, reflexive engagement supports ethical best practice in qualitative research and promotes respectful, meaningful participation. It acknowledges that individuals living with dementia and their carers may require time to process sensitive material and ensures their voices are captured with integrity and care. Personal names will not be used on the vignette, but the UIDs will be included. This will allow any additional data collected during the follow-up call to be linked to transcripts from the interviews. Collectively, this will enable researchers to explore the data using a more informed understanding of under-served groups. The key which includes the participants' UIDs and their personal data

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will be destroyed once the vignettes and transcripts have been linked. This will render the vignettes and transcripts anonymous.

Anonymous transcripts and vignettes will be shared with the University of Nottingham and University of West London, for the purposes of analysis, including thematic analysis using NVivo (Braun & Clarke, 2006; 2023) and subgroup analysis. No directly identifiable personal data will be Processed during the analysis. Analysis will be carried out alongside, and informed by, interviews completed during later phases of the research project, using the principle of constant comparison.

There will be double coding for at least 10% of transcripts with regular discussion between analysts to develop the final codebook and the use of multiple analysts from inter-disciplinary and multi-professional backgrounds, including LEAP co-researchers, following the best practice framework for Patient and Public Involvement (PPI) in collaborative data analysis of qualitative mental health research: methodology development and refinement (Braun & Clarke, 2006; 2023).

Corresponding documents: LEND: Work Package 1: Activity 2 Interview Guide will be available to LEND researchers to prompt participants; WP1.2 Participant Information Sheets; WP1.2 Consent Form.

5.2.1. Work Package 1: Activity 3a & 3b: Narrative Impact Validation & Narrative Rating
This component of the LEND programme aims to explore the emotional and cognitive impact of lived experience narratives on people living with dementia and their carers. A total of 40 participants (people with dementia n=20; carers n=20) will be invited to engage with up to five randomly selected narratives drawn from a larger pool of 30 pre-curated lived experience accounts. These narratives will be selected from reputable existing collections (e.g., Alzheimer's Society, Age UK, etc) and curated for relevance, accessibility, and diversity of representation.

Participants will be recruited through a network of established partners, including Dementia Café groups, carer organisations, social prescribing networks, memory services, third-sector organisations such as Alzheimer's Society UK, and community groups known to the Centre for Ethnic Health Research. Public-facing recruitment strategies will include ethically approved advertisements and engagement through patient and public involvement (PPI) groups. Targeted outreach will support the inclusion of under-represented communities, such as ethnic minority groups, LGBTQIA+ populations, and individuals with Young Onset Dementia (YOD), in accordance with Equality, Diversity, and Inclusion (EDI) principles.

Potential participants will first receive a participant information sheet (PIS) detailing the purpose, procedures, data handling, and ethical safeguards of the study. The PIS will be provided by staff or volunteers working for recruitment partners for example, staff working in Dementia Support Cafes. In the event that an individual would like to express an interest in

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learning more about the research project or is interested in taking part, they will be provided with contact details for the research team. Alternatively, if they prefer, they will be provided with an expression of interest form and a pre-addressed envelope to allow them to send their contact details to the research team at the IMH. Contact details received by the research team will be processed in the manner described previously within this protocol.

Individuals who express an interest in learning more about the study will be contacted by a trained member of the research team, who will explain the study verbally and provide an opportunity for questions. Participants will be given a minimum 48-hour consideration period before formal consent is sought. If a completed consent form hasn't been returned within six weeks of the date of issue, the individual's name and contact details will be deleted from the contact details spreadsheet.

Participants will undergo a capacity assessment by trained researchers prior to giving informed consent. Researchers will have completed Good Clinical Practice (GCP) training and will be experienced in dementia research, including supporting decision-making and recognising signs of fluctuating or diminished capacity.

Consent will be obtained in writing, either physically or electronically, depending on participant preference and the mode of data collection. For participants with dementia, capacity to consent will be assessed immediately prior to each activity. If a participant is deemed to have lost capacity, they will be withdrawn from the LEND programme, but any data collected up to that point will be retained and used in accordance with their previously granted consent, as consistent with HRA guidance, the Declaration of Helsinki, University of Nottingham policies and the sponsor's SOPs on data retention.

To ensure the narrative pool reflects a range of experiences and formats, a maximum variation sampling approach will be used, incorporating:

1. Narrator diversity – including ethnicity, gender identity, sexual orientation, age, and dementia subtype (e.g., Young Onset Dementia).
2. Narrative format – including text, audio, video, and British Sign Language (BSL).

This approach promotes inclusivity, relevance, and accessibility, supporting ethical engagement across diverse participant needs.

In WP1.3a, the focuses will be on narrative impact validation interviews. On receipt of a completed consent form, each participant will be allocated a unique reference number. This will allow data shared during wp1.3a to be linked to additional information shared by the participants during wp1.3b and, where applicable, to allow data collected during the follow-up calls to be linked. A spreadsheet including the unique reference numbers and participants' personal data will be stored securely within the sponsor's IT environment separately from the pseudonymised data, and access to it will be restricted to authorised members of the research team only. The key to allow reidentification of participants will be destroyed once data linkage has been completed. This will render the interview transcripts anonymous.

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Participants will take part in a semi-structured interview, either in person or online, lasting approximately one hour. Interviews will be audio- (via Olympus DS9000) or video-recorded (via an NHS laptop and NHS Teams account using MS Teams functionality) with informed consent provided. The recordings will not contain any directly identifiable data but will include the participants' UIDs to allow data collected during the interview in wp1.3a to be linked to data collected in wp1.3b and, if applicable, any additional data shared during the follow-up calls. Recordings made using MS Teams will be stored securely within the researcher's NHS Teams channel and will be transcribed using the 'speech to text' function. Transcripts will include the participants' UIDs but no directly identifiable data. Recordings will be deleted once the transcript has been checked for accuracy.

Recordings made using a recording device will be uploaded to a secure location within the sponsor's IT environment and will be deleted from the recording device post-successful upload. Transcripts, which will include the participants' UIDs but excluding any directly identifiable Personal Data, will be produced manually by the research team. Audio recordings will then be deleted once the transcripts have been checked for accuracy.

Interview transcripts will be stored within the sponsor's IT environment and access will be restricted to the research team. The transcripts will be anonymised by destruction of the pseudonymisation key once data collected in wp1.3a has been linked to data collected in wp1.3b and, if applicable, any additional data collected during the follow-up calls. The anonymised transcripts will be shared with members of the LEND research team based at the University of Nottingham for analysis and research partners for the purpose of analysis, using the procedure described in WP1.1.

During the interview, physical or electronic copies of the narratives will be provided to the participant during the interviews, while screen-sharing will replicate this process online.

In WP1.3b focuses on a narrative rating exercise. The same participants from wp1.3a will be presented with up to 5 narratives. Following each narrative, participants will be asked to rate the narrative using a 10-point scale (ranging from –5 to +5) to indicate their:

- Perceived connection to the narrator
- Connection to the content of the narrative
- Level of hopefulness evoked

Participants will be encouraged to explain their ratings in brief qualitative statements, facilitating mixed-methods analysis of both quantitative and subjective responses. The researcher will record the participants' rating scores and the responses, and their UIDs. The data collated will be linked to responses in WP1.3a using the participants' UIDs. .

After both activities have been completed, ethical debriefing and support will be offered. Although this is fully outlined in the participant information sheets (PIS), participants will be reminded of their rights to stop their involvement in the study at any time. During the debriefing, participants will be prompted to consider both the immediate and potential delayed impact of the narratives, recognising that emotions may unfold over time. A follow-up phone

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call will be offered approximately one week after participation, providing a space for additional insights or emotional processing. The calls won't be recorded but the researcher will make notes containing the participants' UIDs to allow any additional data provided during the calls to be linked to their interview transcripts. This ethically grounded approach respects participant autonomy, safeguards well-being, and acknowledges the complex and dynamic nature of engaging with peer-led narratives in the context of dementia.

To respect the right to privacy, follow-up phone calls will be done no more frequently than once a week and for no longer than six weeks. As outlined in the participant information sheet, the researcher making the phone call will produce a vignette which will include the participants' UIDs to allow linkage with data collected during wp1.3a and wp1.3b. The vignette will be rendered anonymous by destruction of the pseudonymisation key post-data linkage.

Corresponding documents: LEND: Work Package 1: Activity 3a&b Interview Prompt; Wp1.3a&b Participant Information Sheets; WP1.3a&b Consent Form v0.1.

5.2.3. Work Package 1: Activity 4: Focus Groups

Experience from recent focus groups with south Asian or African-Caribbean family carers has indicated that the LEND programme has a huge potential to better understand and tackle many aspects of stigma in diverse ethnic groups.

Participants will be identified and recruited through the Centre for Ethnic Health Research and the Join Dementia Research database (www.joindementiaresearch.nihr.ac.uk). The Centre for Ethnic Health Research will work with local communities to develop suitable video narratives with 10 people that speak languages other than English. The narratives will be presented to participants in 4 focus groups with 6-10 participants who speak languages other than English. The focus groups will be facilitated in the respective languages by a CEHR community engagement officer who, with the aim to capture and explore the acceptability and utility for populations that speak languages other than English, who are typically under-served by dementia research. All LEND paperwork relevant to research, such as Participant information Sheets and Consent forms, will be available for people at the Centre for Ethic Health Research, via links on recruitment partner websites, and from the LEND website.

LEND researchers will offer people from these focus groups the opportunity to take part in a LEND focus group. LEND will run four focus groups, each focus group with 10 participants each. Staff and volunteers at the Centre for Ethnic Health Research will provide each participant with a participant information sheet and a blank consent form at least 24 hours prior to the LEND focus group taking place. Focus group participants will provide their completed consent forms to the research team on the day of the focus group. Completed consent forms will be transferred securely to the IMH and will be scanned on receipt. Scanned consent forms will be securely stored within the Sponsor's IT environment and access to them will be restricted to duly authorised members of the research team only. Paper consent forms will be securely destroyed post-successful upload of the digital document.

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Due to potential language limitations, the participant information sheets and consent forms for WP1.4 will be interpreted into other languages using support services provided by the Centre for Ethnic Health Research. Using these support services, participants will be given the opportunity to ask any questions and provided with a minimum 48-hour consideration period before formal consent is sought.

All focus group participants will be paid by bank transfer at a rate of £20 per hour through the LEND budget, and payments will be facilitated by the University of Nottingham's finance team. Each focus group will last up to a maximum of four hours with intermittent breaks and refreshments provided. To claim, participants will be provided with the Institute of Mental Health Public and Patient Involvement Expenditure Claim Form. These can either be given to the LEND PM directly at the end of each focus group session, kept in a secure lockable bag and then processed by IMHinvoices@nottshc.nhs.uk or sent directly to IMHinvoices@nottshc.nhs.uk.

Although group demographics will be recorded, individual participant demographic details will not. Focus groups sessions will be anonymously recorded using an Olympus recording device that is approved by Nottinghamshire Healthcare NHS Foundation Trust for this purpose in their SOPs. The recordings will be uploaded to a secure area within the sponsor's IT environment, accessible only to the research team, as soon as practicable after the focus group sessions, and deleted from the recording device post-successful upload. A researcher will listen to these recordings and anonymously transcribe them using a secure NHS laptop, removing any personally identifiable information. The recordings will be securely destroyed once the transcripts have been checked for accuracy and validated. The anonymised transcripts will then be stored to a secure area within the Sponsor's IT environment. The anonymous transcripts will be shared with the University of Nottingham and the University of West London for analysis. Findings will inform the development of future studies and the opportunity to explore the potential impact that this may have on the final development of the online LEND intervention.

Corresponding documents: WP1.4 Participant Information Sheets; WP1.4 Consent Form

5.2.4. Work Package 1: Activity 5: Discrete Choice Experiment

Discrete Choice Experiments (DCEs) require respondents to choose between sets of hypothetical alternatives, each characterized by specific attributes. The responses allow researchers to infer the value assigned to each attribute. Compared to other stated preference methods, which may involve ranking or rating options, DCEs offer a more straightforward and realistic decision-making task. A DCE will be developed for people living with dementia, ranking the importance of the various attributes of narratives with varying levels in three distinct groups:

1) people living with a diagnosis of dementia
2) carers of people living with dementia, and
3) the public.

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Up to 10 participants will be identified and recruited per group. Participants will be purposively identified through a combination of research partner networks, including dementia support groups, carer organisations, community services, PPI networks, and public-facing recruitment strategies. Specific attention will be paid to identifying participants with and without prior experience using online therapeutic or peer-support interventions, including but not limited to dementia care, to facilitate stratification of responses. The involvement of third-sector partners and the Centre for Ethnic Health Research will enable targeted recruitment to ensure representation from under-served and diverse communities. (see **7.3.0. Recruitment Strategies**). Prior to allocation, participants will only be recruited if fully informed written consent can be given.

Identification and recruitment of participants will follow the same process as with earlier phases of work. Participant Information Sheets will be provided to potential participants by recruitment partners or during specific events hosted at the IMH, and individuals will be able to either complete an expression of interest form and return it to the research team at the IMH, or contact the research team directly.

On receipt of an expression of interest form, the potential participant's contact details will be added to the contacts spreadsheet and a consent form will be issued via the individual's preferred medium. Contact details for potential participants who don't return a consent form within six weeks of the date of issue or by the close of recruitment to this phase of the project (whichever is sooner) will be securely destroyed. Paper versions of completed consent forms will be scanned and saved to a secure area within the sponsor's IT environment before being destroyed. Completed consent forms returned by email to the research team will be saved to the same location and the emails will be deleted. Only the CI or authorised members of the research team, by way of the site delegation log, will be able to access the completed consent forms. Access to the consent forms will be logged for auditable purposes.

Participants will then be stratified for previous online therapeutic intervention use (not limited to dementia care) (Phillips et al., 2021). A stepwise qualitative approach (focus groups) to develop attributes and levels for the DCE will be used and pilot the acceptability of a 16 pairwise choice exercise in each of the three group.

Relevant literature will be reviewed to propose potential positive attitudes or scepticism to a website such as that planned for LEND. A preliminary set of attributes will be constructed using levels and draw on the four core determinants of users' behavioural intention to use a technology, namely performance expectancy, effort expectancy, social influence, and facilitating conditions (Venkatesh et al., 2003).

In the analysis, individual user costs will be identified (financial, time etc.) and add these to the DCE to make the choice tasks more realistic and give us the option of being able to estimate willingness to pay. It is anticipated that the final experimental design may have between 4 to 6 attributes with 2 to 4 levels to be manageable in terms of the number of choices for participants. This will be confirmed in the feasibility stage. Choice comparisons will

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be full-profile, unlabelled, paired comparisons. An optout option is unlikely to avoid interpretation bias (Hahn & Shapiro, 1966). An experimental design catalogue is planned to be used, with fold-over design (Gibson et al., 2016; Giebel et al., 2021).

Participants will be asked to attend the Computer Science Building of the University of Nottingham (based on the Jubilee Campus) and will be provided with access to a computer. They will be asked to indicate their preference between two versions of a hypothetical LEND Intervention, each with specified attributes with varying levels. Anonymised statistical information about how the participants use and interact with the hypothetical LEND Interventions will be captured and automatically uploaded to and analysed in STATA using a random-effects logic model that will allow for multiple observations from the same respondent. The regression model will estimate preference weights for each attribute that indicate the importance of attributes and the direction of effect. The coefficients from the regression will be used to calculate the Marginal Rate of Substitution (MRS); the rate at which respondents are willing to substitute one attribute for another. The importance of the various attributes will be ranked. Participants and members of the research team will then discuss the ratings and participants will have the opportunity to explain their preferences if they want to do so. Handwritten notes of the discussion will be taken but without the inclusion of information which could be used to identify an individual or individuals.

Synthesis: We will co-produce with LEAP members, an integration of the findings from Work Package 1, Activity 1-4 to produce LEND programme theory and update the logic model.

Corresponding documents: WP1.5 Participant Information Sheets; WP1.5 Consent Form.

5.3.0. Work Package 2: Activity 1: INCRESE-D Inventory

Development and evaluation of INCRESE-D inventory conceptual framework characterising mental health recovery narratives was developed firstly using evidence from a systematic review and narrative synthesis (Llewellyn-Beardsley et al., 2019a; Rennick-Egglestone et al., 2019). An interview study then assessed the relevance of the framework to the narratives of more diverse populations (Llewellyn-Beardsley et al., 2019b). This framework was used to develop the 77-item INCRESE Inventory (INventory of Characteristics of REcovery StoriEs) which characterises recorded mental health recovery narratives (Llewellyn-Beardsley et al., 2020). INCRESE has seven domains (narrative eligibility, narrative mode, narrator characteristics, narrative characteristics, content warnings, turning points, narrative content). Most of the items in the INCRESE inventory are relevant to dementia, and we will take these items as the starting point to develop the new INCRESE-D inventory to categorise narratives included in the LEND Intervention. LEND researchers will work closely with the LEND lived experience advisory panel (LEAP).

Narratives will be categorised with a version of the NEON 77-item INCRESE (an evaluation tool modified for dementia to categorise/ add/remove using the systematic review results: https://www.researchintorecovery.com/files/INCRESE.pdf
INCRESE comprises sections on:

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a) narrative eligibility (is this a lived experience account, a narrative, contains elements of adversity or struggle and success, strengths, or survival).
b) narrative mode (text, audio, moving images, static images, length of text, length of audio or video); narrator characteristics (for example, gender, age, ethnicity, sexuality, disability, diagnosis)
c) narrative characteristics (for example, genre, positioning, tone).
d) content warnings (for example, injustice, prejudice, and discrimination).
e) turning points (for example, taking charge, intervention/support from others, self-acceptance).
f) narrative content (for example, family, education, friendships, relationships, diagnosis, medication, hospitalisation, being in natural environment, community activities).

We will identify categories to add, remove or change, as well as explore other routes to accessing the narratives, as informed by the results of literature review, knowledge and the interview studies. We anticipate the sections on narrator characteristics (diagnosis) and narrative content will need revisions, with other items needing re-wording to be appropriate for people affected by dementia. We will test feasibility, usability, acceptability, and reliability of the new version INCRESE-D.

Quantitative and thematic analysis will establish face/content validity, test-retest and inter-rater reliability, feasibility, and usability, then LEAP members will review the acceptability of INCRESE-D with further refinement as necessary. All narratives will be assessed for exclusion criteria (for example, hate speech) and suitability using the INCRESE-D inventory.

Corresponding documents: The NEON 77-item INCRESE evaluation tool.

5.3.1. Work Package 2: Activity 2: The LEND Collection

All narratives in the LEND Collection are considered ‘gifts’ and appropriate legal documentation requesting permission to use the narratives in this way will be obtained. They will include pre-existing narratives from verified sources and permission will be sought (such as Alzheimer’s UK, etc). Should a participant wish to donate a narrative to the LEND Collection, then they will have a choice whether to pseudonymise their narrative or not. This is because their narrative belongs to them and the decision to donate narrative is a personal and individual one. A legal agreement will be signed to this effect.

All narratives used about people living with dementia and carers, will have been filtered for exclusion (such as hate speech) and categorised using the developed INCRESE-D criteria. During WP1 and WP2, at least 50 narratives are required to enable design. By WP3, a minimum of 100 narratives should be provided to begin the feasibility study. (By WP4, more than 300 narratives should be provided and would be sufficient to start a full trial. By WP5 there should be at least 500 narratives on the LEND Collection database).

Corresponding documents: WP2.2 Letter requesting permission to use narratives.

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5.3.2. Work Package 2: Activity 3: LEND Intervention Development

The LEND Intervention development consists of the development of the Online LEND Intervention, the potential use of an eBooklet to support inclusion, and LEND Portal.

The LEND portal manages participant registration and consent and hosts all study documents in electronic form. The LEND intervention (web application) is accessed via the portal and delivers personalised dementia-related narratives using a recommender system. The LEND eBooklet offers a portable, standalone video player that requires minimal technical skill to operate to support inclusion.

Participants used to support this development will be identified through multiple ethically approved pathways, including community and voluntary sector organisations (e.g., Alzheimer's Society, Age UK), localised support and social groups, such as Dementia Café groups and carer support networks, the Join Dementia Research database (www.joindementiaresearch.nihr.ac.uk), the Centre for Ethnic Health Research and other local community partners, which will support targeted outreach and ensure the inclusion of under-served populations, as well as public-facing posters (see **7.3.0. Recruitment Strategy**).

The LEND contract developer will include members of the University of Nottingham from the Computer Science department and follow established and emerging guidelines to ensure a high level of usability and user experience for people with dementia (for example, AbilityNet Designing for Dementia factsheet https://abilitynet.org.uk/factsheets/designing-dementia ; Alzheimer's Society Information Blog https://www.alzheimers.org.uk/blog/how-design-website-someone-affected-dementia and others).The portal and web application will have full AA conformance to the W3C Web Accessibility Initiative (WAI) Web Content Accessibility Guidelines (WCAG) as well as the EN 301 549 European accessibility standard. The University of Nottingham (in the capacity of developer of the LEND platform (the Online LEND Intervention and the LEND Portal)) will provide ongoing maintenance and support throughout the programme. The CI and delegated members of the research team, as identified in the site delegation log, will have access to Identifiable Personal Data shared by the participants when creating their unique user account, this will include contact details to enable the progress and development of the Online LEND Intervention.

The LEND Programme researchers will work with the University of Nottingham Computer Science department to design and develop the LEND Intervention over five phases including usability testing:

- Phase 1: Workshops with the developers from the University of Nottingham, research team and LEAP members will determine and prioritise the requirements of the web application and the eBooklet, to support inclusion. LEAP members will be paid £20 per hour via bank transfer using the standardised PPI claim form, sending it directly to IMHinvoices@nottshc.nhs.uk
- Phase 2: The University of Nottingham Computer Science department will develop the first working version of the web application as well as inclusive ways to access the

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online narratives. The research team will develop the relevance based expert system for retrieval of narratives. The first stage of usability testing will be conducted.

- Phase 3: Second working version of the web application including refinement based on feedback from testing and AA accessibility conformance. Integration with the expert system. Second working version of the web application. The second stage of usability and user experience testing will be conducted.
- Phase 4: Third working version of web application developed for use in feasibility study. The Phase 4 in-vivo testing will recruit participants from Phases 2 and 3. It will involve 50% of individuals with a diagnosis of dementia and 50% of carers from each of Phase 2 and 3.
- Phase 5: Final version of web application ready for trial will be completed post feasibility study findings, in preparation for the RCT (Further Work Packages relating to the RCTs will be applied for at a later date, in WP4 and WP5).

Please note, LEND will follow the 2021 MRC Framework for Developing and Evaluating Complex Interventions (60), the UKRI/MRC guidance on diversity in research design (MRC/UKRI, 2022) and the NICE Evidence Standards Framework for Digital Health Technologies (Unsworth et. al., 2021)

Phases 2-4 of Work Package 2.3 (WP2.3) will involve the recruitment of participants to inform the iterative design and development of the LEND digital intervention platform. The recruitment target will be balanced, with approximately 50% of participants being carers and 50% individuals with a diagnosis of dementia. Recruitment and consent processes have been designed in alignment with the UK Policy Framework for Health and Social Care Research, UK GDPR, the Data Protection Act 2018, and Nottinghamshire Healthcare NHS Foundation Trust's SOPs.

Potential participants will be identified and approached through existing recruitment partnerships, including healthcare providers, carer networks, and community-based organisations. Promotional materials (posters, flyers) will also support recruitment and will include a hyperlink and QR code directing interested individuals to the LEND portal, where they would be directed to the participant information. Details of the LEND team will be provided should the participants wish to make contact to ask any questions. They will then be directed to the consent process.

Consent will be captured via the LEND Portal and will be automatically and securely date stamped to ensure activity can be audited if required. When completing the consent form, individuals will be asked to provide their names, email addresses, and mobile telephone numbers. These data will automatically be added to a database table which will be stored within the University of Nottingham's secure IT environment and accessible only to duly authorised members of the research team.

Following completion of the consent form, a LEND user account will be automatically created. A participant's LEND user account name will be their email address. Once the LEND user

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account is created, a verification number will be sent via text. This process will be completed manually by a member of the research team using a mobile phone owned and maintained by the University of Nottingham.

The participant will need to enter this verification code to access their LEND user account. To prevent This will prevent fraudulent or duplicate registrations in the main feasibility trial (WP3.1), (e.g. attempts to access multiple incentives). Each unique email or mobile number may be linked to only one account; any duplicate entries will be automatically flagged for manual review by the research team. Once the LEND user account has been verified, the participants' will be automatically allocated UIDs by the LEND platform. The UIDs will be linked in a back-end table to the participants' user accounts. Only authorised members of the research team will be able to access the back-end table. Participants can choose to add their demographic information to their user profile if they want to. These data will be collected to support the development of an inclusive and representative intervention, and will facilitate analysis across diverse participant groups, ensuring that the intervention is sensitive to varied cultural and social contexts.

In the event that a participant doesn't verify their LEND user account within 28 days of creation, the research team will securely destroy their completed consent form, and all other Personal Data collected up to that point, and their LEND user account will be closed.

At the end of this work package, completed consent forms will be downloaded from the University of Nottingham's IT environment and securely transferred to the Trust to be stored in a secure area accessible only to duly authorised members of the research team.

Participants may withdraw from this work package at any time at by notifying the research team, and providing the email address or telephone number that they used to register. Upon withdrawal, all Personal Data collected about or shared by the participant up to that point will be retained but no further Personal Data will be collected.

Only data provided by participants who have validated their LEND user account will be analysed. The exception will be on a flow diagram included in the research report of the feasibility study, where the number of people who consented, but who did not validate their account, will be reported. This is line with previously reported studies of online interventions, (Robinson et al., 2025).

During engagement with the Online LEND Intervention across all phases, user activity will be digitally monitored. This tracking enables the research team to evaluate user experience, identify areas for improvement, and inform iterative refinements to the intervention in accordance with best practice for co-designed digital tools.

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Participants who have verified their LEND user accounts and allocated a UID, will be invited to attend the Computer Science Building at the University of Nottingham to take part in co-design workshops. Participants will be asked to log into the LEND portal using their user account details. They can either use their own personal devices or hardware provided by the University of Nottingham. Before accessing the LEND intervention, each participant will be told their UID, this will allow their usage data to be linked to their comments in the later part of the co-design workshop.

Participants will be asked to access narratives using their LEND user accounts and their activity (which will be linked to their user account) will be automatically monitored throughout, usage data will be stored within a secure area of the University of Nottingham's IT environment and access to those data will be restricted to authorised members of the research team only.

As participants work their way through the narratives, they'll be asked to verbally comment (including saying their UIDs) on how easy or difficult they find the intervention to use. The comments will be record using a secure, Sponsor-approved Dictaphone, one of which will be available for each participant. Participants will be reminded that they shouldn't use their names, just their UIDs to ensure the recordings are pseudonymised.

The pseudonymised recordings will be uploaded to a secure area within the University of Nottingham's IT environment as soon as practicable after the workshops. The recordings will be stored separately from the pseud key (which will be stored within the LEND back-end portal). The recordings will be transcribed, including the UIDs, by a member of the research team, and the pseudonymised transcripts and usage data will be analysed by members of the research team. Inclusion of the UIDs in the transcripts will allow the research team to cross-reference comments made by participants against their usage data. This will allow the research team to work out what the participant was doing or accessing when they made their comments, to help inform development of the platform. For example, if a participant commented that a certain page was difficult to navigate.

After analysis of the transcripts and usage data has been completed, the UIDs will be removed from the participants' LEND user account thereby rendering the transcripts and usage data anonymous.

Data, once sufficiently anonymised, maybe used in publications, conference presentations, and other forms of dissemination. This includes anonymised quotes. Although personal characteristics will be noted, no direct identifying information will be included in any dissemination materials, and participants will not be identifiable in any outputs arising from the research.

This online consent process supports accessible, user-friendly engagement and adheres to guidance from the HRA and NIHR on digital consent. The ability to navigate and complete the

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consent process will be taken as an initial indicator of capacity to consent. Additional assessments, such as the Dementia Severity Rating Scale (DSRS), will be used where appropriate, and capacity will be reviewed at intervals throughout participation if concerns arise.

The text body of reminder SMS messages or emails will not contain any personalised data. Further, all electronic communications, including SMS messages for account validation and optional research-related reminders, will be sent using mobile phone(s) registered to and manage by the University of Nottingham.

During early development and system testing of the Online LEND Intervention, fictional participant profile pages will be used by the LEND research team to trial platform functionality, content delivery, and interface design. These test accounts will be clearly marked within the system architecture and contain no real participant data.

Access to identifiable data will be strictly restricted to the CI and delegated authorised members of the research team, as identified by way of the site delegation log. This will include IT personnel at the University of Nottingham's, School of Computer Science. Role-based access controls will be logged and auditable and used throughout to limit permissions in accordance with the principle of data minimisation.

Participants in this work package may request account closure at any time. Upon withdrawal or account closure, all personal data (e.g., email, mobile number) will be permanently deleted from the LEND portal and LEND intervention (if applicable).

Please note, all data handling and storage will comply fully with The UK General Data Protection Regulation (UK GDPR), The Data Protection Act 2018, The UK Policy Framework for Health and Social Care Research, Nottinghamshire Healthcare NHS Foundation Trust information governance policies.

This dual-system approach, combining secure university-hosted data collection with periodic transfer to the Sponsor's environment, ensures the highest standards of data integrity, participant privacy, and regulatory compliance throughout the study lifecycle.

Corresponding documents: WP2.3 Participant Information and Consent

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5.4.0. Work Package 3: Activity 1: Recruitment and Consent

Participants will be recruited through ethically approved, inclusive channels to ensure a representative sample. Gatekeepers, such as General Practitioners (GPs), Social Prescribers, and community organisations, will identify suitable individuals based on clinical judgment and trusted therapeutic relationships. Recruitment will also occur via the Join Dementia Research (JDR) registry, third-sector dementia support organisations, carer networks, and the Centre for Ethnic Health Research to ensure engagement with under-served or marginalised groups. No identifiable personal data will be shared with the research team by third-party partners, individuals who would like to take part will be directed to contact the research team directly, or will be provided with a hyperlink and QR code to allow them to access the digital study documents. Additionally, the research team may contact individuals who participated in earlier work packages and who expressed an interest in taking part in later parts of the study.

Potential participants who contact the research team directly or who have previously expressed an interest in taking part in later phases of the study will be provided with a hyperlink or QR code via their preferred medium (email or text). The hyperlink and QR code will provide access to an online version of the Participant Information Sheet (PIS), detailing the study's aims, procedures, potential risks and benefits, data protection protocols, and the voluntary nature of participation. Contact details for the research team will also be included to facilitate questions prior to enrolment.

Individuals who want to participant in this work package will access a digital consent form (via the hyperlink and QR code referred to above) on the LEND portal. The LEND portal will present consent statements sequentially; all must be affirmed before proceeding. Completing the digital consent form via the LEND portal will require participants to provide their name, email address, mobile phone number and the date of consent in accordance with the UK Policy Framework for Health and Social Care Research, UK GDPR, and Nottinghamshire Healthcare NHS Foundation Trust SOPs. Their names, email addresses, and mobile phone numbers will be used to create the participants' LEND user accounts.

To verify identity and enhance data integrity, a two-factor authentication (2FA) process will be implemented. After the online consent form is submitted, a one-time validation code will be sent via SMS to the participant's mobile phone. The participant must enter this code into the LEND portal to verify their identity and activate their account. This ensures that only one profile can be created per mobile number, helping to prevent fraudulent or duplicate registrations. Once the LEND user account has been verified, the participant will automatically be allocated a UID which will be linked to their LEND user account. Personal data shared to create the LEND user account and the UIDs will be stored within a secure location in the University of Nottingham's IT environment and access to those data will be restricted to members of the research team only.

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In the event that a LEND user account isn't verified within six weeks of the validation code being issued, all personal data about the user will be securely destroyed from the LEND platform and the back-end data table.

Participants who do not have a mobile phone or prefer not to share one will be offered alternative recruitment and consent routes, such as email or use of a landline. A member of the research team will contact these individuals directly to complete manual verification and consent, in accordance with Trust SOPs for inclusive research practice.

Data storage and transfer processes have been designed to comply with the data governance policies of both the University of Nottingham and Nottinghamshire Healthcare NHS Foundation Trust. In particular:

- Consent forms (including names, email addresses, and mobile numbers,) will be stored on an encrypted folder within the University of Nottingham's secure network environment. Pseudonymised data will be stored separately from the pseudonymisation key (which will be linked to the user accounts).
- At the end of this work package, personal data, including data provided to allow LEND user accounts to be created, will be downloaded from the University's IT environment and securely transferred to the Trust. All personal data will be securely and permanently deleted from the University's IT environment post-successful transfer.
- , Transferred data will be archived on a secure, access-controlled server maintained by Nottinghamshire Healthcare NHS Foundation Trust.
- Only the CI and authorised personnel, as listed on the site delegation log, will have auditable access to either the University or Trust data environments, in accordance with role-based access protocols.
- At the end of this work package, UIDs will be securely destroyed to render the data collected anonymous.

After validating their LEND user account, participants will utilise their LEND user accounts to complete baseline and periodically collected outcome measures which will be linked to their UIDs. Participants will be asked to provide their demographic data once, at baseline. These data will also be linked to their LEND user accounts and UID, and will support subgroup analyses, including to enabled decisions on procedures for stratified allocation of participants in the trial. Narrative preferences and user engagement analytics will also be stored within the University's secure system but will not be linked to direct identifiers in any exported dataset.

All data shared with collaborators, including the University of Bangor Clinical Trials Unit and the University of West London, will be anonymised. To enable randomisation, the Clinical Trials Unit at the University of Bangor will be provided with participants' UIDs and whether the participant is a person with dementia or a carer. However, as the Clinical Trials Unit won't have access to the pseudonymisation key (which would allow reidentification of participants) those data will be effectively anonymous.

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All data transfers will be documented as part of the programme's audit trail. Access to identifiable data such as mobile numbers and email addresses will be strictly limited to LEND portal administrators and designated IT personnel within the University of Nottingham's Computer Science Department, using role-based access control, which will be identified on the site delegation log. IP addresses will be collected temporarily to identify suspicious or duplicate activity and deleted following completion of identity verification processes.

Participants may withdraw at any time. If a participant closes their account or withdraws from the study:

- Personal identifiers (e.g., name, mobile number, email address) will be automatically removed from the LEND platform.
- Anonymous research data (e.g., sociodemographic details, engagement analytics) will be retained for ongoing analysis, as outlined in the PIS and in accordance with ethical approval and GDPR Article 17 (Right to Erasure) exceptions for scientific research.
- This approach ensures participant autonomy, complies with data protection requirements, and preserves the integrity and value of the research findings.

5.4.1. Work Package 3: Activity 1: Randomisation and Blinding

Ratio 1:1 LEND vs treatment as usual (TAU) care control group allocation accessed via the LEND web portal, stratified by co-resident carer. Analysts will be blind to group allocation. Remote computerised randomisation will be generated using data provided by participants when they registered for a user account i.e., demographic data linked to their LEND user account, their UID, and whether they are a person with dementia or a carer. These data will be transferred to Bangor CTU to support allocation. A randomisation system will be quality assured and accredited by the Bangor Clinical Trials Unit (Bangor CTU), University of Bangor. As previously indicated, self-reported outcome data will be collected from participants via the LEND Portal with no researcher involvement.

The content of the assessments will be tailored according to participant group allocation: individuals in the LEND-C group (carers of people living with dementia) and those in the LEND-P group (people living with dementia) will receive group-specific questions relevant to them (see Figure 2 and Table 1). Both LEND-C and LEND-P intervention arm groups will have access to an eBooklet, if required, to enable access to the Online LEND Intervention and to support inclusion.

In addition to outcome measures, a standardised set of demographic questions will be administered at baseline only. Participant responses will be linked to their unique user profiles within the LEND platform. These data will support monitoring of participant diversity and will enable an evaluation of the representativeness of the sample, particularly with respect to ethnicity and inclusion of under-served populations.

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Figure 2: Flow Diagram of Work Package 3.1 The LEND Feasibility Study

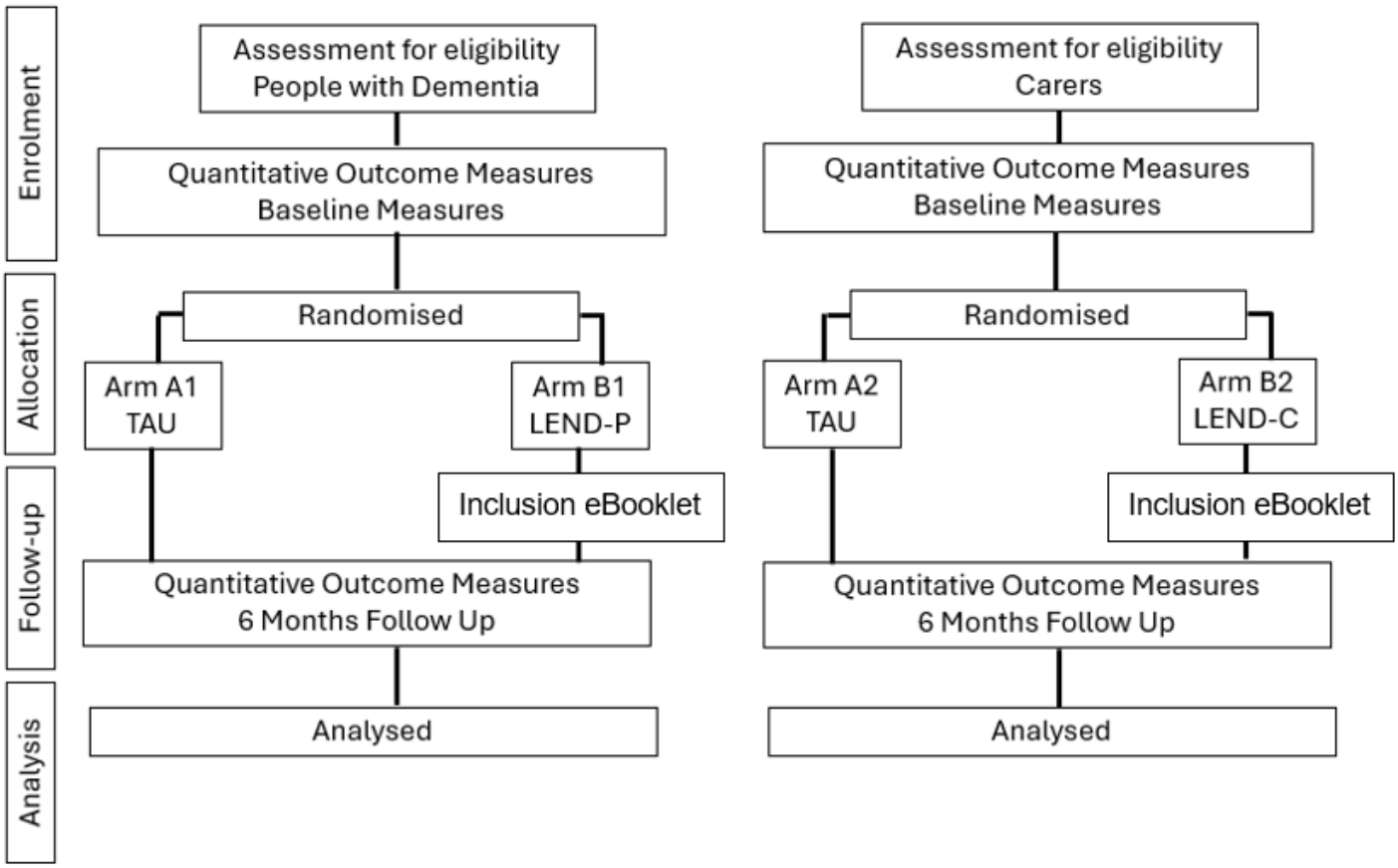


Figure 2. Flow diagram of WP3.1: A randomised, controlled feasibility study involving people living with dementia and informal carers. Following eligibility screening and baseline assessment, participants are randomised to receive either Treatment as Usual (TAU) or the Online LEND Intervention (LEND-P for people with dementia; LEND-C for carers). Participants in the intervention arms also receive access to a digital support aid (eBooklet) to promote accessibility and sustained engagement. All participants complete follow-up outcome measures at 6 months post-randomisation.

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Table 1: Outcome questionnaires

Primary Outcome	**Person with Dementia**	**Carer**
Quality of Life Alzheimer's Disease (QoL-AD) (Kahle-Wrobleski et al., 2017)	X	
Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) (Lancaster et al., 2004)	X	X
Secondary Outcome		
Engagement and Independence in Dementia Questionnaire (EID-Q) (Stoner et al., 2018).	X	
Brief Rosenberg Self-Esteem Scale RSES (Monteiro et al 2022)	X	X
General Self-Efficacy Scale (GSES) (Schwarzer et al 1995)	X	X
Caregiver Self-Efficacy Scale (CSES) (Ritter et al, 2022)		X
Zarit Burden Interview Short Version (Bedard et al 2001)	X	
EQ-5D-5L (Orgeta et al., 2015)	X	X
ICECAP-O (Proud et al., 2019)	X	
Adult Hope Scale (AHS) (DiGasparro et al., 2020)	X	X
Client Service Receipt Inventory (Costs) (CSRI) (Beecham & Knapp, 2001)	X	X

The battery of outcome questionnaires chosen (Table 1) are all self-reported and will measure final and intermediate outcomes from the preliminary LEND Programme theory (as developed in WP1) and the core outcomes of importance to people living with dementia (Fox, 2021; Campbell & Erdem, 2019). These outcomes are provisional and will be informed by the work of Fox determining appropriate and valid outcomes for people with dementia and carers (NIHR203380 SPLENDID study).

5.4.3. Work Package 3: Activity 1: The Online LEND Intervention

The Online LEND Intervention (either LEND-P for people with dementia or LEND-C for carers in the intervention arm of the study) is accessed via the LEND Portal, as developed with LEAP involvement and participant input in WP2.3 The Online LEND Intervention contains a range of lived experience narratives that adhere to the INCRESE-D, developed using the LEND theory in WP1 and the LEND criteria developed in WP2.1 and WP2.2 with LEAP and PPI involvement.

Participants using the Online LEND Intervention can review as many narratives as they choose over 6 months; either by using a filtering system or as identified by a machine learning recommender system. The filtering system and warnings will allow participants to avoid certain narratives, whilst other ones will be recommended. Participants will be able to rate

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each narrative based on how it makes them feel, bookmark or block narratives. Any ratings recorded will be linked to the narrative, not to the users' LEND user accounts. This will support further refinement and development of the Online LEND Intervention. Please note, the design and development of the intervention is dependent on the collective findings from WP1 and WP2, which are yet to take place.

The ability to access the website and navigate recruitment processes will be indicative of capacity for online recruitment (Davis et al., 2003). The LEND portal will include functionality to automatically verify that someone registering is a human being, to monitor suspected repeat registration and to suspend/delete accounts if needed. An automated message will be generated for the research team if the automated monitoring function indicates a potential issue with a user account. On receipt of the message, a member of the research team who has access to the administration portal will review the account and determine if it should be deleted or maintained.

Corresponding documents: WP3.1 LEND Feasibility Participant Information Sheets Carer; WP3.1 LEND Feasibility Participant Information Sheets Person with Dementia; WP3.1 LEND Feasibility Carer Consent; WP3.1 LEND Feasibility Person with Dementia Consent.

5.5.0. Work Package 3: Activity 2: The Long-term Impact of the Online LEND Intervention

To assess the long-term impact of the online intervention, an online or face to face qualitative interview, dependent on preference, will be conducted at 12 months post initial randomisation and 18 months post initial randomisation. Hence, only participants that took part in the intervention arm of WP3.1 will be invited to attend an interview. Participants will already be aware of this from WP3.1 PIS.
The data obtained from this does not need to be linked with any otherdata. People with dementia (n=10) and carers (n=10) will be asked explorative questions about the impact of the online LEND intervention. In addition, accessibility, usability, suitability, and acceptability of the LEND Intervention will be explored, as well as any concerns about the LEND intervention.

Interviews will be recorded (using a Nottinghamshire Healthcare NHS Foundation Trust approved recording device or using a Trust Microsoft Teams account) and transcribed (by a LEND researcher) in the same way as is described earlier in this protocol.Recordings and transcripts will include the participants' UIDs to allow the transcript to be linked to their demographic date, outcome measures, and data about their use of the LEND platform. When all data linkage has taken place, the UIDs will be destroyed. Recordings and transcripts will be managed as previously described in the protocol.

Corresponding documents: WP3.2 The Long-Term impact of the Online LEND Intervention, WP3.2 Long-term Impact Consent Form

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5.6.0 Integrated Development and Delivery

Work Packages 1 to 3 are interdependent, with development in one influencing development and outcomes in another. This integrated approach enables researchers to continually refine their understanding of LEND theory and how individuals living with dementia use narratives and how an online LEND intervention could benefit their quality of life and well-being.
The interplay among Work Packages fosters flexibility, allowing for the iterative refinement of LEND Theory while advancing practical intervention development. This approach ensures the LEND Collection remains relevant and inclusive for all individuals living with dementia.

WP1, LEND Theory development consists of five interrelated activities. WP1.1 is a continuous survey that exams how individuals with dementia and their carers engage with social media, technology, and online narratives, providing continual insights to inform subsequent activities as well as an oversight of engagement over time. WP1.2, is an interview, designed to begin upon ethical approval, will include an invitation for participants to engage in additional activities outlined by LEND researchers and LEAP members, and dependent on the sub-stage of the research programme and what it will be engaged in. WP1.3a and WP1.3b will commence once a robust understanding of effective online narratives is established through LEND Theory, with WP1.2 continuing in parallel. WP1.4 will explore the applicability of these findings within ethnic minority groups and can only be completed after WP1.3a and WP1.3b are concluded. In WP1.5, the discrete choice experiment, is an independent task building on the knowledge from WP1.3a and WP1.3b and will progress without causing delays to other activities in WP1. However, it could impact WP2 as WP1 informs WP2.

Timely completion of WP1 in its entirety, WP2.1 and WP2.2 will support the development of the intervention framework up to WP2.3 phase 1. The development of the LEND Collection, despite being shaped by Work Package 2, is an ongoing task throughout the LEND programme. WP2.1 focuses on developing the criteria of INCRESE-D to identify narratives that can be used in the LEND Collection, accessed through the Online LEND Intervention, guided by the collaborative opinions of researchers and LEAP members without the need for recruited participants. WP2.1 and WP2.2 can run alongside Work Package 1, while WP2.3 must conclude at the end of Phase 1 until other phases in WP2.3 can be completed.

WP3.1, the main feasibility study, and WP3.2, the interview exploring the long-term impact of using the Online LEND Intervention, will evaluate the process of research delivery anticipated in Work Package 4 (not described in this protocol). The collation of findings from WP3.1 and WP3.2 will support the evaluation of the accessibility and acceptability of the Online LEND Intervention via the LEND Portal. WP3.1 will also identify the use of outcome measures and inform the research process in Work Package 4. Findings may lead to adjustments in the delivery of the intervention, the design, or use of outcome measures.

Corresponding documents: WP3.2 Feasibility Interview Participant Information Sheet; WP3.2 Feasibility Interview Consent Form.

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6. STUDY SETTING

The LEND programme prioritises the inclusion of under-served groups of people with dementia and carers by ensuring adequate representation of people from these communities, including Black, South Asian, LGBT+ and people with Young Onset Dementia and/or rare dementias (please view additional document: LEND Equality Impact Assessment).

Nottinghamshire Healthcare NHS Foundation Trust are Sponsor for this study. The main study site for WP1-3 is Nottinghamshire Healthcare NHS Foundation Trust, although other sites will be responsible for randomisation (University of Bangor, Bangor Clinical Trials Unit) or analysis of data (University of Nottingham, University of West London, University of Bangor, University of Bournemouth). Identifiable Personal Data will be Processed by the University of Nottingham on behalf of the Trust to support administration and operation of the LEND portal and intervention.

The LEND Programme researchers will be working closely with the Centre for Ethnic Health Research at the University of Leicester and anonymised data analysis updates may be shared with them in secure Teams meetings or via NHS email. Our close links with the national LGBT Network and King's College Hospital LGBTQ+ Network will strongly enhance our recruitment for these groups. Diversity of recruitment to the study will also be much enhanced by linking to the Join Dementia Research (JDR) database (www.joindementiaresearch.nihr.ac.uk). Data from the JDR currently shows 2533 people registered with younger onset dementia (below the age of 65) and 639 people from ethnic minority groups (not white British).

Localised GP surgeries, health care centres and social prescribers may identify participants, particularly in WP3.1. Participants recruited will be tracked using a secure Excel spreadsheet on a secure NHS shared drive, with restricted access to limited LEND members, accessed on an NHS laptop. The Excel spreadsheet will contain contact details for each potential participant.

Corresponding documents: LEND PIC Agreement

7. SAMPLE AND RECRUITMENT

7. 1. 0. Inclusion Criteria Per Work Package

All participants are required to provide consents. For the purposes of intervention development, design and feasibility, with the exception of WP1.4, there is requirement that all participants can communicate in English.
In WP1.4, there is an inclusion-criteria that English must not speak English or, alternastively, only speak English as an additional language.

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In addition. each work package will have its own inclusion criteria.

WP1.1 (Online or Paper Questionnaire):
A minimum of 1500 participants are required over five-year period, including both people with dementia and their carers. At least 50-60 participants per year are required from each under-served group.
Inclusion Criteria:

- A diagnosis of dementia or care for someone with dementia
- Are an adult, aged 18 years or over
- Can read and respond in English
- Capacity to consent.

WP1.2 (Semi-Structured Interviews):
30 participants (15 with dementia, 15 carers) will explore how people engage with dementia-related narratives.
Inclusion Criteria:

- Formal diagnosis or carers of someone with dementia.
- Must consent or have a representative.
- Adults aged 18+.
- Able to engage verbally/non-verbally, with adjustments if needed.
- Able to engage in the study language (e.g., English).
- Capacity to consent.

Interviews must be conducted in a supportive environment, with carers providing assistance if needed, without influencing responses.

WP1.3a&b (Narrative Impact Validation):
40 participants (20 with dementia, 20 carers) will assess narrative impact.
Inclusion Criteria:

- **People with Dementia:** Formal diagnosis; able to participate in interviews with/without support and provide consent.
- **Carers:** Those with direct experience supporting someone with dementia and capacity to consent.
- Adults aged 18+.
- Willing to engage with narratives in text, video, or audio formats.
- Open to discussing the impact and completing a 10-point scale about connection and hopefulness.

WP1.4 (Focus Group Work):
Feedback will be gathered from four Focus Groups, each with 10 participants (a total of 40 participants), where recruitment will be supported by the Centre for Ethnic Health Research.
Inclusion Criteria:

- Formal diagnosis or carers of someone with dementia.

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- Must have capacity to consent including people with capacity to consent who require support to articulate consent via a representative.
- Adults aged 18+.
- Able to engage verbally/non-verbally, with adjustments if needed.
- Must not be able to communicate in English or, alternatively, is able to communicate in English but only as an additional language
- Able to engage in the language suitable for that specific Focus Group.

Interviews must be conducted in a supportive environment, with carers providing assistance if needed, without influencing responses.

WP1.5 (Discrete Choice Experiment):
30 participants (10 with dementia, 10 carers, 10 public members) will engage in hypothetical decision-making.
General Inclusion Criteria:

- Adults aged 18+.
- Capacity to consent.
- Willingness to participate in hypothetical scenarios and complete a 16-pairwise choice exercise.
- Proficiency in the study language.

Group-Specific Criteria:

- **People with Dementia:** Formal diagnosis and interest in online interventions.
- **Carers:** Actively caring for someone with dementia.
- **Public:** No caregiving role or dementia diagnosis but willing to contribute.

WP2.1 (INCRESE-D Inventory):

- Feedback will be sourced from LEAP and PPI members. No exclusion criteria required as LEAP members have relevant lived or caregiving experience. Data is not collected. Instead, the LEAP group will be asked to collaborate with the research group to develop the criteria for INCRESE-D. This is an involvement activity that requires the expression of opinion.

WP2.2 (The LEND Collection):

- Involves selecting and analysing existing narratives. No exclusion criteria required as LEAP members contribute based on their experiences.

WP2.3 (LEND Intervention Development):
20 participants (10 with dementia, 10 carers) will help design the intervention.
Inclusion Criteria:
General:

- Adults aged 18+.
- Capacity to consent.
- Basic digital skills or willingness to engage with the web application.
- Interest in usability, accessibility, and user experience.

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Specific:

- **People with Dementia:** Mild-to-moderate stage; able to provide structured feedback.
- **Carers:** Experience caring for someone with dementia and insights into digital challenges.
- **The ability to communicate fluently in English**

WP3: Feasibility Study
WP3.1: 60 participants (30 with dementia, 30 carers).
WP3.2: 20 participants (10 with dementia, 10 carers).
Inclusion Criteria for WP3.1 and WP3.2:
General:

- Adults aged 18+.
- Capacity to consent.
- People living with dementia or carers.
- Able to access the internet with/without support.
- Willing to complete (with support) baseline and follow-up questionnaires.
- The ability to understand English and communicate in English
- Able to sustain 30 to 40-minute task activity or interview with/without support.

Please note, sampling Goals: Ensure diverse representation, robust data collection, and alignment with ethical standards.

The inability to comprehend participant information would exclude a participant.

A family carer is defined as “any relative, partner, friend or neighbour who has a significant personal relationship with, and provide a broad range of assistance for, an older person or an adult with a chronic disabling condition (Family Caregiver Alliance, 2019). In this case, that condition would be dementia.

7. 1. 1. Exclusion Criteria

Exclusion criteria ensure participants can meaningfully contribute without distress or undue burden. Several general exclusion criteria apply to all Work Packages:

- Living in hospital or healthcare institution at the time of the study would exclude a potential participant from engaging in the LEND programme.
- Refusal of consent or an unwillingness or inability to provide consent.

WP1.1 (Online (WP1.1O) or Paper (WP1.1P) Survey:

- Severe cognitive impairments preventing capacity to provide informed consent.
- Inability to understand English

WP1.2 (Semi-Structured Interviews):

- Lack of capacity to or declined provision of informed consent.

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- Symptoms, such as poor cognition, preventing meaningful engagement, even with support.
- Inability to communicate in the interview's language
- Emotional or psychological distress when engaging with dementia narratives

WP1.3a & WP1.3b (Narrative Impact Validation):

- Inability to engage with interviews or rating scales, with or without support. For example, having severely poor cognitive abilities.
- Distress caused by engaging with dementia-related narratives.
- Lacking capacity to provide or declined provision of informed consent.
- Inability to access or use narrative formats and associated technology, even with support.
- Impairments that prevent engaging with narrative formats when accommodations are unavailable.

WP1.4 (Focus Group Work):

- Inability to communicate, with no feasible accommodations.
- Lacks capacity to or declined provision of consent.
- Distress caused by engaging with dementia-related narratives.

WP1.5 (Discrete Choice Experiment):

General Exclusions Across Groups:

- Cognitive or emotional impairments preventing meaningful engagement, even with support.
- Lacking capacity to or declined provision of informed consent.
- Inability to understand DCE tasks, despite explanations.
- Significant distress when engaging with hypothetical scenarios.
- Prior participation in similar studies, risking bias.

Group-Specific Exclusions:

- Carers: Minimal caregiving involvement, limiting informed feedback.
- Public: Professional or caregiving experience, aligning their perspective more with carers.

WP2.1 & WP2.2 (INCREASE-D Inventory & LEND Collection):

- No additional inclusion or exclusion criteria as feedback is provided by LEAP members with lived dementia or caregiving experience.

WP2.3 (LEND Intervention Development):

General Exclusions Across Phases:

- Severe cognitive or physical impairments preventing meaningful engagement.
- Distress discussing dementia-related topics.
- Lack of access to required digital devices.

Group-Specific Exclusions:

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- People with Dementia: Advanced stages or lack of capacity/refusal to provide informed consent.
- Carers: Minimal caregiving experience, limiting relevance, refusal to provide informed consent.

Work Package 3.1 (Feasibility Study):

- Lack/refusal of Consent/ lacking capacity to provide ongoing informed consent.
- Technology Barriers: Lack of access to necessary technology without feasible accommodations.
- Sustained Engagement Limitations: Inability to complete outcome measures or interviews via the LEND Portal.

Work Package 3.2 (Long-term Impact of the Online LEND Intervention):

- Lack/refusal of Consent/lacking capacity to provide ongoing informed consent.
- Did not take part in WP3.1

The LEND programme's design ensures diverse and under-served groups are represented while safeguarding participants' well-being and maximizing the quality of their contributions.

7.1.2. Sampling

Recruitment for the LEND programme will utilise multi-source, purposive, and convenience sampling techniques to ensure a diverse and inclusive participant cohort across all work packages and activities. Sampling will be stratified by role and experience, specifically targeting carers (C), people living with dementia (P), and specifically for the WP1.5, the Discrete Choice Experiment, members of the general public (G) will also be identified. A focus throughout will be to focus on recruitment that targets under-represented groups within dementia research.

As already identified in individual work package descriptions, participants will be identified and recruited through a variety of means (see **7.3.0. Recruitment Strategies**). In brief, direct collaboration with NHS partners, including the display of study advertisements in GP surgeries and support from healthcare professionals to raise awareness of the research and distribute the posters, (see **WP1.1 LEND Posters 1-3**). These posters as well as other advertisements, will be used in social media, and community partner websites (additionally, see **LEND General Poster 1-8)**, In addition to this, there will be local engagement within the Nottinghamshire region, including visits to dementia cafes, support groups and social prescribing networks to provide talks about the research to support engagement with the programme. Third-sector organisations, including the Alzheimer's Society, Age UK, and the Centre for Ethnic Health Research, which will assist in promoting the study to a wide demographic, with particular emphasis on under-served communities. **LEND General Posters 1-8** will be used to support this.

For WP1.2 onwards, the Join Dementia Research (JDR) database will be utilised (www.joindementiaresearch.nihr.ac.uk), through which researchers will contact registered

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individuals to discuss potential involvement in relevant work packages, providing appropriate study information and consent documentation.

For WP2.1 and WP2.3, as previously noted in **5.3.0. Work Package 2: Activity 1: INCRESE-D Inventory**, and **5.3.2. Work Package 2: Activity 3: LEND Intervention Development,** members of the Lived Experience Advisory Panel (LEAP) will be directly engaged in co-design workshops alongside the research and development team.
WP3.1, the main feasibility study, although other recruitment methods will be used, the LEND team will focus on recruitment from GP and social prescriber recommendations and referral (see **7.3.0. Recruitment Strategy**).

Across all work packages, specific emphasis will be placed on recruiting individuals from minority and under-served populations, including but not limited to Black, Asian, and other ethnically minoritised communities, and those who identify as LGBTQIA+. Representation from these groups is essential to ensure that the LEND intervention is inclusive, culturally sensitive, and applicable to the full diversity of individuals affected by dementia. This approach aligns with NIHR guidance and the UKRI/MRC guidance on diversity in research design (2022). Hence, it seeks to reduce health inequalities by addressing structural barriers to participation and inclusion in research.
For further detail on recruitment pathways and engagement strategies see **7.3.0. Recruitment Strategies.**

7. 2. 1. Sampling Targets

The sampling strategy for this study includes specific participant requirements across different work packages (WPs), as outlined below:

- **WP1.1 (Online or paper survey)**: A total minimum of 1500 participants are required over the five-year duration of the programme, comprising of people with a diagnosis of dementia and carers, with at least 300 people from each identified under-served groups.
- **WP1.2 (Semi-structured interviews)**: A total of 30 participants are required, comprising 15 individuals with a diagnosis of dementia and 15 carers.
- **WP1.2a & WP1.2b (Narrative impact validation)**: This phase requires 40 participants, including 20 individuals with a diagnosis of dementia and 20 carers.
- **WP1.4 (Focus Group Work)**: 40 new participants are required, as feedback will be gathered from four focus groups, containing 10 participants. This can be a mix of people living with dementia or carers.
- **WP1.5 (Discrete Choice Experiment)**: A total of 30 participants will be recruited, including 10 individuals with a diagnosis of dementia, 10 carers, and 10 members of the public.
- **WP2.1 (INCREASE-D Inventory)**: Feedback will be sourced from LEAP and PPI members, with no additional participants recruited.
- **WP2.2 (The LEND Collection)**: No new participants are required, as this work package will involve the selection and analysis of existing narratives, for which all relevant ethical and legal permissions will be obtained.

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- **WP2.3 (LEND Intervention Development)**: This will involve 20 participants, including 10 individuals with a diagnosis of dementia and 10 carers.
- **WP3.1**: 60 participants, divided into 30 individuals with a diagnosis of dementia and 30 carers.
- **WP3.2**: 20 participants (that took part in WP3.1) will be recruited, with 10 individuals with a diagnosis of dementia and 10 carers.

These sampling targets ensure robust data collection across each stage, aligned with ethical standards and methodological rigor.

7. 2. 2. Sampling Techniques

Non-probability sampling techniques will be employed throughout WP1 and in WP2.3, focusing on equality and diversity inclusion (please see **Section 7: Sample and Recruitment**, and corresponding document, **LEND Equality Impact Assessment**).

The DCE outlined in WP1.5 will recruit 10 people with dementia, 10 carers and 10 members of the public. This will be stratified for previous online therapeutic intervention use (not limited to dementia) and we will use a stepwise qualitative approach (focus groups) to develop our attributes and levels for the DCE pilot the acceptability of a 16 pairwise choice exercise in each of the three groups.

The feasibility study outlined in WP3.1 will employ a process of probability sampling and will randomly assign participants to either the intervention or control group in the two. From this feasibility group, 10 people with dementia and 10 carers will be chosen to undertake a semi-structured interview from the intervention arm of the study. Potential participants will only be eligible to take part in WP3.1 if they agree to be interviewed during WP3.2.

Corresponding document: LEND Equality Impact Assessment

7. 3. 0. Recruitment Strategies

Recruitment of non-English-speaking participants will occur only within WP1.4 focus groups, facilitated by the Centre for Ethnic Health Research. All other Work Packages will recruit English-speaking participants only

Participant recruitment for the LEND programme will involve a multi-method approach to ensure inclusivity, broad reach, and representation from under-served and diverse communities. Recruitment will take place through the following mechanisms:

- **Third Sector and Community Organisations (including NGOs)**
  Recruitment will be supported by engagement with third sector and community-based organisations, including Black Majority Churches, mosques, community centres, and other places of worship and communal gathering. The research team will liaise with these organisations to explore appropriate and culturally sensitive methods of dissemination (e.g., attendance at community events or group meetings by a researcher). Interested individuals will be provided with a Participant Information Sheet

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(PIS), either in person or electronically, and encouraged to make direct contact with the research team if they wish to take part. No personal details about potential participants will be shared with the research team by the third-party organisation. All participants will be given sufficient time to consider the study, ask questions, and provide informed consent if they wish to participate.

Posters will also be displayed in these settings where appropriate, (see **LEND General Poster 1-8**). Potential participants will contact LEND (contact details will be clearly displayed on all posters) and LEND Booklet, the Participant information Sheets (PIS) and consent forms will ensure clarity regarding which aspect of the study is being promoted and provide the person with time to consider their involvement. Posters will be distributed in a staged fashion over the course of the study to avoid overlap or confusion.

- **Peer Support Groups**
  Recruitment will also occur through existing peer support mechanisms, such as dementia cafés (including Alzheimer's Society's *Singing for the Brain*), and NHS-organised service-user groups facilitated by Nottinghamshire Healthcare NHS Foundation Trust.

  A member of the research team will attend selected sessions to present the LEND programme and distribute relevant PISs as well as the LEND Booklet. Attendance will be pre-agreed with group facilitators, and individuals will be invited to contact the team directly if they wish to participate.

- **Primary Care and NHS Networks**
  Posters will be placed in GP surgeries across Nottinghamshire, subject to site approvals. The NIHR Research Delivery Network (RDN) has been approached for support, and formal application for site network approval is underway. LEND GP-specific posters (see **WP1.1 Poster 1**, **WP1.1 Poster 2, WP1.1 Poster 3, LEND General Posters 1-8** and **WP3.1 LEND GP Poster),** have been developed and will be provided to practices and social prescribing teams.
  In addition, both GPs and Social Prescribers will be asked to identify people and approach them, to ask them if they would like to engage with the research. If it is agreed, the LEND Participant Information pack will be provided (consisting of the LEND Booklet, PIS and consent form). As above, no personal details about potential participants will be shared with the research team by third-parties.

- **LEAP and PPI Groups**
  LEND will utilise existing Patient and Public Involvement (PPI) networks and the Lived Experience Advisory Panel (LEAP). Researchers will present the study at relevant meetings to raise awareness, seek feedback, and invite members to share study details within their own networks or via social media. PISs and posters will be disseminated appropriately.

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- **Online Communities and Digital Platforms**
  Recruitment will be supported through online forums and social media platforms. Moderators of relevant forums will be contacted to seek permission to share study posters and information. Where possible, a member of the research team may also attend virtual support groups or Q&A sessions. The project will be advertised via:
  Social media platforms
  The dedicated LEND website (in progress): www.dementianarrative.org
  The Join Dementia Research (JDR) database (www.joindementiaresearch.nihr.ac.uk), where interested individuals will be contacted directly by members of the research team to discuss eligibility for current activities.
  NHS Trust websites, dementia newsletters, and journals
  Posters placed in community and clinical settings (as noted above)

All promotional materials clearly state how individuals can contact the team and what to expect next.

Upon receipt of an enquiry, a trained member of the research team will contact the prospective participant using their preferred mode of communication (e.g. telephone, email, or video call). During this initial conversation, the researcher will provide an overview of the LEND programme and assess which Work Package (WP) or activity is most appropriate, based on the current phase of the study, relevant inclusion and exclusion criteria, and individual preferences. Where multiple participation options are suitable, prospective participants will be given the opportunity to choose between them, with clear information provided regarding time commitments and expectations.

7. 3. 1. Informed Consent

People who do not have capacity to consent will not be able to participate in this study. Initial awareness of the LEND study will be generated through the recruitment strategies, social prescriber or professionals within clinical settings, as detailed in **7.3.0. Recruitment Strategies**. Interested individuals will be invited to make first contact with the research team via one of the following methods:

- **In person**: For example, following a researcher's attendance at a community or peer-support group event.
- **Via telephone or email**: Following responses by potential participants to promotional materials or direct communication through approved channels such as the Join Dementia Research (JDR) database (www.joindementiaresearch.nihr.ac.uk).
- **Via online access:** Using a web link or QR code to access the LEND Portal and register

At the point of first contact, the research team will assess initial eligibility using inclusion and exclusion criteria. Participants will be given the opportunity to ask questions about the study.

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For the majority of study components, excluding WP1.1O, WP2.3, and WP3.1, the Participant Information Sheet (PIS) and consent form will be sent using the participant's preferred method of communication. A minimum 48-hour period will be observed before any follow-up, in line with best practice to ensure informed consent. Thereafter, participants will receive up to six weekly reminders to support their decision-making. If no response is received within six weeks, the individual's contact details will be securely deleted in accordance with data protection procedures.

WP2.3, and WP3.1 will adopt a fully online consent and recruitment model, whereby the PIS and consent materials are hosted on the LEND digital platform. Participants are able to review all relevant study information and provide electronic consent through a secure web-based process. The contact details of the LEND research team are clearly displayed on the platform, allowing prospective participants to reach out directly with any questions prior to completing the consent process. As previously outlined, WP1.1O (hosted by the Trusts server) will store responses directly on the Trusts secure IT environment, as the survey is anonymous, participants don't need to provide consent. However, individuals who want to express an interest in taking part in later work packages can, if they so choose, complete a separate MS Forms document to leave their names and contact details. These data will also be stored directly within the Trust's secure IT environment. For WP2.3 and WP3.1 (hosted by the University of Nottingham secure IT environment), which involved the development of the Online LEND Intervention, consent information will be stored within the University of Nottingham's secure IT environment. All data collected via the LEND platform, including consent data, will be securely transferred to the Trust's secure IT environment at the end of the work package.

All personal contact data provided by individuals expressing an interest in the study will be stored in a secure spreadsheet, maintained within the Sponsor's protected IT environment. Access will be strictly limited to authorised research team members with a legitimate operational need, as identified on the site delegation log. Contact information will be deleted under the following conditions:

- If no consent form is returned within six weeks of issue (for non-digital WPs),
- If the individual communicates that they do not wish to proceed,
- If the individual consents but is subsequently unable to participate (e.g. due to closure of a relevant recruitment phase).
- If a participant doesn't verify their LEND user account within six week of being provided with the verification code.
- Where participants have expressed an interest taking part in the study but are not subsequently recruited, their personal data will be destroyed when recruitment to a specific phase (if a specific phase has been indicated by the potential participant) or the study as a whole has closed.

All remaining contact data will be securely destroyed at the end of the study in line with ethical approvals and data governance requirements.

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In line with MRC/UKRI (2022) guidance on diversity in research, the LEND study is committed to recruiting participants from under-served groups, including ethnic minority communities and LGBTQIA+ individuals. This approach is essential for ensuring that the intervention is culturally appropriate, accessible, and responsive to diverse needs.

As part of WP1.4, participants will be recruited from existing community focus groups coordinated by the Centre for Ethnic Health Research. These groups include individuals living with dementia who may speak English as an additional language or not at all. Recruitment will be facilitated by trusted group leads, and interpreters will be available as needed to ensure understanding of the PIS, consent process, and study activities. All participants will receive language support appropriate to their needs to facilitate equitable participation.

No research activities will be undertaken until written informed consent has been accepted (online) or received (paper or emailed digital versions). Consent forms completed via the LEND platform will be stored in a secure location within the University of Nottingham's IT environment for the duration of the research study. At the end of the study, all study data, including the completed consent forms, will be securely transferred to the sponsor for archiving. No study data will be retained by the University of Nottingham after the end of the study. All other completed consent forms and documentation will be uploaded directly to a secure and encrypted Nottinghamshire Healthcare NHS Foundation Trust server. Access to completed consent forms will be restricted to the PM, the sponsor and associated delegates for the purpose of research governance auditing.

7. 3. 2. Consent and Capacity

The LEND programme will only include individuals who are able to provide informed consent in accordance with the principles of the Mental Capacity Act 2005. As such, capacity to consent is a prerequisite for participation. All prospective participants will be explicitly informed that they must be able to:

- Understand the nature, purpose, and requirements of the study;
- Retain the information provided;
- Weigh the potential risks and benefits;
- Communicate their decision voluntarily.

In-person consent will involve an informal assessment of capacity that will be conducted by trained members of the research team at the point of first contact and prior to any consent being obtained. This assessment will follow an observational and conversational approach based on established ethical guidance and will be documented where appropriate. If concerns are raised about a prospective participant's ability to provide informed consent, they will not be enrolled in the study.

In situations where consent is obtained remotely (e.g. via Microsoft Teams using an NHS account), the following procedures will apply: The Participant Information Sheet (PIS) and consent form will be shared with the prospective participant in advance, either via post or email, depending on their preference. During the scheduled video meeting, the researcher will

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recap key elements of the study, including its aims, procedures, time commitment, risks, and rights to withdraw, and will allow time for questions and clarification. Informed consent will be recorded using one of the following approved formats:

- Typing the participant's name as an electronic signature on the digital form;
- Returning a scanned or photographed image of the signed consent forms via email;
- Returning a signed paper copy by post, which will be scanned and securely stored by the research team.

Scanned and returned copies will be uploaded directly to the relevant consent file within a password protected folder, held within the Trust's secure IT environment.

The online consent process includes an embedded capacity assessment (WP1.10, WP2.3, WP3.1), which will be obtained via a secure, web-based system hosted on the Trust's (WP1.1O) or the University of Nottingham's (WP2.3 and WP3.1) secure IT environment. The PIS will be presented in an accessible format on the LEND platform, accompanied by contact details for the research team, enabling participants to ask questions before proceeding.

In line with Nottinghamshire Healthcare NHS Foundation Trust SOPs, NIHR guidance on digital consent, and UK GDPR requirements, a digital capacity screening tool will be embedded into the LEND registration process. Online consent will ask participants a brief series of questions to assess their understanding of the study, including its purpose, what participation involves, and the voluntary nature of involvement; their responses to those questions won't be recorded. Only individuals who demonstrate sufficient understanding will be able to progress to the digital consent stage.

Consent data will be securely captured, time-stamped, and stored within the University's encrypted digital infrastructure for WP2.3 and WP3.1. A detailed audit trail will document each step of the consent process for governance and quality assurance purposes.
Participants will be informed that they may withdraw from the study at any time without giving a reason and without any impact on their care or services. Instructions for withdrawal will be clearly included in all participant-facing materials.

All consent procedures, whether in person, remote, or digital, will be implemented in accordance with:

- Nottinghamshire Healthcare NHS Foundation Trust Standard Operating Procedures (SOPs),
- UK GDPR and the Data Protection Act 2018,
- The UK Policy Framework for Health and Social Care Research, and
- Guidance issued by NHS Research Ethics Committees and the NIHR.

7. 4. 0. Data Management

Please refer to the **LEND Data Management Plan for Work Packages 1 to 3** for more detailed explanations of data management throughout WP1 to WP3.

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7. 4. 1. Consent Information

The principles outlined below reflect the overarching data governance strategy for the LEND programme and ensure full compliance with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and Nottinghamshire Healthcare NHS Foundation Trust's Standard Operating Procedures (SOPs).

Prior to formal consent, only minimal personal data will be collected for the purposes of communication and follow-up. This includes:

- Full name
- Contact information (email address, telephone number, and/or postal address)
- Preferred method of communication

These data will be stored in a secure, encrypted location within the Sponsor's IT environment and accessible only to the Chief Investigator (CI) or authorised delegates listed on the study delegation log. The data will be used exclusively to provide potential participants with the relevant Participant Information Sheet (PIS), consent forms, and to facilitate follow-up discussions.

If an individual does not proceed to consent, follow-up contact will occur no sooner than 48 hours after the initial invitation and will continue at weekly intervals, for up to six weeks. If no response is received within this period, the individual's contact details will be permanently deleted. All pre-consent data will be securely destroyed in accordance with Sponsor data retention policies, and no further contact will be made.

All completed consent forms, which include identifiable personal data, will be retained by the Sponsor for a period of five years following the end of the study in line with standard archiving policies.

Personal data relating to participants who provide consent via the LEND portal and who subsequently don't verify their LEND user account will be destroyed six weeks after the verification code is sent to them.

7. 4. 2. Pseudonymisation

The LEND programme WP1-3, requires the collection and processing of personal data over multiple timepoints and to support the integrity of longitudinal analysis. As such, participants involved in these activities will be assigned a Unique Identifier Code (UID), (Table 2). The UID will enable the accurate linkage of participant data across timepoints while supporting the principles of data minimisation and confidentiality.

Table 2: Unique Identifier Codes (UIDs) used within the LEND Programme WP1-3

Unique Identifier Codes (UIDs) used within the LEND Programme WP1-3

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Work Package (WP)	Purpose of UID	UID Use Case
WP1.3a & WP1.3b	To link data from reflective interviews at two timepoints and follow up calls for thematic analysis and to ensure data consistency across activities.	Repeated measures, longitudinal data linkage, pseudonymisation.
WP2.3	To support development and testing of the Online LEND Intervention while tracking usability metrics.	Prototype development, usability feedback
WP3.1	To link user registration, outcome measures, and engagement data over time (e.g. baseline and 6-month follow-up).	User account management, data analysis, pseudonymisation, follow-up monitoring.
WP3.2	To link interview data at 12 and 18 months post-randomisation while maintaining confidentiality during transcription and analysis.	Interview tracking, data quality assurance, pseudonymisation.

7. 4. 3. Digital Recording and Transcription

Interview data will be collected through digital audio recording using Sponsor-approved devices (e.g. Olympus DS9000) or via the NHS Microsoft Teams platform. Olympus recordings will be securely transported by hand to the Institute of Mental Health (IMH) as soon as practicable after the recording. These files will be uploaded to a secure Sponsor server or secure server operated by the University of Nottingham, after which the original recordings will be deleted from the device.

Recordings made via MS Teams will be saved directly to a secure location within the Sponsor's IT environment and accessed via Sponsor-approved, encrypted laptops. No data will be saved to local hard drives. All recordings, regardless of collection method, will be permanently deleted once the accuracy of the associated transcript has been verified. Transcripts will remove all directly identifiable information and be stored in a restricted-access, encrypted area of the Sponsor's IT environment. Only authorised research personnel will have access to these data. Transcripts will be used for qualitative analysis using NVivo software. Where applicable, hse transcripts will have a UID so they can be linked with portal and intervention usage, outcome data and demographic data, and any other data collected from follow-up phone calls. The pseudonymisation keys to reidentify the participants will be destroyed once data has been linked at the end of the corresponding work package.

Only anonymous data may be securely transferred for analysis to collaborators at the University of Nottingham (all WPs), University of Bournemouth (WP1.1O and WP1.1P), and the University of West London (WP1.2 and WP3.2). No personally identifiable data will be

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transferred. Data transfers will be conducted via password-protected Sponsor email accounts, with appropriate safeguards in place.

Research findings derived from these analyses will be sufficiently anonymised for dissemination through internal reports, academic publications, and conference presentations in accordance with ethical approvals.

7. 4. 5. Optional Future Contact

Participants will be given the opportunity to opt in to future contact for LEND-related research. Where optional consent is provided, individuals will be asked to supply their preferred contact method (e.g. email address, telephone number, or postal address). These data will be stored in a separate, password protected encrypted database within the Sponsor's secure IT environment, distinct from both research data and any pseudonymisation keys, and accessible only to the CI or authorised members of the LEND team as identified on the site delegation log.

7. 4. 6. Data Collection Within the LEND Portal

Participants in WP2.3 and WP3.1 may interact with the LEND Portal, and/or the Online LEND Intervention, a secure, university-hosted digital platform. In WP2.3, fictional test accounts will be used to support the iterative development of the Online LEND Intervention. These accounts will only be available to members of the LEAP and the research team and they will not contain real or identifiable participant data.

In WP3.1, participants will be required to create a LEND user account using their names, email addresses and mobile telephone numbers. They will have the option to provide demographic data which will be linked to their LEND user account. The user names will be the participants' email addresses and as such, may contain directly identifiable data. When a LEND user account has been verified, the LEND system will automatically allocate a UID. He UID will be linked to the user account details and accessible to authorised members of the research team only via the back-end portal.
As this study is explorative and developmental, profile data will either be pseudonymised, anonymised or deleted, as appropriate, in line with data minimisation principles and described in the relevant PIS. All data collected via the LEND Portal and the Online LEND intervention will be processed in compliance with the UK GDPR, Data Protection Act 2018, and institutional digital governance standards.

7. 5. 0. Data Governance, Access, and Oversight

All data will be collected, processed, and stored in accordance with Nottinghamshire Healthcare NHS Foundation Trust's SOPs, the UK GDPR, and the HRA's guidance on non-CTIMP research. Only data that are necessary, proportionate, and justified for the approved research purposes will be collected.

The Chief Investigator will act as Data Custodian, with oversight for all data handling practices. All members of the research team will receive training in information governance,

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data protection, and ethical handling of participant data. Information governance training will need to be successfully refreshed annually by all members of the research team who have access to personal data. Data will only be used for purposes detailed in this protocol and in the approved participant-facing materials.

Upon completion of the study, all data held by the University of Nottingham will be securely transferred to the Sponsor's IT environment for long-term archiving. No study data will be retained by the University following this transfer.

The Chief Investigator or delegate will act as Data Custodian for all research data generated during the study. Data access, storage, and processing responsibilities will be clearly documented in the delegation log. The Trial Master File, held on secure Sponsor servers, will contain documentation related to data management, participant tracking, , and audit trails.

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1.0. Right to Withdraw

At first contact, through the Participant Information, and when providing fully informed written consent, participants will be informed that:

- Their participation is voluntary
- They can withdraw their participation at any time without any impact on their care or, where the participant is a carer, the care provided to the person they are supporting.
- The procedure for withdrawal is identified in the Participant Information Sheet or on the online Participant Information.
- If they choose to withdraw their participation, any data shared by them or collected about them up to the point of withdrawal will be retained and may be used, but no further data about them will be collected.

At no point during the LEND programme will a participant be obliged to provide their personal narrative (personal stories).

8.1.2. Confidentiality

Arrangements for maintaining the confidentiality of research participants, and for the safety and security of their personal data, will be clearly identified on the Participant Information Sheets. Identifiable personal information (whether medical or personal) obtained via the research process will be considered strictly confidential, and disclosure to third parties will be prohibited. Any exceptions to this, which might require the research team to breach confidentiality, will be clearly described on the Participant Information Sheet (for example, if there is a danger to the participant hurting themselves or other people). Further, participants will be informed through the Participant Information Sheet that the Sponsor or delegates may wish to audit identifiable personal information that is held by the study, but that a strict condition of confidentiality will be imposed on them.

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9.0.0. Regulatory Aspects

9.1.0 Ethical and NHS Regulatory Approvals

Prior to commencement, ethical approval will be obtained from an NHS Research Ethics Committee (REC) and governance approval will be sought from the Health Research Authority (HRA) via the Integrated Research Application System (IRAS). No participant recruitment or data collection activities will begin until all appropriate approvals have been received.

All protocol amendments will be submitted for review and approval by the REC and/or HRA as appropriate. Amendments will not be implemented until formal approval has been confirmed.

The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research (2017), the principles of Good Clinical Practice (GCP), the Declaration of Helsinki (1996), and applicable Sponsor Standard Operating Procedures (SOPs).

9.2.0. Ethical Considerations and Risk Management

The inclusion of non-English-speaking participants will be limited to Work Package 1.4 (Focus Groups). This approach is ethically and methodologically justified to balance inclusivity with data integrity. All other work packages will require precise linguistic comprehension to ensure 1) valid development of LEND theory 2) reliable and valid iterative feedback from participants to researchers 3) methodological consistency 4) valid interpretation of outcome measures and 5) minimisation of interpretation bias. Conducting these activities in English ensures increased reliability and validity of findings and avoids the introduction of linguistic or cultural bias at early developmental stages.

Work Package 1.4, however, has been specifically designed to explore accessibility and cultural relevance among under-served and linguistically diverse groups. Inclusion of non-English-speaking participants in this activity only will therefore ensure that the wider LEND intervention is informed by a representative range of lived experiences. Participation will occur only where interpreter support, or where appropriate, a carer acting as interpreter, is available through the Centre for Ethnic Health Research to safeguard understanding, informed consent, and participant welfare.

This targeted inclusion strategy is consistent with HRA and NIHR guidance on equality, diversity, and inclusion, ensuring fair representation while maintaining scientific validity and ethical rigour across the programme.

Other ethical considerations within the LEND programme include ensuring the dignity, autonomy, and well-being of people living with dementia and their carers. It is the well-being of this cohort group that is the ethos underpinning the LEND Programme research. This includes providing clear, accessible information to support informed consent, protecting participants' rights, and ensuring inclusion of under-served voices in a respectful and meaningful way.

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In this context, risk management involves proactively identifying and minimising potential emotional, cognitive, or logistical burdens participants may experience, such as distress from engaging with dementia narratives or challenges related to memory, communication, or daily routines. Safeguards include the use of lived experience advisors, trained researchers, flexible participation options, and clear pathways to support should distress arise. Further, information is clearly stated in the Participant Information Sheets to enable participants to access support, should anything during the research cause distress.

9.2.1. Changes in Informed Consent and Capacity

Only participants with capacity to provide informed consent will be included in this studyConsent will not be sought from individuals who lack capacity, and no personal consultees or legal representatives will be used for consenting purposes. This will be made clear within all participant-facing documents.

Translated participant materials and interpreter support will apply exclusively to WP1.4, with the support from Centre for Ethnic Health Research. For all other Work Packages, study materials and consent discussions will be conducted in English.

To ensure that individuals fully understand the implications of participation, the consent process will be continuous and include checks for comprehension and the use of plain language. This includes digitalised online assessment checks via the LEND Portal. Participants will be reminded of their right to withdraw their participation at any time without consequence.

If a person loses their capacity to consent during the course of the study, they will be withdrawn from the study. Withdrawals will be dealt with on a case-by-case basis, with the final decision for withdrawal being made by the CI or another appropriate person as identified on the site delegation log.

9.2.2. Psychological Distress and Emotional Risk

Given the nature of the study, which involves engagement with dementia-related narratives, there is a possibility of psychological discomfort or emotional distress. To mitigate this:

- Narratives will be pre-screened for emotional sensitivity in collaboration with the Lived Experience Advisory Panel (LEAP).
- Participants will not be obliged to share personal stories, although they may do so by ‘gifting’ them, voluntarily.
- Researchers will be trained in trauma-informed approaches, empathetic communication, and signs of distress.
- Participants will have the option to pause or withdraw from the session at any time without justification.

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- Each session will include a debrief and provision of appropriate support resources, including signposting to national helplines (e.g., Dementia UK, Samaritans) and local services.
- All Participant Information Sheets will include signposting for well-being and mental health support services, referencing their GP, NHS 111 (www.111.nhs.uk), Samaritans (www.samaritians.org) and the Alzheimer's Society Dementia Support Line (www.alzheimers.org.uk).

9.2.3. Burden and Disruption to Routine

To minimise the risk of fatigue, disruption, or inconvenience:

- Study tasks have been designed to be segmented, so they are short and flexible
- Scheduling will be participant-led, emphasising options for remote participation.
- Participants will be encouraged to take breaks when they need to and this has been factored into all research activities.

9.2.4. Technological Barriers

As part of its core aims, the LEND programme seeks to inform the design and development of an online narrative intervention that is both accessible and acceptable to individuals living with dementia and their carers. To achieve this, it is essential to capture the perspectives of participants who may experience challenges in using digital technology. In accordance with principles of equity, inclusivity, and reasonable accommodation, the research team will endeavour to offer appropriate support and alternative modes of participation, where feasible and ethically approved, so that individuals with limited digital confidence are not excluded from contributing to the development process.
For example, within WP1.1, participants may be offered a paper-based, questionnaire-style survey as an alternative to digital participation, where this is deemed appropriate and does not compromise the scientific validity of the study. Across relevant work packages, technical assistance will be made available to participants on an as-needed basis. However, such support will be carefully balanced to avoid inadvertently influencing participants' responses or introducing bias that may affect the reliability of the research findings.

Within WP2.3 and WP3.1, the feasibility and usability of a digital support aid, eBooklet, will be explored. This tool is designed to facilitate inclusive engagement with the Online LEND Intervention, particularly among individuals living with dementia and carers who may lack confidence in using technology or experience a decline in digital literacy over the course of the study. The eBooklet will be evaluated for its role in supporting equitable access to the Online LEND intervention, in alignment with the LEND programme's broader aim to develop a user-centred, ethically robust digital health resource. The eBooklet won't collect or be used to store pseudonymised and/or identifiable data.

All adaptations and support strategies will be implemented in line with ethical approvals, HRA guidance on inclusive research practice, and the UK General Data Protection Regulation, ensuring that no participant is disadvantaged on the basis of digital exclusion.

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9.2.5. Safeguarding and Disclosure

In rare cases where a participant is assessed to be at risk of harm to themselves or others, researchers will follow the safeguarding protocols set out by the Sponsor. This may include breaking confidentiality regarding the disclosure of information to relevant professionals or authorities, as outlined in all Participant Information Sheets and Consent forms.

9.3.0: Table 3: Identified Risks and Mitigation Measures

Potential Risk	Mitigation Strategy
Cognitive/emotional fatigue	Tasks segmented by design; breaks encouraged; continuous monitoring for signs of fatigue; flexible scheduling; researcher training provided.
Emotional distress from narratives	Screening for sensitive content (outlined in the INCRESE-D criteria); informed consent includes narrative overview; opt-out encouraged at any point.
Unintended disclosure of personal experience	Voluntary disclosure only; compassionate interviewing;
Disruption to daily routine	Flexible, participant-led scheduling; remote options; prior discussion of preferred times.
Difficulty using technology	Assessing alternative formats available; technical support identified during development; reasonable adjustments that can be made without compromising research integrity, in line with the Equality Act.
Confusion during consent process	Plain language used in the Participant Information Sheets; comprehension checks; carers consulted where necessary; additional support offered.

9.4.0 Additional Safeguards

Standardised safeguarding strategies have been integrated into all aspects of the LEND Programme, specifically focusing on:

- **Participation discussions**: Unforeseen risk factors identified. Addressed with the CI and Sponsor on a case-by-case basis.
- **LEAP collaboration**: Continuous consultation ensures sensitivity in study design and delivery.
- **Ongoing monitoring**: Real-time observation of participant distress with participants reminded about their ability to pause or terminate any session. LEND researchers will be trained to manage such events in a sensitive, supportive and professional way.
- **Post-task debriefing**: All participants are offered a debrief and post-debrief follow-up communication, which they are reminded, they have authority to refuse or accept this.
- **Researcher training**: All team members will complete bespoke LEND training in ethics, consent, and dementia-sensitive practice.

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10.0.0. Research Ethics Committee (REC) and Other Regulatory Review & Reports

This study will be conducted in accordance with all applicable regulatory and ethical guidelines, including the UK Policy Framework for Health and Social Care Research (2020), the Declaration of Helsinki (2013), Good Clinical Practice (GCP), and the Research Governance Framework for Health and Social Care (2nd ed, 2005).

Favourable ethical opinion will be sought from a recognised NHS Research Ethics Committee (REC), alongside approval from the Health Research Authority (HRA) via the integrated IRAS application system. No participant recruitment or data collection will commence until all necessary approvals have been obtained. Local NHS capacity and capability checks will also be completed as required.

Any non-substantial or substantial amendments to the protocol, including changes to Participant Information Sheets, or other supporting documents, will be submitted to the REC and HRA for approval, following prior review and authorisation by the Sponsor. Amendments will not be implemented until full regulatory approval has been granted. All amendments will be recorded and shared with relevant parties as appropriate.

The LEND research team will comply with all reporting obligations to the Research Ethics Committee (REC) and the Health Research Authority (HRA). This includes:

- Notification of the end of the study within 90 days of planned completion, or within 15 days if terminated prematurely, using the appropriate REC/HRA reporting templates.
- Submission of a final report within 12 months of study completion, summarising study outcomes, key findings, and referencing any related publications or outputs.
- Immediate notification to the REC and HRA in the event of early study termination, including a rationale and any relevant participant safety concerns.

The Sponsor will be informed of all key milestones and will receive copies of all regulatory submissions and amendments to the REC and HRA throughout the study lifecycle.

10.1.0. Regulatory Review & Compliance

This research project will comply with all applicable regulatory, legal, and ethical standards, ensuring full adherence to the governance requirements of Nottinghamshire Healthcare NHS Foundation Trust, acting as Sponsor. The study will be conducted in accordance with:

- Good Clinical Practice (GCP)
- The UK Policy Framework for Health and Social Care Research (2020)
- The UK General Data Protection Regulation (UK GDPR)
- The Data Protection Act 2018
- Nottinghamshire Healthcare NHS Foundation Trust's Standard Operating Procedures (SOPs)

All members of the LEND research team will be required to confirm that they have read and understood the relevant SOPs of the Sponsor organisation, and that they have successfully completed Trust-mandated information governance training (where their role will involve access to pseudonymised and/or identifiable personal data). Furthermore, such individuals will be required to and must successfully refresh the information governance training at least annually.

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Prior to the commencement of any research activity, all required approvals will be obtained, including:

- Favourable ethical opinion from an NHS Research Ethics Committee (REC)
- Approval from the Health Research Authority (HRA)
- Capacity and capability confirmations from all participating NHS organisations

No participants will be enrolled, and no research procedures will begin, until all necessary procedural and ethical approvals are in place.
The Chief Investigator (CI), or an individual with delegated authority as documented in the Site Delegation Log, will be responsible for ensuring compliance with this requirement.
All amendments to the study, both substantial and non-substantial, will be managed in accordance with HRA guidance on categorising amendments. The CI or delegated person identified on the Site Delegation Log, will seek agreement with the Sponsor before submitting amendments to the HRA and/or REC via the HRA Amendment Tool, (as outlined above in section **10.0.0 Research Ethics Committee (REC) and Other Regulatory Review & Report**). This process will be conducted in collaboration with LEND team members (e.g., Programme Manager or Research Associate), and Sponsor review and sign-off will be obtained prior to submission to ensure quality, consistency, and compliance with SOPs.

All amendments will also be discussed at Study Management Group (SMG) meetings. Where appropriate, feedback will be sought from the Lived Experience Advisory Panel (LEAP) and other Patient and Public Involvement (PPI) members to ensure that changes are responsive to participant needs and perspectives. Guidance on the categorisation of amendments for studies involving the NHS can be found on the HRA website.
http://www.hra.nhs.uk/resources/after-you-apply/amendments/
Once approved, amendments will be communicated promptly to all relevant stakeholders, including the Sponsor and any applicable regulatory authorities. Amendment history will be tracked in a version control log to ensure clarity on the most current protocol and associated documents.

The Sponsor will be kept informed of all study activity and will receive regular updates, including audit and monitoring reports, to ensure continued regulatory compliance throughout the duration of the study.

10.2.0 Peer Review
The LEND programme has undergone rigorous peer review in accordance with the standards set by the National Institute for Health and Care Research (NIHR) and the NIHR Clinical Research Network (CRN). This process ensures the study design meets the principles of independence, expertise, and proportionality required for high-quality peer review.
Specifically:

- Independence: The LEND study has been peer reviewed by at least two individuals who are external to the Chief Investigator's host institution and are not involved in the study's development, delivery, or oversight. These reviewers were selected to provide an objective and impartial evaluation of the research proposal.

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- Expertise: Reviewers possessed relevant academic and/or clinical expertise in dementia research, mental health, and qualitative research methodologies. Their feedback contributed significantly to refining the research aims, methodological rigour, and ethical considerations of the protocol.
- Proportionality: Given the scale and complexity of the LEND Programme - comprising multiple work packages, stakeholder engagement, and involvement of under-served populations - a proportionate level of review was applied. This included both national and subject-specific peer review as part of the NIHR funding application process, which included scrutiny by members of the NIHR Research for Patient Benefit (RfPB) Programme Board, external expert assessors, and public contributors.

Full documentation of the peer review process, including reviewer comments and responses, is available upon request and has been submitted to the Sponsor as part of the protocol development and funding approval process. This ensures that the LEND programme meets the NIHR's standards for methodological quality, feasibility, and relevance to patients and the public.

10.2.1. Patient & Public Involvement

The LEND Programme utilises two PPI groups:

1. Existing PPI Group, “Dementia, Frail Older People and Palliative Care” facilitated by the School of Health Sciences at the university of Nottingham. To be addressed twice a year. First address 20th September 2024.
2. Lived Experience Advisory Panel (LEAP) Group (Consists of at least 10 individuals with dementia and/or carers). Support provided from Centre for Ethnic Health Research and LGBT+ support groups. Will meet four times a year. Preliminary meeting with the chair has taken place (16th July, 2024) and three LEAP groups have meet since (14th November 2024 (at Institute of Mental Health, Nottingham); 17th March 2025 (at the Institute of Mental Health, Nottingham) and 31st March 2025 (within the University of West London, London).

All patient-facing documents and the development of the protocol have been approved by either PPI or LEAP members, either as groups or individually via email. Guidance used on involving the public in research can be found on the INVOLVE website.
http://www.invo.org.uk/

10.2.2. Protocol Compliance

The LEND programme, WP1-3, will be conducted in strict adherence to the approved protocol, subject to any future amendments authorised by the Health Research Authority (HRA). Ongoing compliance will be monitored continuously by the CI and those with documented delegated authority, to ensure the study remains aligned with ethical, regulatory, and methodological standards.

Any protocol deviations, non-compliances, or breaches, defined as departures from the approved protocol, will be documented promptly using the appropriate deviation reporting tools (e.g., Protocol Deviation Form). All such instances will be reviewed and reported to the

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Sponsor without delay. In accordance with Good Clinical Practice (GCP), appropriate documentation will also be maintained in the site file, including a File Note to provide contextual information.

Where applicable, deviations may additionally require the completion of an Adverse Event (AE) or Serious Adverse Event (SAE) form, depending on the nature and severity of the incident. All deviations will be assessed for impact on participant safety, data integrity, and ethical compliance, with appropriate corrective and preventive actions implemented as required. In all cases, the Sponsor will be immediately notified.

10.2.3. Data Protection and Patient Confidentiality
The NHS Code of Confidentiality, Nottinghamshire Healthcare NHS Foundation Trust's Policies and Standard Operating Procedures, and GCP guidelines will be adhered to, as will the UK GDPR and the Data Protection Act (2018)

All research staff involved in the study will be appropriately trained, supervised and supported with regards to the collection, storage, processing and disclosure of personal information. Training will be successfully refreshed at least annually. All data will only be used for purposes of the research set out in the participant information sheet and this protocol.

The CI for LEND will act as the data custodian for data generated by this research in addition to those deemed appropriate and documented in the site delegation log.

10.2.4. Indemnity
Nottinghamshire Healthcare NHS Foundation Trust, as sponsor, has indemnity through the Clinical Negligence Scheme for Trusts, to meet the potential legal liability for harm arising from the design and management of the study.

If applicable, participating site must have appropriate insurance in place to indemnify themselves for the conduct of the research study as outlined in this protocol.
There are no special compensation arrangements in place in the event of harm to participants, but trial participants may have recourse to the NHS complaints procedure.

10.3.0. Access to the Final Study Dataset
Only duly authorised members of the research team will have access to all full databases, datasets and link files. Participant recruitment contact information will only be available to LEND researchers involved with recruitment and participant facing activities. Anonymised datasets will be shared via secure and encrypted NHS email to other LEND researchers, including those at the University of Nottingham, at the University of West London and those at the Clinical Trial Unit at the University of Bangor. This will be for the purpose of both randomisation (Clinical Trial Unit at the University of Bangor only) and further analysis.

Upon request, the Sponsor and Funder will have access to the pseudonymised and anonymised datasets. To maintain academic integrity and preserve the rights of the

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investigators, the research team will retain ownership of the dataset and control over its use until the primary findings have been published. This ensures the results are not disclosed prematurely while safeguarding investigator rights to analyse and disseminate the data in accordance with the research objectives.

10.4.0. Dissemination Policy

Findings from data analysis will not contain any individually identifiable information. Once analysed, only anonymised data will be shared with other academic and clinical institutions via presentations disseminated and in publications and press releases. The study results are intended to be disseminated to all key stakeholders, including participants, following the completion of Work Package 3 (WP3). This will be within a 12-month period of completion.

Findings will be periodically shared with the Lived Experience Advisory Panel (LEAP), Patient and Public Involvement (PPI) groups, all advisory and monitoring panels, the sponsor and other relevant groups that have been involved with the LEND Programme. This ensures that all stakeholders are kept informed at key stages of the study. Additionally, the results will be disseminated to under-served groups in a timely, inclusive, and accessible manner.

Dissemination materials will be developed in consultation with LEAP to ensure they are relevant, free of charge, and tailored to the specific needs of these populations.
Upon completion of the study, the data will undergo rigorous analysis and will be compiled into a comprehensive Final Study Report. Dissemination strategies will include co-produced online resources and guidelines, developed in collaboration with LEAP, as well as presentations at academic and professional conferences. A dedicated LEND dissemination event will be organized, and findings will be shared through peer-reviewed publications, articles in professional journals, voluntary sector newsletters, social media channels, and the LEND portal.

Key outputs will involve submitting research manuscripts to high-impact international open-access journals (e.g., British Medical Journal, PLoS Medicine, Lancet Psychiatry, Age and Ageing). Protocols and findings will be published in alignment with reporting standards for quantitative (CONSORT), qualitative (COREQ), and systematic review (PRISMA) methodologies.

The findings will be disseminated nationally and internationally at conferences such as Alzheimer's Europe, the International Psychogeriatric Association, and the European Health Psychology Society. Anonymised results will also be shared through academic publications, practitioner and consumer-focused articles, and tailored presentations for academic, professional, and public audiences.

Intellectual property generated during the project will be managed in accordance with Nottinghamshire Healthcare NHS Foundation Trust policies.

10.4.1. Authorship Eligibility Guidelines and Any Intended Use of Professional Writers

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The final study report will be completed with collective input from the Researchers, the Programme Manager and the Chief Investigator.

Authorship for individual papers should include the relevant members of the LEND team that contribute to the writing and/or analysis of the data. The Chief Investigator and Programme Manager should be listed on all manuscripts as their involvement would be required. The ICMJE criteria on authorship will be followed (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

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12. APPENDICIES

12.1. Appendix 1- Required Documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).
Participant Facing Documents:

- WP1.1O Survey (Online Participant Information and Consent Agreement)
- WP1.1P Paper Survey PIS and Consent Form
- WP1.2 Participant Information Sheets
- WP1.2 Consent Form
- WP1.3a&b Interview Prompt
- WP1.3a&b Participant Information Sheets
- WP1.3a&b Consent Form
- WP1.4 Participant Information Sheets
- WP1.4 Consent Form
- WP2.3 LEND Online Participant Information
- WP2.3 Online Consent Agreement and Acceptance
- WP3.1 LEND Online Feasibility Participant Information
- WP3.1 Online Consent Agreement
- WP3.2 Feasibility Interview Participant Information Sheet
- WP3.2 Feasibility Interview Consent Form
- WP1.1 Poster 1
- WP1.1 Poster 2
- WP1.1 Poster 3
- LEND General Poster 1
- LEND General Poster 2
- LEND General Poster 3
- LEND General Poster 4
- LEND General Poster 5
- LEND General Poster 5
- LEND General Poster 7
- LEND General Poster 8
- LEND Data Management Plan for Work Packages 1 to 3

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12.3. Appendix 2 – Schedule of Feasibility Procedures

WP3.1 & 3.2: Feasibility Procedures	Interaction with Participants				
	Screening	Baseline (BL)	SIx Months (T1)	Post-INT: WP3.2 12 Months (T2)	Post-INT: WP3.2 18 Months (T3)
Informed consent	X		X	X	X
Socio-demographics		X		X	
Outcome Measures via Questionnaire		X	X		
Intervention Arm		X	X	X	X
Control/TAU Arm		X	X		
LEAP / PPI Involvement	X	X	X	X	X

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.
Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

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