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| **Full title of trial** | Assessing the feasibility and acceptability of a training and support intervention for homelessness hostel staff supporting older residents with memory problems: Work package 3 of HOME (Homeless, Older and experiencing MEmory problems) study. |
| **Short title** | Feasibility trial of the HOME intervention. |
| **Version and date of protocol** | Draft Version 0.2 [11/04/23] |
| **Sponsor:** | University College London (UCL) |
| **Sponsor reference number:** | 157693 |
| **Funder (s):** | NIHR Advanced Fellowship (NIHR300844) |
| **IRAS Number:** | 324735 |
| **ISRCTN:** | To be added |
| **UCL Data Protection Number:** | Z6364106/2023/02/35 |
| **Intervention:** | Non-randomised feasibility trial of training intervention |

## PROTOCOL VERSION HISTORY

| Version Stage | Versions Number | Version Date | Protocol updated & finalised by; | Reasons for Update |
|---|---|---|---|---|
| Current | 0.2 | [11.04.2023] | Dr Penny Rapaport Chief Investigator | |
| Previous | 0.1 | [01.12.2022] | Dr Penny Rapaport Chief Investigator | Sponsor initial review |
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## DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

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

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) 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. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

**Chief Investigator: Signature:**  **Date 11/04/23**

**Print Name (in full): Dr Penny Rapaport**

**Position: Principal Research Fellow / chief investigator**

**On behalf of the Study Sponsor:**

**Signature: Pushpsen Joshi Date27.04.23**

**Print Name (in full): Pushpsen Joshi**

**Position: Research Governance Officer**

## STUDY SUMMARY

| IDENTIFIERS | |
|---|---|
| IRAS Number | 324735 |
| REC Reference No. | |
| Sponsor Reference No. | 157693 |
| Other research reference number(s) (if applicable) | Z6364106/2023/02/35<br>To add ISCTRN |
| Full (Scientific) title | Assessing the feasibility and acceptability of a training and support intervention for homelessness hostel staff supporting older residents with memory problems: Work package 3 of HOME (Homeless, Older and experiencing MEmory problems) study. |
| Health condition(s) or problem(s) studied | Dementia, memory problems, homelessness. |
| Study Type i.e. Cohort etc | Mixed-methods Intervention study. |
| Aim(s): | To test the feasibility and acceptability of a co-produced staff intervention to support older people with memory problems living in hostel accommodation. |
| Objectives: | **Primary objectives**<br>Phase one:<br>To assess whether the HOME intervention is feasible to deliver and acceptable to staff recipients in practice.<br>Phase two:<br>To obtain acceptability and feasibility estimates to inform continuation to a cluster randomised controlled trial (RCT) testing clinical and cost-effectiveness. Specifically, to test whether a priori progression criteria are met for the proportion of participants offered the intervention adhering to it and of eligible participants agreeing to trial participation (detailed below under trial design).<br>**Secondary objectives**<br>Phase two:<br>- To obtain estimates required for main trial's sample size calculation for primary outcomes, having confirmed a meaningful and practical primary outcome.<br>- To use economic measures to consider their feasibility in a full RCT and to calculate intervention costs. |

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| | - To conduct a mixed-methods process evaluation to assess intervention acceptability and required refinements. |
| Type of trial: | Pre-pilot study (Phase one) and non-randomised multi-site feasibility trial (Phase two). |
| Trial design and methods: | Phase one:<br><br>A single pilot of the co-produced six-session HOME intervention in one hostel delivered over three months followed by a three month 'implementation period'. We will hold a qualitative focus group at the end of the three-month HOME intervention and conduct a brief semi-structured interview with participating staff at 6 months. The intervention will be refined based on findings from the pilot.<br><br>Phase two:<br><br>A non-randomised feasibility trial of the six-session HOME intervention followed by a three-month implementation period. We will inform feasibility and test procedures by collecting validated clinical and cost-effectiveness measures planned for a full trial at baseline and at six-months from participating hostel staff and residents. We will keep records of eligible referrals, consent, intervention attendance and losses to follow-up to inform intervention adherence and acceptability of measures.<br><br>We will complete qualitative interviews, with 8-10 hostel workers who received the intervention and their managers using a semi-structured interview guide and we will audio record intervention sessions to assess facilitator fidelity to the intervention. |
| Trial duration per participant: | Seven months |
| Key Study milestones | Study submission (1st February 2023), finalisation of intervention for initial testing (1st June 2023), training of researchers (1st July 2023) Phase one: first participant recruitment (1st August 2023), end of recruitment (1st October 2023), end of intervention delivery (1st January 2023), end of follow-up (31st January 2024); Phase two: first participant recruitment (1st February 2024), end of recruitment (31st January 2025), end of intervention delivery (1st April 2025), end of follow-up (1st July 2025); final qualitative interviews (1st August 2025) project write up (31st Feb 2026). |
| Estimated total trial duration: | 24 months - 1st August 2023 (First participant recruited) 1st August 2025 (Final qualitative interview and follow up completed). |

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| Planned trial sites: | Multi-site (Sites will be participating third sector homelessness hostels with residents aged fifty and over in London and southern England). |
| Total number of participants planned: | Phase 1: 6-8 hostel staff (Max n=8)<br>Phase 2: 40 hostel staff and 40 older hostel residents with memory problems<br>Total n=88 |
| Main inclusion/exclusion criteria: | **Inclusion criteria**<br>Hostel staff:<br>• 18 years or older.<br>• Providing direct support to some residents with memory problems.<br>• Working any weekday, daytime shifts.<br>• Willing and able to give written or audio recorded informed consent.<br>• Able to understand spoken English.<br>Hostel residents:<br>• Aged 50 years or over.<br>• A recorded diagnosis of dementia.<br>• a score of ≥2/6 on the Noticeable Problems Checklist proxy measure (indicative of significant memory disorder).<br>**Exclusion criteria**<br>• Staff planning on leaving work within the hostel within six months.<br>• Residents with memory problems known to be moving on within the next three months. |
| Statistical methodology and analysis: | Baseline data will be summarised using means (with standard deviations (SD)), medians (with interquartile ranges), counts and proportions, as appropriate, to describe characteristics. We will produce a consort diagram to describe the flow of participants through the trial and consider potential bias arising from dropouts and losses to follow-up.<br>1. We will calculate the proportion of staff adhering to the intervention (attending a predetermined number of sessions) with 95% confidence interval.<br>2. The EuroQol 5 dimension 5 level (EQ-5D-5L), Sense of Competence in Dementia Care Staff (SCIDS) and Maslach Burnout Inventory (MBI) scores will be summarised to provide distributional information and |

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| | obtain estimates of SDs, and correlation needed for main trial's sample size calculation.<br><br>3. Referral rates, drop-out and loss to follow-up rates will be calculated with 95% confidence interval.<br><br>4. Other staff and resident outcome data will be summarised using appropriate estimates with 95% confidence interval.<br><br>To calculate the unit costs of intervention delivery we will include: the hourly cost of training and supervising facilitators; hours spent by facilitators delivering training and supervision in hostels; hours spent by staff engaging in the intervention; capital travel and materials costs; and numbers of residents supported. We will calculate service use for people with memory problems with data collected using the Client Services Receipt Inventory (CSRI). |
| FUNDING & OTHER | |
| Funding | National Institute for Health and Care Research (NIHR) Advanced Fellowship (NIHR300844) |
| Other support | Research support from Professor Gill Livingston (UCL Division of Psychiatry) Professor Jill Manthorpe (King's College London, NIHR Health & Social Care Workforce Research Unit), Dr Caroline Shulman (UCL Division of Psychiatry) & Professor Martin Knapp (Department of Health Policy and Care Policy and Evaluation Centre) London School of Economics and Political Sciences and Dr Julie Barber (UCL Department of Statistical Sciences) |
| KEY STUDY CONTACTS | |
| Committees | The trial management group will include Dr Penny Rapaport, Chief Investigator, Dr Caroline Shulman (UCL Division of Psychiatry), Professor Gillian Livingston (UCL Division of Psychiatry), Gareth Davies and Peter Bull (PPI) and recruited UCL project staff. An Independent trial steering committee will be convened ahead of phase 2. |
| Sub-contractors | N/A |
| Other relevant study personnel | UCL is the data controller and Dr Penny Rapaport is the data processor. The data protection officer at UCL can be contacted at data-protection@ucl.ac.uk |

## KEY ROLES AND RESPONSIBILITIES

**SPONSOR:** The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

**FUNDER:** The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

**CHIEF INVESTIGATOR (CI):** The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

**PRINCIPAL INVESTIGATOR (PI):** Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

**OTHER:** Research supporters will contribute to the overall conception and design of the study and will contribute to the project management meetings.

## TRIAL PERSONNEL

*See protocol cover page for Chief Investigator and Sponsor contact details*.

| | |
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| **Research Assistant** | Name: Garrett Kidd<br>E-mail: G.Kidd@ucl.ac.uk<br>Tel: [tel no.] |

## KEY WORDS

Memory problems, dementia, homeless, intervention, feasibility

## LIST OF ABBREVIATIONS

| | |
|---|---|
| AE | Adverse Event |
| APR | Annual Progress Report |
| CFIR | Consolidated Framework for Implementation Research |
| CI | Chief Investigator |
| CRF | Case Report Forms |
| CSRI | Client Services Receipt Inventory |
| DADS | Disability Assessment for Dementia scale |
| EQ-5D-5L | EuroQol 5 dimensions 5 level |
| GDPR | General Data Protection Regulation |
| HOME | Homeless, Older and experiencing MEmory problems |
| HRA | Health Research Authority |
| IPR | Intellectual Property Rights |
| ISF | Investigator Site File |
| MBI | Maslach Burnout Inventory |
| NIHR | National Institute for Health and Care Research |
| NPC | Noticeable Problems Checklist |
| NPI-Q | Brief Neuropsychiatric Inventory Scale |
| NRES | National Research Ethics Service |
| PI | Primary Investigator |
| PIS | Participant Information Sheet |
| PPI | Patient and Public Involvement |
| PR | Penny Rapaport |
| QoL | Quality of Life |
| RCT | Randomised Controlled Trial |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SCIDS | Sense of Competence in Dementia Care Staff |
| SD | Standard Deviation |
| SOP | Standard Operating Procedure |
| TBI | Traumatic Brain Injury |
| TMF | Trial Master File |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |

## Contents

# 1. INTRODUCTION

This protocol describes work packages three and four of the HOME (Homeless, Older and experiencing MEmory problems) study. It builds on findings from work package one, an in depth qualitative and ethnographic of the lived experiences of older (aged fifty years and over) people who are homeless and living with memory problems. The findings of work package one have been used in stream two to inform the co-production of a support intervention for staff working with older people with memory problems living in hostel accommodation with experts by experience, staff working with older people living in hostels, professionals and academics. In this study (work packages three and four) we will initially assess whether the HOME intervention is feasible and acceptable to deliver in practice (phase one) then test this intervention in a non-randomised feasibility trial and conduct a process evaluation (phase two).

The primary intended output from this research is a feasible, acceptable and reproducible co-produced intervention, with potential to improve (a) support for people living with memory problems and (b) their quality of Life (QoL) and functioning and successful transition to a suitable and settled home. Having embedded stakeholder involvement and implementation throughout, we aim to deliver:

- An evidence-based intervention (product and procedure):
    - Manualised training package
    - Practice guidelines
    - Implementation tools
    - Training materials
- Grant application for full Randomised Controlled Trial (RCT) (if feasible and acceptable)
- Peer-reviewed publications.
- Evidence-based policy briefings and recommendations

To facilitate this research, we are collaborating with a range of homelessness service providers, policy makers, academics and practitioners who are committed to supporting the project (see Figure 1). The study is funded by the NIHR and hosted and sponsored by UCL. Patient and public involvement with people with lived experience of homelessness and dementia will be embedded throughout.


Figure 1: HOME project collaborators

## 1.1 The HOME intervention

Based upon previous experiences of co-producing dementia care and support interventions (1, 2), we have convened a coproduction group with user, professional and research membership. We are collaborating with these multiple stakeholders (3, 4) to ensure the acceptability of interventions in diverse settings (5, 6). We have engaged stakeholders, including experts by experience, third sector organisations providing hostel accommodation, homelessness service commissioners, clinicians and professionals, policy makers and have met for two face-to-face and two online co-production workshops to develop the intervention (this work is ongoing, and a summary of the draft intervention is included below). Preliminary work and work package one outputs have informed the process, content and form of the intervention; the exact content and mode of delivery will be finalised in future co-production workshops (completed by April 2023) and revised iteratively based on discussion.

The findings from our qualitative study exploring stakeholder perspectives on the care and support needs of older people experiencing memory problems and homelessness (London (Brighton and Sussex) National Research Ethics Service (NRES) ref: 21/LO/0541) highlighted key themes (Manuscript under peer review). We identified how older people experiencing homelessness and memory problems and those supporting them often feel that their needs are not taken seriously and staff feeling they do not get listened to when advocating for those in their care. Additionally, those interviewed described how it was difficult to 'see the wood for the trees' regarding the underlying causes of memory and cognitive problems in those experiencing homelessness and as such knowing how best to respond and support individuals to move on to suitable, settled accommodation. Those with memory problems and living in hostel accommodation experienced intense social isolation and extreme vulnerability. Staff providing support required flexibility and persistence, with staff moving

beyond traditional roles to advocate, provide care and safeguard individuals. Staff interviewed also highlighted content that they felt should be included in the support intervention. These included the possible causes of memory problems and exacerbating factors such as alcohol use, recognising memory and other cognitive problems, how to respond and support functioning, understanding difficult behaviour, communicating with people with memory problems, understanding and assessing capacity and safeguarding and how to access support more effectively. They also highlighted the process and form of the intervention that they believed would be most acceptable in hostel settings.

Based on these findings and the coproduction workshops the intervention sessions will be:

1. Introduction to understanding memory problems
2. Communicating with people with memory problems
3. Understanding and managing distress behaviours and unmet needs.
4. Strategies to support functioning, meaningful interaction & harm minimisation
5. Understanding and assessing capacity
6. Keeping it going and developing individual and hostel wide plans

Based upon our previous (1, 2, 7) and related work (8-10) and the co-production workshops, the intervention will be delivered to small groups of 6-8 hostel staff, supporting them to make and integrate changes to their practice with older people with memory problems and to help residents move to settled accommodation. The intervention will be manual based, to ensure future scalability but individually tailored. Staff will attend sessions of 1.5 hours (2 hours including break) delivered 1-2 weeks apart over a three-month period. The last session will be co-producing a future action plan from actions which the staff have found feasible and useful during the intervention. We will take a collaborative and reflective practice-based approach, valuing the expertise of participating staff and the lived experiences of the older people in their care, drawing on individual case discussions. The groups will be interactive and include between session tasks for staff. Sessions will be facilitated by a trained research assistant and a senior hostel 'champion' trained to deliver the intervention and supervised by the chief investigator (CI) Penny Rapaport (PR) an experienced clinical psychologist. Following the training sessions there will be a three-month implementation period during which PR will offer reflective practice and case discussions supporting staff to implement action plans. Throughout the intervention and implementation periods PR will meet with hostel managers and champions to troubleshoot any challenges and embed changes.

During phase one we will pilot the intervention in one hostel, with a group of 6-8 staff, then explore in a focus group if and how it impacted upon practice, and make changes as indicated for the non-randomised feasibility trial in phase two. During phase two we will aim to deliver the intervention to all eligible staff in each participating hostel groups of 6-8. Participating hostel managers will be asked to agree to all staff attending the sessions although we will only collect outcomes on those who give informed consent to participate in the research project.

## 1.2 Study outline

This protocol describes a two-phase study and we will seek approval from NRES to test our HOME intervention in third sector homelessness hostels (there will be no NHS sites). This is a standalone study but will build on the findings from an ethnographic qualitative study exploring in depth the

experiences of people aged fifty and over experiencing homelessness and memory problems (London (Brighton and Sussex) NRES ref: 21/LO/0541). In the qualitative study we have conducted interviews with 47 stakeholders (people living with memory problems and experiencing homelessness, practitioners and frontline hostel staff) and conducted ethnographic observations in hostels of thirteen people aged over fifty with memory problems. A paper of the initial findings has been submitted for publication and we found that recruitment was not challenging as there was buy in from the supporting organisations and it was a subject with which people were keen to discuss and engage.

This proposal is for:

**Phase one:** An initial pilot of the HOME intervention in one homelessness hostel

**Phase two:** A non-randomised feasibility trial of the HOME interventions in up to five hostels.

In phase one a trained facilitator and a trained senior hostel staff member will facilitate the six-session intervention with a group of 6-8 hostel staff over three months followed by a three month 'implementation period' with reflective practice sessions led by PR. The purpose of this pilot phase is to test our newly co-produced HOME intervention and obtain qualitative feedback that we can use to finalise study manuals and processes for phase two. We will not collect outcome measures at this stage. We will conduct a qualitative focus group with the staff participating in the intervention, including any staff who 'dropped out' of the intervention and the hostel manager after the three-month intervention period about their experience and what worked and what changes they would suggest. We will also invite staff to take part in a brief telephone or face-to-face interview at the end of the implementation period regarding their experiences of the reflective practice sessions and how they have put into practice any learning from the HOME intervention. PR will then lead discussion about these findings with our co-production group and final changes incorporated into the intervention manual for phase two.

In phase two we will conduct a non-randomised feasibility trial of the six session HOME intervention followed by a three-month implementation period. Outcomes intended for a full RCT will be completed with participants to consider feasibility and acceptability in this population (all eligible hostel staff and eligible residents aged fifty and over with either diagnosed dementia or screened as having memory problems) will be collected at baseline and six months, in up to five hostel sites. Our main outcomes will be the proportion of eligible hostel staff adhering to (attending at least 4/6 sessions of) the intervention and the proportion of eligible hostel staff and residents agreeing to participate in the trial. We will conduct focus groups with hostel staff and individual interviews with managers, using the same methods as for study one, as part of our process evaluation to understand if the intervention works, how they work. We will inform feasibility and test procedures for a future RCT by collecting validated clinical and cost-effectiveness measures planned for a full trial at baseline

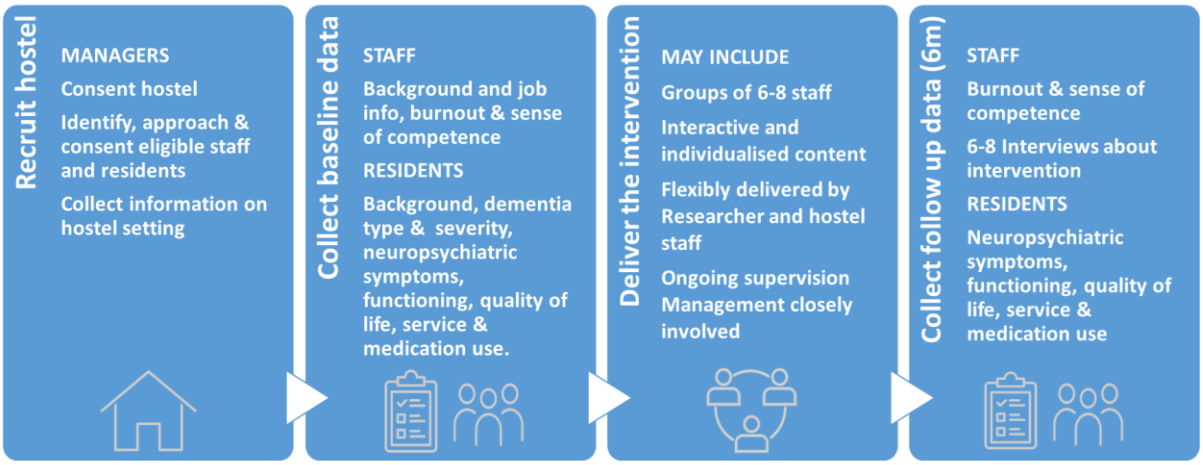


Figure 2: Stages of phase two feasibility study

and at six months from participating hostel staff and residents. The stages of the non-randomised feasibility trial are outlined in Figure 2.

## 2. BACKGROUND AND RATIONALE

The older population experiencing homelessness and living with memory problems is growing (11, 12). Those experiencing homelessness have higher levels of cognitive impairment than those of equivalent age who have not (13-17) and are significantly more likely to have Alzheimer's disease and related dementias than stably housed populations (18, 19). The most deprived fifth of adults are 50% more likely to develop dementia than the fifth least deprived and live with its health and social care challenges (20, 21). People experiencing homelessness frequently have long-standing and interacting physical and mental health conditions, substance misuse (and Alcohol related brain damage) and history of traumatic brain injury (TBI) (22-24), undergoing accelerated ageing (16, 25-27) associated with increased service use and early death (15, 18).

There are few studies of dementia and memory problems in homeless people and these mainly consider prevalence (13), assessment and identification (14), with only one published intervention study and no RCTs. Prior to the HOME study there has been one recent non-interventional UK study on dementia and memory problems in people who are homeless, and we are building on their work in their study (28). Although studies suggest potential areas for intervention, only one Australian project evaluated potential solutions trialling a specialist residential model for older people with dementia linked to Alcohol Related Brain Damage (9). Their model included high staffing ratios, behaviour management, neuropsychological assessment, staff supervision, targeted activity and an individualised harm-minimisation approach to alcohol consumption. They compared seven residents with seven 'waitlist controls' over 18 months. After six months, compared to control group, residents displayed less challenging behaviour, reduced alcohol use, depression and anxiety and increased activity and QoL with reduced health and social care service use (9). This small, resource-intensive, non-randomised trial was the first attempt to evaluate an intervention in this population.

Little is known about how frontline staff provide support and how people with memory problems experience homelessness. Our recent qualitative study focused upon this and has shed light on the complex reality of support for older people experiencing homelessness and memory problems

(Manuscript under review). Challenges within care pathways for older homeless people with memory problems include lack of flexibility in dementia support services and of appropriate housing (17, 28). Hostel staff are proficient at identifying residents' memory problems but struggle to access external input on residents' behalf and want specialist training and support (28). Hostels are commissioned to provide short-term accommodation with a model of residents advocating for new accommodation, yet residents with memory problems are often unable to self-advocate, with hostel staff advocating for them (28). Residents with memory problems are more likely to have lived in their current hostel over 25 months (generally there is 2-year maximum stay) than those without memory problems (53% with vs 24% without memory problems), requiring intensive support from hostel staff, beyond the typical 'hostel worker' role. Residents with memory problems have higher personal and social care needs (50% with vs 12% without memory problems received additional local authority care) and use more emergency and out-of-hours services than those without (28).

At all stages of this research planning, including the intervention coproduction we have met with stakeholders to ensure alignment with what those commissioning, delivering and using homelessness services judge important. Commissioners, clinicians, homeless charity and housing association strategic managers, hostel managers, frontline staff and people who have experienced homelessness and memory problems, agree that this is an overlooked and vulnerable population and that there is a need for intervention to support staff and ultimately work towards improving the quality of life of older people experiencing memory problems in the context of homelessness and ultimately them moving to stable and settled accommodation. Participants in our qualitative study discussed the multiple potential causes of memory problems and that older people had distinct needs from younger homeless populations. Frontline staff expressed concern that available models of care and support, such as trauma and psychologically informed environmental approaches (8), did not equip them to support older people with memory problems and wanted tailored support to enable more effective working.

In summary, the older homeless population with memory problems living in temporary hostels is growing rapidly, yet their complex health, housing and social care needs remain unmet by existing service provision. Although hostels are ill-equipped and may be unsuitable for older people with memory problems, their staff are often an overlooked 'dementia care workforce' and hostels themselves are inadvertent 'dementia communities' (28). Our previous research has focused on developing, testing and implementing psychosocial interventions in dementia across complex health, housing and social care settings (1, 7, 29) and we aim here to extend this work to improving the care and support of those experiencing memory problems in the context of severe and multiple disadvantage. As there have been no previous intervention studies of its kind conducted in the UK, in this study we will conduct a non-randomised feasibility trial, answering the question "can this be done", to determine whether an RCT is feasible and inform its design (30).

# 3. OBJECTIVES

## 3.1Primary Objective

To determine the feasibility and acceptability of a staff training and support intervention (HOME intervention) through:

**Phase one:** Assessing whether the HOME intervention is feasible to deliver and acceptable to recipients in practice.

**Phase two:** Obtaining acceptability and feasibility estimates to inform continuation to a cluster RCT testing clinical and cost-effectiveness. Specifically, to test whether *a priori* progression criteria are met for the proportion of participants offered the intervention adhering to it and of eligible participants agreeing to trial participation.

## 3.2 Secondary Objectives

**Phase two:**

- To obtain estimates required for main trial's sample size calculation for primary outcomes, having confirmed a meaningful and practical primary outcome.
- To use economic measures to consider their feasibility in a full RCT and to calculate intervention costs.
- To conduct a mixed-methods process evaluation to assess intervention acceptability and required refinements.

# 4. TRIAL DESIGN

This study comprises a pre-pilot study (Phase one) and non-randomised multi-site feasibility trial (Phase two).

**Phase one:** A single pilot of the co-produced six-session HOME intervention in one hostel staff delivered over three months followed by a three month 'implementation period'. We will hold a focus group at the end of the three-month HOME intervention and conduct a brief semi-structured interview with participating staff at six months. The intervention will be refined based on findings from the pilot.

**Phase two:** A non-randomised feasibility trial of the six-session HOME intervention followed by a three-month implementation period. We will inform feasibility and test procedures by collecting validated clinical and cost-effectiveness measures planned for a full trial at baseline and at six-months from participating hostel staff and residents. We will keep records of eligible referrals, consent, intervention attendance and losses to follow-up to inform intervention adherence and acceptability of measures.

We will complete qualitative interviews, with 8-10 hostel workers who received the intervention and their managers using a semi-structured interview guide and we will audio record a random selection of intervention sessions across groups in each hostel to assess facilitator fidelity to the intervention.

# 5. SAMPLING METHODS

We will use the same inclusion and exclusion criteria for both phase one and two of the study.

## 5.1Inclusion criteria

**Hostel staff:**

- 18 years or older.
- Providing direct support to some residents with memory problems.
- Working any weekday, daytime shifts.
- Willing and able to give written or audio recorded informed consent.
- Able to understand spoken English.

**Hostel residents:**

- Aged 50 years or over. This decision is based on: 1. Existing evidence that people experiencing homelessness ≥50 have more comorbidities, cognitive problems and unmet needs (28, 31) than younger people (16); 2. The former UK Coalition on Older Homelessness definition of 'older' homeless people as those aged ≥ 50 years (11); 3. Discussions with academic, policy, clinical and service providers.
- A recorded diagnosis of dementia or a score of ≥2/5 on the Noticeable Problems Checklist (NPC) proxy measure. A score of ≥2/6 indicates significant memory disorder and has been validated against clinical diagnosis (32). This proxy measure is preferable to cognitive screening as it is neither invasive nor distressing and is independent of culture and education. Older people experiencing homelessness have multiple causes of memory disorder not all of which are classified as dementia and diagnosis is challenging (15, 33). However, many present with memory and other cognitive problems impacting everyday functioning, vulnerability, disinhibition and complex health, social and housing needs. By including those with a recorded diagnosis of any dementia or those who are screened to have a significant memory disorder, without any formal diagnosis, we will increase the external validity of the study.
- Willing and able to give written or audio recorded informed consent or if not capacitous, consultee gives consent and participant not unwilling.

## 5.2 Exclusion criteria

**Hostel staff:**

- Staff planning on leaving work within the hostel within six months.

**Hostel residents:**

- Resident with memory problems known to be moving on within the next three months.

## 5.3 Recruitment

Recruitment will be in London and Southern England across culturally and socioeconomically diverse semi-rural and urban sites. Participants with memory problems and hostel staff and managers will be recruited from third sector homelessness service providers by UCL staff. In addition to our agreed collaborations with third sector Homelessness organisations, we will liaise with the Homelessness Research Programme in the NIHR Policy Research Unit in Health and Social Care Workforce at King's College London and the Faculty for Homeless and Inclusion Health to assist us in identifying homelessness hostels. Consent logs will be completed by UCL researchers to record eligibility / ineligibility and participation/non-participation.

**Phase one:** The research team will recruit one hostel (through contacting the hostel manager) and will seek to recruit around 8 eligible staff over a four-week recruitment period. Hostel managers will approach 8 hostel staff to invite them to take part. We will not recruit a hostel where the manager cannot identify at least 8 staff who would be asked to take part in the study, and where there are less than 5 residents aged fifty and over who the managers and staff feel have memory impairment (there will be no formal screening of residents for phase one as we are not recruiting residents for this phase).

**Phase two:** We will recruit up to five hostels (not including the hostel recruited in phase one), from which we plan to recruit all (estimated total across all agencies: 40) hostel staff, and all (estimated total: 40) hostel residents aged fifty years and over living with a dementia diagnosis or screening positive for significant memory disorder on the NPC (32).

The initial approach in phase one and phase two will be by the CI (PR) to hostel managers. We are in contact with several organisations through the wider project and specifically with a wide range of hostels that have participated in stream 1 of the HOME study. The CI or HOME researcher will meet with interested hostel managers to explain the study. Managers who are interested in taking part will be asked to approach staff and residents to ascertain whether they are interested in taking part in the study. If they are, we will carry out the processes below. For consent and assessment of capacity please refer to section 5.5. All potential participants will be given or sent a study leaflet and the Participant Information Sheet (PIS) and asked for their permission for a researcher to contact them. Recruitment will take place over one year. We will not recruit a hostel where the manager cannot identify at least 15 staff (this is more than in phase one as we want to recruit a larger sample overall) who would be asked to attend the training (whether or not they agree to take part in the study), and the hostel manager agrees to delivery of the HOME training as part of their core training, or where there are not at least 8 residents who have a dementia diagnosis or significant memory disorder (NPC Score 2≥).

1. Hostel managers: We will initially approach hostel managers to invite them to participate. We will aim to recruit hostels via organisations that have already participated in our earlier qualitative study as well as through existing relationships with homelessness service providers. We will obtain consent from the hostel managers for the hostel participation in the observations (see Section 5.5). If they agree to hostel participation, we will elicit their written, informed consent or (audio-recorded) verbal consent for hostel.

2. Hostel staff: In participating hostels, we will ask managers to approach eligible hostel workers and give them a PIS if they express an interest in taking part in the study. We will ask them to explain that while the HOME intervention will be part of core training, they can decide whether or not they would like to participate in the research study evaluating it, this will also be explained in the PIS. Researchers will also, with agreement of the hostel manager, arrange to talk to groups of hostel workers about the study at staff meetings (either face to face or remote meetings). At these meetings they will be invited to take a PIS away to read, and to contact researchers about the study directly if they would like to participate. At least 24 hours after they have received the PIS, the researcher will contact the hostel worker, provided they have indicated to the manager that they agree to this, and arrange a meeting to provide an opportunity for them to have any questions they have about the study answered and for them to give their written, informed consent or (audio-recorded) verbal consent.

3. People with memory problems: The researcher will then work with participating hostel staff and ask the hostel staff to approach eligible residents. Researchers will provide the manager and senior staff with the NPC and ask them to use it to determine whether residents aged ≥ 50 without a known dementia diagnosis are eligible (NPC Score 2≥). The NPC is a six-item questionnaire that can be used with professionals and carers and has been shown to correlate well with assessments made by old age psychiatrists using a standardised clinical interview. It does not require any training, merely a familiarity with the person about whom information is being provided. A score of 2 to 6 indicates significant memory disorder (32). They will be invited to take part by the hostel staff and if they agree to consider the study they will give or send them a PIS. For those who do not read English we will have an easy read PIS (developed with PPI input) and ask staff who have approached them to read it with them. At least 24 hours after they receive the PIS, the researcher will make contact with the person with memory problems, provided they have agreed to this when asked by hostel staff. This will be to give an opportunity for potential participants to have their questions answered, and if the person with memory problems agrees to meet with them to elicit written, informed consent or (audio-recorded) verbal-consent. For those people with memory problems who the hostel staff or manager consider would not have capacity to consent to the study, we will ask staff to contact a relative/friend in closest regular contact and seek permission for us to contact them to act as a personal consultee. If none is available, we will ask the team to identify a professional as nominated consultee, costing for their time. We will provide training for hostel staff to equip them with the skills to evaluate whether clients with memory problems have capacity to give informed consent. This training will explain that capacity is decision-specific, and that it is necessary to consider whether or not their clients are able to understand what they would need to do if they took part, to decide whether or not they wanted to do so, and to understand that they could decide freely and their care would not be affected in any way if they decided not to. The training will be based on the Mental Capacity Act (2005). Full details of consent procedures and use of personal or nominated consultees for people who lack capacity to decide whether to take part are given below in section 5.5.

We will ask hostel managers to complete a screening log to monitor the number of people approached for the study, the number who refused further information on the study and the number who were not eligible and the reasons why they were not eligible/refused participation.

Researchers will also complete screening logs containing information on all participants that agreed to be contacted by a researcher, the number who refused participation and the number who were not eligible and the reasons why they were not eligible/refused participation.

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed by the Sponsor (or it's delegated representative), and
2. Been issued with Confirmation of Capacity and Capability from each participating site (where applicable).

## 5.4 Participant reimbursement

**Hostel staff:** Hostels will be reimbursed for time staff are engaged in the study; receiving the HOME intervention and completing outcomes (at London Living Wage hourly rate). This involvement will take place during their paid, work time.

**People with memory problems:** In phase 2, each participating hostel resident will be offered a £20 gift voucher after completion of the baseline assessment.

## 5.5 Informed Consent

It is the responsibility of the Investigator, or a person delegated by the Investigator to obtain written informed consent from each participant prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the trial.

The person taking consent will be suitably qualified and experienced and will have been delegated this duty by the CI on the Staff Signature and Delegation of Tasks.

The participant information sheet and informed consent form contain the Health Research Authority (HRA)'s General Data Protection Regulation (GDPR) recommended wording. This can be found on the HRA website: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

"Adequate time" must be given for consideration by the participant before taking part. Consent will be sought at least 24 hours after being given the study documentation. It must be recorded in the case notes/source documents when the PIS has been given to the participant.

The Investigator or designee will explain that participants are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason.

No clinical trial procedures will be conducted prior to the participant giving consent by signing the consent form. Consent will not denote enrolment into trial.

A copy of the signed informed consent form will be given to the participant. The original signed form will be retained in the trial file at site and a copy placed in the case notes/source documents.

The PIS and consent form will be reviewed and updated if necessary, throughout the trial (e.g: where new safety information becomes available) and participants will be re-consented as appropriate.

We will include people living with dementia who lack capacity to decide to take part, to ensure we are able to obtain the viewpoint of people with more severe impairment. We will abide by the Mental Capacity Act (England and Wales) (2005) throughout. We will ensure potential participants are assisted to understand studies and to give informed consent. If they are unable to give informed consent we will ensure they are assisted to use personal or nominated consultees.

The identification and approach for potential participants is set out in section 5.3 above.

**Hostel managers (both phase one & two):** We will arrange to meet with hostel managers interested in participating as described in section 5.3. This meeting could be face-to-face or remote. The meeting will be to give an opportunity for them to ask questions about the study and elicit informed consent for the hostel to take part in the study. We will also ask managers to give individual informed written or (audio-recorded) verbal consent to participate the study.

**Hostel staff (Phase one & two):** We will ask hostel managers to invite eligible staff to participate in the study. The hostel managers will ask hostel workers interested in taking part in the study their permission to pass their contact details to the research team. The research team will then contact the hostel staff, and if they agree, arrange a time to meet in person or remotely to give an opportunity for them to ask questions about the study and elicit informed consent.

**People with memory problems (Phase two):** If the hostel staff, who will be trained to evaluate capacity, believe that the client has capacity to consent to participate in the study, they will follow the steps below.

- They will inform them that they are being asked to participate in a project to trial a new staff intervention delivered to staff who support older people who are experiencing homelessness and have memory problems. They will be given a simple information sheet informing them about the study and given at least 24 hours to consider this. They will be informed that they do not have to decide immediately and will have two weeks to decide whether they want to participate and time to discuss the study further if they wish, with research staff. They will also be informed that if they decide not to take part that this will not adversely affect their care in any way either currently or in future. If they indicate either physically or verbally that they do not wish to participate or become distressed by this approach they will not be assessed further.
- They will be asked if they agree to a researcher having their contact details so they can meet with them to discuss the study. If they do, the researcher will be passed their details.

The researcher will then follow the steps below:

- They will meet the potential participant ideally face-to-face, but this could be a remote meeting by telephone or video call. If they agree to take part, the researcher, who will be trained to assess capacity, will conduct a brief test of capacity, as assessment of capacity is an on-going process. If the person has capacity, they will then be given a consent form to sign or (they will audio-record verbal consent). If the person no longer has capacity to consent to participate, the

stages below will be followed. If the person is intoxicated either due to heavy alcohol or drug use, the researcher will arrange to come back at a different time to gain informed consent.

When a hostel worker/ research team decides that a person does not have capacity to consent for themselves, the following steps will be taken:

- On our behalf, a hostel staff member or manager will contact their next of kin, family carer or someone close to the person (who does not receive remuneration for this role) who will act as a "personal consultee" (we recognise that in many cases there may be no personal consultee available). They will give them a written information sheet about the study. The hostel staff or manager will explain that this is an intervention study targeting staff, that the person with memory problems will not be in intervention sessions and that all measures related to the person with memory problems will be proxy measures. They will be encouraged to consider the person's prior wishes or thoughts regarding taking part in research. They will be asked to give permission to be contacted by the research team and given the information sheet. They will have the information sheet for at least three days before they are contacted by the researcher to make an appointment for discussion of consent. We will provide the PIS for people with memory problems who lack capacity to consent, unless the consultee who is advising us about them considers that this may cause the participant confusion or distress.

- If a) no friend or next of kin that can act as a personal consultee is documented in the care notes, or b) after two attempts at telephone contact over 48 hours by the hostel worker they are unable to contact a personal consultee, then the research team will use a nominated consultee. The nominated consultee will be defined as a senior experienced health or social care practitioner who is not directly involved in the research or care of the participant. These "consultees" will be given the Consultee Information Sheet to read and trained on their responsibilities by the research team. They will be asked to sign the Consultee Declaration Form or (audio-recorded) verbal agreement if they consider that the person they are advising us about would want to participate in the study if they had capacity to make this decision.

**Procedure to be used if a participant loses capacity during the study or if a participant who originally did not have capacity regains capacity (Phase two)**

If the hostel staff raise with the research team that they have reason to believe a participant with memory problems has lost capacity then the researcher would seek to understand whether this loss of capacity was likely to be temporary or permanent. If the latter they would proceed as detailed above, as described for potential participants with memory problems believed to lack capacity to decide whether to take part.

It is possible that a participant who lacked capacity at the commencement of the study might regain it. If the hostel staff raise with the research team that they have reason to believe a participant with memory problems has regained capacity, they would discuss this with the consultee. They would proceed as detailed above, as described for potential participants with dementia believed to have capacity to decide whether to take part, The researcher would provide them with a PIS in line with the above processes in order to elicit their written, informed or (audio-recorded) verbal consent before continuing with the study. If they do not wish to consent at this point, no further data will be

collected any data that has been collected up to the point of withdrawal will be retained and used in the study unless the participant wishes for it to be withdrawn.

## PRODUCT/INTERVENTIONS

### 5.6 HOME Intervention

**Facilitator training and supervision:** HOME researchers are psychology/social science graduates selected based on personal and professional experience working with people living with memory problems and those experiencing homelessness but without a formal clinical training. Our current research assistant has already collected qualitative data in hostels as part of HOME Work Package one. In each of the hostel sites we will also train a senior and experienced hostel worker as a HOME champion to co-facilitate intervention with supervision. Researchers and nominated hostel staff aka "facilitators" will be trained to deliver the HOME intervention to groups of hostel staff. This training will take place over 2 full days. To ensure intervention integrity, they will be required to demonstrate competence in delivering the intervention by role-play before we begin recruitment. Training will be facilitative and encouraging. It will emphasise the need to operate from an inclusive values base and to respect diversity and the existing knowledge and skills hostel staff. They will learn through a combination of seminars, discussion, reflective learning, and guided reading.

Facilitators will have fortnightly group supervision with the CI, an experienced clinical psychologist with additional individual supervision as requested by facilitators or the study team. The group supervision format makes most effective use of available resources and enables the facilitators to benefit from the professional expertise of their supervisor and the experiences of their peers. Supervision will include skills development, risk management and safe practice and staff support. Researchers will attend clinical supervision at least every 2 weeks. There will be top-up training sessions and opportunities for telephone and group supervision throughout the intervention delivery period. The intervention delivery training will be provided by the CI with input from experts in homelessness and dementia and people with lived experience of homelessness and memory problems who have contributed to our HOME intervention coproduction.

**HOME Intervention facilitated group sessions:** The HOME intervention will be delivered to all hostel staff who work weekday, daytime shifts and provide direct support to some residents with memory problems within participating hostels. It will be delivered to small groups of around 6-8 staff by pairs comprising one trained researcher and one trained senior hostel worker. Each of these groups will receive six training sessions, which will each last 2 hours, with a break when drinks and snacks will be provided. Groups will be 1-2 weeks apart over a three-month period. Hostel staff will be asked to try and attend the same group for all six of the sessions, but they can attend a different group if needed. The manager may attend different groups for each session, so that hostel workers have sessions with and without the manager present. The session content will be written in a manual so that it is delivered the same way each time and so that hostel workers have their own copy to keep and make personalised notes in. Those who attend all sessions will receive a certificate. The six sessions will be:

1. Introduction to understanding memory problems
2. Communicating with people with memory problems
3. Trauma informed understanding and managing distress behaviours and unmet needs.

4. Strategies to support functioning, meaningful interaction & harm minimisation
5. Understanding and assessing capacity and safeguarding
6. Keeping it going and developing individual and hostel wide plans

Sessions will be informed by a collaborative and reflective practice-based approach, valuing the expertise of participating staff and the lived experiences of the older people in their care, drawing on individual case discussions. The groups will be interactive and include between session tasks for staff.

**Sessions with hostel managers:** During the intervention period we will hold three meetings with the hostel manager each lasting 30 minutes. These will include the CI, researcher and hostel champion. These sessions will focus on ensuring buy in and attendance within the hostel and troubleshooting any challenges as they arise. In the first session we will develop a strategy for maximising attendance, for example by deciding on the best times and days to offer training and ensuring that staff feel able to attend. The later sessions will focus on gaining management support for staff to implement any changes to their practice based on the intervention sessions and action plans.

**HOME implementation period:** This will be followed by a three month period of implementation, where we visit hostels and support them to implement action plans they have developed. We will develop a manual to guide input of team clinical professionals and facilitators during this period. It will involve at least monthly face to face meetings with the hostel manager and hostel champion.

# 6. TRIAL PROCEDURES

## 6.1 Pre-intervention assessments

We will keep careful records about eligible referrals and consent to participate, these will inform intervention adherence and acceptability measures. We will document these in a CONSORT flow diagram. We will collect most interview data from hostel staff, to reduce resident burden and ensure that data is comparable if the degree of impairment of the resident prevents them completing questionnaires. Baseline appointments will take place at the hostel in person. At the baseline appointment, researchers will obtain written or audio-recorded verbal informed consent to take part in the study from staff (Phase one and two) and older residents with memory problems (phase two) who have capacity (or a personal/nominated consultee will sign for older people who lack capacity to consent). Recruitment, approach and consenting procedures are detailed above in sections 5.3, 5.4 and 5.5). Hostel staff will complete outcome assessments and senior staff familiar with participating older residents will complete the proxy measures.

All pre-treatment procedures will be carried out as specified in the schedule of assessments (appendix 1).

## 6.2 Registration Procedures

Participant registration will be undertaken centrally by the coordinating trial team.

Following participant consent, and confirmation of eligibility (see section 7.1 for pre-treatment assessments) a participation trial identification number will be generated centrally by the coordinating trial team. The hostel will be informed that a resident is enrolled in the study (phase two).

## 6.3Baseline and Intervention Procedures

### 6.3.1 Baseline data

#### Sociodemographic and background data

The following data will be collected from all participants recruited into phases one and two at the baseline assessment:

**Information about the hostel**

Provider, resident and staff numbers, support level, accessibility, admission criteria, funding arrangements, alcohol permitted, permanent and temporary staffing numbers, key working, available and mandatory training and in reach health and social care services available. Although not randomising hostels, PR will survey consenting managers regarding hypothetical willingness to be randomised in a future study.

**Information about hostel staff**

1. Age, sex, ethnicity, first language.
2. Role, time in current role, years of experience, work pattern, employment history in homelessness and dementia, qualifications and last six months training.

At phase 2 the following information will also be collected:

**Information about the person living with memory problems**

1. Age, sex, ethnicity, first language.
2. Education, last occupation, contact with friends/family.
3. Physical and mental health history, alcohol and substance use.
4. If diagnosed, type of dementia, time since diagnosis.
5. Accommodation history, time in hostel.

#### Quantitative outcomes (phase two only)

In phase two, all outcomes intended for the full RCT will be collected at baseline (pre) and six months (post) intervention delivery. The primary outcomes for this feasibility trial will be:

- The proportion of hostel staff participants adhering to intervention (attending at least 4/6 sessions)
- The proportion of participating staff completing candidate primary outcome for a full trial at follow up (Sense of Competence in Dementia Care Staff (SCIDS) or Maslach Burnout Inventory (MBI)).

**Hostel staff will be asked to complete at baseline and six months after baseline:**

Sense of Competence in Dementia Care Scale (35): This asks staff 17 questions to find out about how able they feel to deliver person-centred care. Adequate psychometric properties are reported.

Maslach Burnout Inventory (36). This questionnaire measures burnout and is widely validated and used in staff working with residents with dementia(37) and in homelessness(38). It comprises 22 items scored on a 0 – 6 Likert Scale.

The staff member working most closely with each participating resident will be asked to complete the following measures:

Disability Assessment for Dementia scale (DADS), a standard measure of functional independence (basic and instrumental activities of daily living) (39).

Brief Neuropsychiatric Inventory Scale (NPI-Q)(40): A 12 domain survey assessing neuropsychiatric symptomatology. The NPI-Q provides symptom Severity and Distress ratings for each symptom reported, and total Severity and Distress scores reflecting the sum of individual domain scores.

Modified Client Service Receipt Inventory (CSRI)(41): A proxy questionnaire asking about health and social care service use information in the past 4 months for the participant. This will enable us to calculate intervention and other costs.

EQ-5D 5 level (EQ-5D-5L)(42) proxy: A generic measure of health related quality of life.

**People living with memory problems will be asked to complete at baseline and six months after baseline:**

EQ-5D 5 level (EQ-5D-5L)(42): A generic measure of health related quality of life.

### 6.3.2 Intervention Procedures

Details of the HOME intervention are in section 6.1 above. Researchers and nominated hostel staff will be trained and supervised to deliver the HOME intervention to groups of hostel staff. Researchers will consult with hostel managers to arrange one series (for phase one) and 2-4 series (for phase two) of six intervention sessions (every 1-2 weeks) for groups of 6-8 hostel workers. Attendance at training sessions will be monitored and if a hostel worker is unable to attend a session, they will be offered an alternative session with a different group.

Intervention measures: We will keep records of staff attendance at intervention sessions, reasons for non-attendance or cancellation, time taken delivering intervention, hostel-based action plans, attendance at implementation visits, supervision and training and facilitators. We will audio record a randomly selected intervention sessions for each group in each hostel to assess facilitator fidelity to the intervention.

## 6.4 Subsequent assessments and procedures

**Phase one:** The focus group will take place at three months, within one month of completion of the final session. We will also invite researchers who have delivered the HOME intervention to take part in a structured qualitative interview to understand their experiences. At six months, following the completion of the implementation visits we will conduct a structured qualitative interview with the staff who received the intervention.

**Phase two:** The follow up assessments will take place at six months, by which time all intervention sessions and implementation visits will have been completed. Please see section 7.3.1 for a list of follow-up measures. We will also conduct qualitative interviews with 8-10 staff participants (including managers) to evaluate their experiences of receiving the interventions. We will invite researchers who have delivered the intervention to take part in a structured qualitative interview to understand their experiences.

At six month follow up we will collect information on staff turnover in each hostel and if at follow-up participants are no longer resident, we will collect information about where they are (e.g., settled community placement, residential care, hospital, deceased, missing).

A schedule of all trial assessments and procedures is set out in Appendix 1.

## 6.5 Discontinuation/withdrawal of participants

Researchers will explain to the participant at the point of consent and at the baseline assessment (if at separate times) that they are free to withdraw from the study at any time without this having any effect on their care or employment and without having to give a reason. Any data that has been collected up to the point of withdrawal will be retained and used in the study unless the participant asks for it to be withdrawn. After analysis withdrawal of data will not be possible. No further information will be collected from the participant after withdrawal. Participant withdrawal will be documented in the Case Report Forms (CRFs) and the hostel staff informed. Participants who withdraw from the study will not be replaced. Participants would be withdrawn from the study if:

- They actively stated that they no longer want to take part
- If the staff member loses capacity
- If a participant with memory problems who had capacity at the start of the study loses capacity and a personal/nominated consultee cannot be identified.

## 6.6 Definition of End of Trial

The expected duration of the trial is 25 months from recruitment of the first participant.

**Phase one:** The end of the study period will be when the final participant has completed the qualitative focus group/interview. Data will then be analysed and used to modify the final intervention manual and training programme ready for testing in the feasibility RCT.

**Phase two:** The end of the study period will be when the final participant has completed the follow-up outcome measures. Data will then be analysed and used to modify the final intervention manual and training programme ready for testing in a full RCT.

# 7. FINANCE AND SUPPLY OF EQUIPMENT

The research costs for the study have been supported by a National Institute for Health and Care Research (NIHR) Advanced Fellowship (NIHR300844) - £854,616.00 Date of award 01.03.21. The study funding has been reviewed by the UCL Research Office and deemed sufficient to cover the requirements of the study. There are no NHS costs associated with this study.

# 8. DATA MANAGEMENT

## 8.1 Confidentiality

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is [data-protection@ucl.ac.uk]. The data processors are Dr Penny Rapaport and those detailed in delegation log. The study will be collecting the following personal data: names, addresses, email addresses, telephone numbers, dates of birth, professional statuses, ethnicity, diagnosis.

**Where data is coming from?**
Participant names and contact details will be obtained from the hostel manager once verbal consent has been given to share this information. The demographic and outcome data will be obtained directly from participants. Some demographic and clinical information will be obtained from hostel records for example to aid completion of the CSRI or demographic data. This is specified in Consent/consultee declaration forms.

**What personal data is being collected?**
The personal data being collected will include identifiable data (1. name and address to enable recontact; 2. Demographic details including age, gender, ethnicity, employment, education, first language, housing history, physical and mental health status and substance use; 3. Audio recordings which will likely contain participant's first name and possible other identifiers until they are transcribed and cleaned). Each participant will be assigned a participant ID number and demographic and outcome data will be pseudo-anonymised and stored separately from the subject name or address.

**Where will the data be recorded or stored?**
Personal data needed to re-contact participants for follow up assessments and intervention sessions will be held securely on password protected excel spreadsheets on password-protected computers at UCL and accessed only by the UCL research team.

Consent forms will be held manually at UCL Maple House under the supervision of CI Dr Penny Rapaport. The data will be held in a locked filing cabinet in UCL Maple House, only Penny Rapaport and named members of the research team will have access, we will abide by UCL data protection policies.

The CRFs will not bear the participant's name or other personal identifiable data and will be stored in a separate locked filing cabinet to the consent forms. The participant's initials, date of birth and trial identification number, will be used for identification and this will be clearly explained to the participant in the participant information sheet. Participant consent for this will be sought. Data from the paper CRFs will be entered by the study team into the password protected study database and stored on password protected computers on UCL servers.

Researchers will have their own GDPR compliant audio recording devices. The recordings of qualitative interviews and focus groups will be uploaded through a secure server to a UCL approved provider for interview transcription. They will be transferred back through the same server when transcribed. Researchers who conducted the interviews will read them through and remove all identifiable data. Once they have done this, they will destroy the non-anonymised transcript and recording. Audio recorded intervention sessions will be stored password protected on password protected computers on UCL servers. Once the recordings of sessions have been listened to and fidelity to the intervention rated, these recordings will be deleted.

**Who will have access to the data?**
Only Penny Rapaport, CI, and research assistants and other members of the research team (including associated PhD and MSc students) will have access to electronically and manually stored data. Only UCL substantive employees and students working under their supervision will have access. It will be the responsibility of the investigator and delegated members of the research team to ensure the accuracy of all data entered in the CRFs.

Data will not be transferred outside UCL computer systems unless in aggregated, anonymised form. It will be disseminated in aggregated, anonymised form in research publications and conference presentations.

**How long with the data be stored for?**
We will store personal data for up to three years to enable us to send participants a summary of the results and contact them about future research studies. Electronic data will be deleted after this time and paper copies will be destroyed via confidential waste.

Audio-recordings will be stored as stated above, only until transcriptions have been checked. Other data will be saved for 20 years in line with UCL policies for archiving.

The research data will be well-managed and submitted for archiving as per NIHR requirements, maximising potential for further research. All data will be managed within UCL information security policies https://www.ucl.ac.uk/informationsecurity/policy .

## 8.2 Data collection tools and source document identification

A data management plan will be created which will include details of the data collection tools, methods of completing case report forms, sign off completed CRFs, source document identification and methods to maximise completeness of data collection.

It will be the responsibility of the investigator, PR, to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

Data will be collected from sites on trial specific CRFs. Data collected for the study will be entered into the paper CRFs by the central team researchers and brought back to UCL within 5 days of a participant visit and then entered into the online database.

## 8.3 Completing Case Report Forms

All CRFs will be completed and signed by staff that are listed on the site staff delegation log and authorised by the CI to perform this duty. The CI is responsible for the accuracy of all data reported in the CRF.

Once completed the original CRFs must be brought to UCL Maple House. The CRFs must be returned within five days of the participant visit.

## 8.4 Data Handling

In the study, all will be collected from participants in accordance with the consent form, information sheet and sections 7 of this protocol. All data will be collected and handled in accordance with GDPR & UK Data Protection Act (2018)

The data collected in the CRFs and qualitative data will be appropriately stored at UCL Maple House for data analysis and UCL will act as the data controller of such data for the study.

Dr Penny Rapaport and those detailed in the delegation log will process, store and dispose of data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 2018 and any amendments thereto.

No data will be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the participant's consent.

Direct access to the data will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections, in line with participant consent.

## 8.5 Personal Data breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer [data-protection@ucl.ac.uk], and to the Sponsor via the UCL JRO research incident reporting form (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.

# 9. STATISTICAL CONSIDERATIONS

## 9.1Primary outcome

**Phase one:**

- The proportion of participating staff adhering to the intervention (attending at least 4/6 sessions).
- The acceptability and perceived usefulness of the intervention established through focus group and qualitative interviews to inform revision of the intervention for the feasibility trial.

**Phase two:** The primary outcomes for the feasibility trial will be:

- The proportion of hostel staff participants adhering to intervention (attending at least 4/6 sessions)
- The proportion of participating staff completing candidate primary outcome for a full trial at follow up (SCIDS or MBI).

## 9.2Secondary outcome(s)

- The proportion of participating older people for whom primary outcome for the main trial is completed at follow up (EQ5D-5L / DADS).
- The estimated cost of delivering the intervention to inform their feasibility in a future full trial.
- The acceptability of and fidelity to the intervention established through a mixed methods process evaluation to assess intervention acceptability and required refinements.

## 9.3Sample size calculation

**Phase two only:** With 40 staff participants we will achieve the following 95% confidence interval for expected adherence and participation estimates:

1. Proportion of participants adhering to intervention (attending at least 4/6 group or individual sessions) (expected value 75%, 95% confidence interval: 59-87%).

2. Proportion of staff for whom potential staff outcomes (SCIDS or MBI) completed at 6-month follow-up (75%, 95% confidence interval = 59-87%).

With these numbers we will be able to estimate parameters with sufficient precision to inform continuation to an RCT. "Stop go" criteria will be related to intervention adherence:

- >=70%: go to main trial
- 60-69: modified trial to increase adherence
- <60: do not progress to main trial using this model.

This sample size will also be sufficient to estimate the standard deviation required for the sample size calculation in the main trial (43, 44).

## 9.4Planned recruitment rate

We estimate that recruitment referral rate will be approximately 10 potential staff participants month; 5 participants will be suitable and 4 will agree to participate and follow-up will be approximately 70%.

## 9.5Statistical analysis

### 9.5.1 Phase one

**Assessment of outcomes**

The proportion of eligible hostel staff approached who agreed to take part in the study will be reported with a 95% confidence interval and reasons for refusal summarised. Demographic characteristics of participating hostel staff will be summarised using means (with standard deviations (SD), medians (with interquartile ranges), counts and proportions, as appropriate.

**Qualitative analysis of interviews**

We will analyse the data thematically (45), inductively analysing interview data. We will check professional transcriptions against audio recordings and enter transcribed interviews into NVivo 12 software. We will code transcripts into meaningful fragments labelling initial codes. We will then organise data into preliminary themes responding to research questions and seeking connections. We will seek respondent validation, with Patient and Public Involvement (PPI) representatives to comment on the credibility of interpretations. Our findings will be used to adapt the HOME intervention and the supervision and training programme for facilitators delivering it if required before phase two. As the data will be collected by more than one researcher, PR will lead the analysis but each researcher will maintain their own reflective log and we will meet regularly to compare observations, explore differences and collaboratively and iteratively refine the analysis (46).

**Assessment of fidelity to intervention**

To analyse fidelity to the HOME intervention during delivery, checklists will be applied independently to transcribed audio recordings of the training sessions by two researchers. A mean fidelity score will be produced by dividing the number of items on the checklist identified as being delivered in the training sessions, by the number of items on the checklist that should have been delivered per training session, per facilitator and across all training sessions. We will adopt thresholds used in other intervention fidelity work: where 81–100% constitutes high fidelity, 51-80 is moderate fidelity and 50% or lower constitutes low fidelity.

### 9.5.2 Phase two

**Assessment of outcomes**

The statistical analyses will be described in a predefined analysis plan. The main analyses are: Baseline data will be summarised using means (with SD), medians (with interquartile ranges), counts and proportions, as appropriate, to describe characteristics. We will produce a consort diagram to describe the flow of participants through the trial and consider potential bias arising from dropouts and losses to follow-up.

1. We will calculate the proportion of staff adhering to the intervention (attending a predetermined number of sessions) with 95% confidence intervals.
2. The EQ-5D-5L, SCIDS and MBI scores will be summarised to provide distributional information and obtain estimates of SDs, and correlation needed for main trial's sample size calculation.
3. Referral rates, drop-out and loss to follow-up rates will be calculated with 95% confidence intervals.
4. Other staff and resident outcome data will be summarised using appropriate estimates with 95% confidence intervals.

**Intervention costs**

To calculate the unit costs of intervention delivery we will include: the hourly cost of training and supervising facilitators; hours spent by facilitators delivering training and supervision in hostels; hours spent by staff engaging in the intervention; capital travel and materials costs; and numbers of residents supported. We will obtain staff costs from published sources (47).

We will calculate service use for people with memory problems with data collected using the CSRI. Although previous research found only 15% of older UK hostel residents had monthly contact with family or friends (28), we will also collect information on informal support (via staff proxy) to inform the full trial. Unit costs from published sources (47) will be applied to each service for each participant and summed to give total service-related cost per participant in the three months before baseline and from baseline to six month follow-up. We will calculate summary statistics using means (with SDs) or medians (with interquartile ranges) across all participants for each service. Missed appointments will be costed as if the contact took place and the proportion of missed appointments reported. I will calculate unpaid care costs adapting existing methods (48); calculating replacement costs of equivalent number of hours of formal home care and applying a value for the hours of unpaid care equivalent to the national living wage (as we are unlikely to have details on informal carers to calculate more accurate costs).

**Qualitative analysis of interviews**
This will proceed as for phase one. Additionally, the evaluation will be informed by the Consolidated Framework for Implementation Research (CFIR)(49), a comprehensive tool to assess determinants of implementation. It includes considering how to adapt knowledge to local context, barriers to knowledge use and intervention tailoring. We will seek views on the potential impact of the intervention and any practice changes, as well as impacts on residents with memory problems. We will collate suggested changes to improve the intervention and future uptake and ask about experiences of completing outcome measures.

**Measuring fidelity to intervention**
This will proceed as for Phase one.

## 10. ASSESSMENT AND MANAGEMENT OF RISK

We do not think there are significant risks associated with the intervention or trial participation. intervention arm of the trial. The CI, study personnel and the trial management group will ensure that the study is conducted within appropriate NHS and professional ethical guidelines. Training and regular supervision will be provided to researchers on study procedures and intervention delivery by the CI.

The table below summarise the risks and mitigations:

| Intervention | Potential risk | Risk Management |
|---|---|---|
| | **Researcher safety** | We are aware that hostels support individuals with complex mental health and substance misuse issues and we will follow local risk management procedures and liaise closely with hostel management when undertaking research activities in hostel settings. Researchers will be trained and will follow the UCL lone working policy which can be found on the UCL website: http://www.ucl.ac.uk/estates/safetynet/guidance/lone_working/lone_working.pdf<br><br>At hostels, researchers will carry personal alarms and will follow local hostel safety procedures. Researchers will carry mobile phones and they will be able to contact the CI during work hours and out of hours. If the CI is unavailable (for example off sick or on holiday, researchers will be given an alternative name to contact). Researchers will contact a member of the study team after a hostel visit. The study team will have addresses, phone numbers and 'next of kin' details of all research assistants. |

| | | |
|---|---|---|
| | **Psychological distress** | Where this occurs during an assessment it will be mitigated by asking the participant if they wish to continue with the session, suggesting a break, moving on from the topic or the researcher terminating the interview. The researcher will ask if the participant would like to talk about their distress or discuss problems with staff members or clinical services. It is possible that some topics discussed as part of the intervention may be upsetting for hostel staff. The researcher delivering the intervention will be trained to manage situations in which the staff member becomes distressed, the researcher will receive regular clinical supervision from a trained clinical psychologist to help them to manage and process these situations. Information for the MIND and Shelter helplines will be provided to participants in the PIS and by the researcher. If a participant becomes distressed, it will be mitigated by asking the participant if they wish to continue with the session, suggesting a break in the intervention session (for the whole group if appropriate or the participant being invited to take time out from the group), or moving on from the topic or the researcher terminating the intervention session if the group does not want to continue. The CI is a clinical psychologist with extensive experience working with those with complex mental health needs and will support any research staff offering regular supervision. PR will have regular supervisory meetings with GL and CS both clinicians experienced in working in dementia and homelessness respectively. |
| | **Safeguarding and abuse** | If information disclosed by a staff member or older person leads us to believe that any person at significant risk, the researcher will discuss this with their supervisor. If appropriate they will approach the participant and seek their consent for disclosure to the hostel manager who will follow their local safeguarding processes. The PIS explains this:<br><br>"We respect confidentiality but cannot keep it a secret if anyone is being seriously harmed or is at risk of serious harm. If the researchers are concerned that you are at risk of serious harm, they will ask your permission to discuss this with the service who referred you. If you do not agree to this, they may do so without your consent if they have concerns that you or others are at risk of serious harm. If the researchers observe what they consider to be poor care or neglect, they will discuss this with the relevant service manager. If they remain concerned, or if at any time they find that someone is being |

| | | |
|---|---|---|
| | | harmed or at risk of harm, they will raise a safeguarding alert with the local authority."<br><br>The decision about whether disclosure of information without a participant's consent is warranted will be made by the CI, Penny Rapaport (Clinical psychologist), who has many years' clinical experience working in older people's mental health services. Decisions will be in line with the Mental Capacity Act (2005, England and Wales). If a participant is considered to lack capacity to make a decision about whether information should be disclosed about a risk situation to the relevant NHS service or local authority, then a decision will be made in their best interests, in discussion with a family member where possible. |
| | **Covid-19** | We are aware that the situation with the Covid 19 pandemic is less acute. However, we have included in our protocol that we will, if necessary be able to conduct assessments over the telephone or by video calling and that we can also take verbal as well as written consent if necessary. We do not feel that the intervention will be possible without being able to enter hostels in person. At all times we will follow government guidance as well as the hostel policies and procedures as to whether we can safely enter hostels in person. |

# 11.RECORDING AND REPORTING OF ADVERSE EVENTS

## 11.1 Definitions

| **Term** | **Definition** |
|---|---|
| Adverse Event (AE) | Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved. |
| Serious Adverse Event (SAE). | Any adverse event that:<br>• results in death,<br>• is life-threatening*,<br>• requires hospitalisation or prolongation of existing hospitalisation**,<br>• results in persistent or significant disability or incapacity, or<br>• consists of a congenital anomaly or birth defect. |

| | |
|---|---|
| | • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences |
| * A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.<br>** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE. | |

## 11.2 Assessments of Adverse Events

Each adverse event (AEs) will be assessed for severity, causality, seriousness and expectedness as described below.

### 11.2.1Severity

| **Category** | **Definition** |
|---|---|
| Mild | The adverse event does not interfere with the participant's daily routine, and does not require further intervention; it causes slight discomfort |
| Moderate | The adverse event interferes with some aspects of the participant's routine, or requires further intervention, but is not damaging to health; it causes moderate discomfort |
| Severe | The adverse event results in alteration, discomfort or disability which is clearly damaging to health |

### 11.2.2Causality

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form. As above, we do not

anticipate that any adverse events will arise from this project. However, if necessary the following categories will be used after review by the CI to define the causality of the adverse event:

The differentiated causality assessments will be captured in the trial specific SAE form.

The following categories will be used to define the causality of the adverse event:

| **Category** | **Definition** |
|---|---|
| *Related* | A causal relationship between the intervention and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. |
| *Not related* | There is no reasonable possibility of a causal relationship between the intervention and an adverse event. |
| *Not Assessable* | Unable to assess on information available. |

### 11.2.3Expectedness

| Category | Definition |
|---|---|
| *Expected* | An adverse event which is consistent with the information about the intervention listed in the current SmPC, Manual of Operation (amend as appropriate) **or clearly defined in this protocol.** |
| *Unexpected* | An adverse event which is not consistent with the information about the intervention listed in the current SmPC, Manual of Operation (amend as appropriate) * **or clearly defined in this protocol.** |

** This includes listed events that are more frequently reported or more severe than previously reported.*

### 11.2.4 Recording of Adverse Events

All adverse events will be recorded in the CRF and on the sponsor's AE log until the participant completes the trial with a simple, brief description of the event, including dates as appropriate on the trial database.

## 11.3 Procedures for recording and reporting Serious Adverse Events (SAEs)

All serious adverse events will be recorded in the CRF, and the sponsor's SAE log. The AE and SAE logs will be stored in the TMF and may be subject to Sponsor monitoring and auditing.

All SAEs (except those specified in the protocol as not requiring reporting to the Sponsor) will be reported to the Sponsor within 24 hours of becoming aware. The CI/PI or designated individual will complete the Sponsor's online Research Incident Reporting Form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo) within 24 hours of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the Sponsor as soon as possible.

Where the SAE is unexpected and thought to be related to the intervention, this must be reported by the Investigator to the main REC that approved the study within 15 days of the Investigator becoming aware of the event, using the non-CTIMP safety report to REC form. This form can be found on the HRA website: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/. The Sponsor should be copied into this, so they are aware. Discuss with the JRO Quality Assurance team in the first instance.

## 11.4 Serious Adverse Events (SAEs) that do not require reporting (if applicable)

12.5 We will report any unexpected SAE to the study Sponsor. People experiencing homelessness frequently have long-standing and interacting physical and mental health conditions, substance misuse and history of TBI (22-24), undergoing accelerated ageing (16, 25-27) associated with increased service use and early death (15, 18). As such, the following events listed below describe expected disease related AEs that are not related to the trial intervention and we will not complete an SAE form and report it to the sponsor:

- For those experiencing homelessness and memory problems death, hospitalisation due to common causes related to their condition (e.g. Urinary tract infections, delirium, common infections, pneumonia) or transition to a care home as a result of progression of existing illness.

## 11.5 Incidental Findings in Research

We do not foresee any incidental findings as part of the study.

## 11.6 Unblinding

This is a non-randomised study.

## 11.7 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice in the form of a substantial amendment to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

## 11.8 Protocol Deviations and Violations

A reportable protocol violation is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

The Sponsor will be notified immediately of any protocol violations during the trial conduct phase by completion of the online JRO Research Incident Reporting Form: https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo. All protocol violations must be recorded on the Protocol Violation Log and filed in the TMF.

Protocol deviations are **minor** unintended departures from the expected conduct of the study protocol/SOPs, which **does not impact** the participants' safety or compromises the integrity of the study data. E.g. a study visit date being outside the window defined in the protocol. Protocol deviations do not need to be reported to the Sponsor but should be recorded in the Protocol Deviation Log and filed in the TMF.

## 11.9 NHS Serious Incidents and Near Misses

We do not have any NHS trust sites.

## 11.10 Complaints from research participants

In the first instance, research participant complaints will be reported to the CI to investigate, as documented in the participant information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy.

# 12.OVERSIGHT COMMITTEES

## 12.1 Trial Management Group (TMG)

The TMG will include the CI and trial staff. The TMG will be responsible for overseeing the trial. The group will meet approximately every 3-6 months. The TMG role, arrangements and frequency of meetings will be detailed in a TMG charter and will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC.

## 12.2 Trial steering committee (TSC)

The role of the TSC is to provide overall supervision of the trial. The TSC will review the recommendations of the (Independent) Data Monitoring Committee (if applicable) and, on consideration of this information, recommend any appropriate amendments/actions for the trial as necessary. The TSC acts on behalf of the funder(s) and Sponsor.

We are testing a low risk intervention therefore we will not convene a Data Monitoring Committee. No interim analyses will be conducted on the data.

# 13. REGULATORY REVIEW AND PATIENT AND PUBLIC INVOLVEMENT

## 13.1 Regulatory Review

The Sponsor will ensure that the trial protocol, participant information sheet, consent form, GP letter and submitted supporting documents have been approved by the appropriate research ethics committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

The study was deemed to require regulatory approval from the NHS NRES and HRA. Full approval will be obtained before the study commences.

There are no NHS sites planned for this study.

All correspondence with the Sponsor, REC and HRA will be retained. The CI will notify the Sponsor and REC of the end of the study.

It is the CI's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

Within 90 days after the end of the trial, the CI will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

## 13.2 Peer Review

The study has been peer reviewed in accordance with the requirements outlined by UCL:

The Sponsor considers the procedure for obtaining funding from NIHR to be of sufficient rigour and independence to be considered an adequate peer review.

## 13.3 Patient and public involvement (PPI)

**Involvement of service users and members of the public in the design of research**
In designing this study (and the wider research project), PR talked to five older people with memory problems who have experienced homelessness. She also spoke to frontline staff supporting this group; hostel and service managers, health and social care professionals, and commissioners to ensure that this proposal fitted their key priorities and concerns. We incorporated their ideas into the proposed research design, especially focusing on what meaningful and positive outcomes would look like for those experiencing memory problems and homelessness. PR sought and received written feedback on the full draft application from four Alzheimer's Society Research Network Volunteers; people whose lives are affected by dementia and memory problems. Three individuals with lived experience of homelessness and or dementia and several hostel workers and managers have been involved in the co-production of the HOME intervention. One member of the Alzheimer's society research network was on the interview panel for the study research assistant and has read and commented on a draft of this protocol.

**Involvement of service users and members of the public in the management, analysis and dissemination of the research findings.**
Patient and public involvement is embedded throughout the proposed research and we are partnering with third sector homelessness organisations and the Alzheimer's Society to connect with diverse groups of service users. PR has budgeted for additional training and support for PPI representatives and our existing PPI representatives will comment on the credibility of the qualitative findings. As part of the project we have a PPI community of interest group who will meet annually providing advice on dissemination and knowledge exchange. The group will provide external advice and scrutiny, ensuring the project is situated in current policy and practice, providing a roadmap for future action.

## 14.MONITORING AND AUDITING

The CI will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The CI will conduct a risk assessment for this trial. The degree of monitoring will be proportionate to the objective, purpose, phase, design, size, complexity, endpoints and risks associated with the trial. A trial specific oversight and monitoring plan will be established for studies. The trial will be monitored in accordance with the agreed plan. The degree of monitoring will be proportionate to the risks associated with the trial. Risk will be assessed on an ongoing basis by the CI, and adjustments made accordingly (in conjunction with the Sponsor).

The CI will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures. The study trial management group will meet face to face at least twice a year.

We are conducting a low risk non-CTIMP (non-clinical trial of an investigational medicinal product) therefore no criteria have been set to stop the trial prematurely.

The UCLH/UCL Joint Research Office, on behalf of UCL as Sponsor, will conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, and in accordance with the Sponsor's monitoring and audit policies and procedures.

## 15.TRAINING

The CI will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

A short training programme will be delivered by the CI to any research staff. There will be a strong practical focus on empathic listening skills, making effective use of supervision and when to ask for help. Training will emphasise the need to operate from an inclusive values base and to respect diversity and the existing knowledge and experience staff and service users. Researchers delivering the intervention will receive a bespoke training described above in section 6.1. Because of the sensitive nature of this work and the fact that researchers may witness directly or via staff accounts potentially distressing incidents, we will provide additional support that we have found has been highly valued by staff collecting similar data in previous end of life care and dementia studies. This includes 1) swift access to senior clinical researchers i.e. by mobile phone to debrief on any incidents, 2) regular confidential clinical supervision with an experienced practitioner where incidents can be discussed as can other challenging issues such as maintaining the boundary whilst doing research observations, 3) regular peer group support with other project staff.

## 16.INSURANCE AND INDEMNITY

University College London holds insurance against claims from participants for injury caused by their participation in the trial. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this trial is being carried out in third sector homelessness hostels, the hostels continue to have a duty of care to the participant of the trial. University College London does not accept liability for any breach in the hostel's duty of care, or any negligence on the part of their employees.

Participants may also be able to claim compensation for injury caused by participation in this trial without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the CI, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Hostels selected to participate in this trial shall provide negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London, upon request.

## 17.RECORD KEEPING AND ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The CI confirms that he/she will archive the Trial Master File at UCL Maple House for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

## 18.INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it agrees hereby to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL.

Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of UCL or its funder. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

## 19.PUBLICATION AND DISSEMINATION

We will disseminate our findings in peer reviewed journals; develop policy briefings and present findings in appropriate local forums for health and social care professionals and at national and international conferences; participants who have indicated they are interested in reading the final paper will be sent it.

Our publication policy is as follows:

Authorship for any paper or conference abstract will be agreed by completion of the first draft.

To be considered for publication it will be expected that authors have contributed to each of the following:

a. Conception and design of the study, or acquisition of data, or analysis and interpretation of data;

b. Drafting the article or revising it critically for important intellectual content;

c. Final approval of the version submitted.

We will discuss the most useful form in which to disseminate our findings within the Trial Management Group and with PPI representatives. We intend to write up findings of the work included in this protocol, for publication in a peer reviewed journal. The work will also inform an application for funding for a definitive trial. All conference posters and presentations will acknowledge NIHR as the funder.

All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings. Resulting publications and/or abstracts will be emailed to the JRO.

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## 21.APPENDIX -Schedule of assessments

| | **Screening (Pre-treatment assessment)** | | **Intervention phase** | | | | | **6 Month follow up assessment** | **Optional qualitative interview** |
|---|---|---|---|---|---|---|---|---|---|
| Visit No: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | Weeks 1-8 | Week 9 | Week 11 | Week 13 | Week 15 | Week 17 | Week 19 | Week 36 | Week 38 |
| Window of flexibility for timing of visits: | | | +/- 2 weeks | +/- 2 weeks | +/- 2 weeks | +/- 2 weeks | +/- 2 weeks | +/- 2 weeks | +/- 2 weeks |
| Informed Consent | X | | | | | | | | |
| Eligibility confirmation | X | | | | | | | | |
| Baseline assessment (self-report questionnaires) | X | | | | | | | | |
| Training intervention | | X | X | X | X | X | X | | |
| 6 month follow up assessment (Self report questionnaires) | | | | | | | | X | |
| Optional qualitative interview | | | | | | | | | X |
| Adverse Events review | X | X | X | X | X | X | X | X | X |