Full title of trial	Clinical and cost-effectiveness of an in-home personalised health promotion intervention enabling independence in older people with mild frailty ('HomeHealth'): A Randomised Controlled Trial
Short title	HomeHealth RCT
Version and date of protocol	Version 4.0 09.12.20
Sponsor:	University College London (UCL)
Sponsor protocol number	128987
Funder (s):	NIHR Health Technology Assessment NIHR128334
ISRCTN no:	ISRCTN54268283
Intervention:	HomeHealth intervention (complex multi-domain behaviour change intervention for older people with mild frailty, delivered face to face by a support worker over six sessions)
Control:	Treatment as usual (TAU)
Phase of trial	Phase III
Sites(s)	Multi-site: Camden, West Yorkshire, East and North Hertfordshire
Chief investigator:	Professor Kate Walters Research Department of Primary Care and Population Health University College London Royal Free Campus Rowland Hill Street London, NW3 2PF k.walters@ucl.ac.uk 0208 016 8039

PROTOCOL VERSION HISTORY

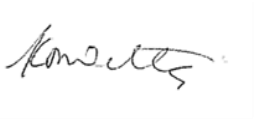
Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update
V1.0	03.03.20	Rachael Frost	
V2.0	10.06.20	Rachael Frost	Amendments for REC and HRA and after Trial Steering Committee review
V3.0	11.11.20	Rachael Frost	Minor clarification regarding allowable time window between baseline assessment and randomisation
V4.0	09.12.20	Rachael Frost	Clarification on how goal progress will be measured for different types of goals, correcting error in study summary that stated we would adjust for therapist effect, making clear throughout that participants will be approached for further research including 24 month outcome assessment (consistency with consent form), correcting error that unblinded trial staff could include TM.

SIGNATURES

The Chief Investigator and Priment have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, GCP, the UK Data Protection Act (2018), any applicable EU/UK amended acts to the Data Protection regulation, the Trust Information Governance Policy (or other local equivalent), the UK Policy Framework for Health and Social Care Research , Priment's SOPs, and other regulatory requirements as amended.

Chief investigator
Professor Kate Walters



02.03.20

Signature Date

Sponsor
Pushpsen Joshi

03.03.2020

UCL Signature Date

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2 LIST OF ABBREVIATIONS

Term	Definition
ADL	Activities of daily living
AE	Adverse Event
AR	Adverse Reaction
BI	Barthel Index
BCT	Behaviour Change Technique
BME	Black and Minority Ethnic
CCG	Clinical Commissioning Group
CI	Chief Investigator
CFS	Clinical Frailty Scale
CRF	Case Report Form
CSRI	Client Services Receipt Inventory
DI	Designated Individual
DSMB	Data Safety and Monitoring Board
eFI	Electronic Frailty Index
EU	European Union
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GHQ-12	12 item General Health Questionnaire
GP	General Practitioner
HRA	Health Research Authority
HTA	Health Technology Assessment
ICC	Intraclass Correlation Coefficient
ICECAP-O	ICEpop CAPability measure for Older people
ICF	Informed Consent Form
IPAQ-E	International Physical Activity Questionnaire-Elderly

ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
LA	Local Authority
MCID	Minimal Clinically Important Difference
MoCA	Montreal Cognitive Assessment
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PPIE	Public and Patient Involvement and Engagement
QALY	Quality-adjusted Life Year
RA	Research Associate
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SD	Standard deviation
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TAU	Treatment as Usual
TMG	Trial Management Group
t-MoCA	Telephone Montreal Cognitive Assessment
TSC	Trial Steering Committee
UCL	University College London
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale
YFC	Years of Full Capacity

3 TRIAL PERSONNEL

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

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4 SUMMARY

Objectives:

1. Test the clinical effectiveness of HomeHealth in maintaining independence in a randomised controlled trial (RCT)

2. Determine the cost-effectiveness of HomeHealth

3. Quantify the cost/savings of HomeHealth to different health and social care providers

4. Explore the context, mechanisms and impact of the intervention and barriers and levers to implementation at scale in a parallel mixed-methods process evaluation and impact stream.

Type of trial:

Single-blind two arm individually randomised controlled trial of the HomeHealth intervention compared to Treatment As Usual (TAU) in older people with mild frailty, with an embedded process evaluation.

Trial design and methods:

An individually randomised, parallel-group, multi-site trial comparing the HomeHealth intervention to TAU. The HomeHealth intervention is a multidomain six-month behaviour change intervention delivered face-to-face by a support worker in participants' homes. Participants will be individually randomised using sealed envelope web based online system set up by Priment Clinical Trials Unit (CTU) after baseline assessment. Data will be collected at 0, 6 and 12 months face-to-face, by video or by telephone, by a Research Associate (RA) blinded to intervention status. The primary outcome measure is basic Activities of Daily Living (modified Barthel Index, 12 months). Secondary outcomes include: Instrumental ADLs (Nottingham Extended Activities of Daily Living), Fried Frailty Phenotype score (components: gait speed, grip strength, physical activity (International Physical Activity Questionnaire-Elderly (IPAQ-E)), exhaustion, weight loss), wellbeing (Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)), loneliness (UCLA 3-item), psychological distress (12 item General Health Questionnaire (GHQ-12)), cognition (Montreal Cognitive Assessment (MoCA)), falls (ProFANE consensus criteria), mortality and carer burden. At each timepoint we will also collect data on Covid-19 status, whether the participant is classed as 'clinically extremely vulnerable' and data on long term health problems as a result of

	Covid-19. We will also seek consent to be involved in further research (e.g. collecting 24 month routine data as a post-trial follow up). For the health economic analysis, we will collect quality of life (EQ-5D-5L), capability (ICEpop CAPability measure for Older people (ICECAP-O)), healthcare and additional services (e.g. paid and unpaid care) utilisation (modified Client Services Receipt Inventory (CSRI) and primary care medical record extraction). Process evaluation: We will carry out an embedded process evaluation. After trial completion, we will carry out up to 40 semi-structured interviews with a purposive sample of participants, service providers and stakeholders. We will also collect intervention process data from trial documentation (e.g. goals set, appointments attended) and audio-recordings of intervention appointments. The process evaluation will additionally explore the impact of Covid-19 upon intervention delivery, particularly use of videoconferencing and telephone appointments, technical issues and support needed, and perceived impact upon intervention delivery.
Trial duration per participant:	12 months (up to 13 months for participants taking part in process evaluation interviews). Participants will also be consented to be approached for further research (e.g. at 24 months for longer-term follow-up).
Estimated total trial duration:	24 months
Planned trial sites:	Camden, Yorkshire, Hertfordshire
Total number of participants planned:	386
Main inclusion/exclusion criteria:	Inclusion criteria: Community-dwelling older people aged 65+ years with mild frailty defined using the Clinical Frailty Scale (those with more evident slowing and needing help in Instrumental Activities of Daily Living e.g. finances, heavy housework, shopping) Exclusion criteria: Those in care homes, on palliative care register, who lack capacity to consent, already case managed (e.g. by community teams).

Statistical methodology and analysis:	The primary outcome will be analysed by intention-to-treat using mixed effects linear regression, controlling for site (the straification variable) and baseline BI score. Secondary outcomes will be analysed with analogous linear or logistic regressions.
Health economic analysis	For the health economic analysis, we will calculate the mean incremental cost per quality adjusted life year and years full of capability gained for the duration of the trial and report this from cost perspectives of the NHS and personal and social care services. We will conduct a budget impact analysis to quantify the costs to different health and social care providers.
Process evaluation analysis	We will undertake a mixed-methods process evaluation exploring fidelity, dose and reach of the intervention, potential mechanisms, contextual factors, pathways to impact and impact of Covid-19 upon intervention delivery. Interviews will be recorded, transcribed and analysed using thematic analysis. Normalisation process theory will be used to explore barriers and facilitators to implementation. We will compare the characteristics of participants to area level characteristics. We will descriptively summarise the use of videoconferencing and telephone appointments and any issues arising from this. We will explore mechanisms/pathways to impact including goals selected, goal attainment, intervention effects stratified by behavioural target(s) chosen and impact of the intervention on behavioural outcomes.

5 BACKGROUND AND RATIONALE

Frailty is a condition caused by the accumulation of multiple deficits and reduction in physiological reserves that occur across multiple body systems as we age (1). Frail individuals have poor recovery from even minor events, such as a urinary tract infection or a non-injurious fall, and are vulnerable to multiple adverse health outcomes including falls, disability, hospitalisation, moves to care homes, dementia, poor quality of life and death (1-4). Healthcare costs estimated to be 5-6 times higher in frail older people compared to those who are robust (5). The impact of frailty on health and social care is likely to increase as the number of people aged 75+ in the UK is estimated to rise from 5.2 million to 9.9 million by 2039 (6).

Frailty is best understood as a continuum, from those in robust health to those with severe frailty. The prevalence of frailty varies depending on how it is measured, but around 11% of people aged 65+ years

worldwide (7) and 14% in England (8) can be categorised as physically frail, while 13% can be defined as 'mildly frail' (9). Mild frailty is an intermediate stage where a person has some loss of physiological reserves but can recover after a stressor event (10). They typically feel "slowed up", with increasing need for assistance in instrumental activities of daily living e.g. cooking, shopping and money management (9). Mild frailty is associated with adverse outcomes, including a progressive functional decline (11) and 2.5 times the risk of a move to care homes compared to those without frailty (12). Those with mild frailty can progress to severe frailty (13) with increasing loss of independence, need for care and other adverse outcomes. However this is not inevitable (10, 13) and may be modifiable.

Previous interventions have often focussed on preventing decline or reducing frailty in the highest-risk populations with moderate-severe frailty, with limited success (14, 15). By contrast, older people with mild frailty are more likely to transition back to non-frailty or remain stable than those who are frailer (13, 16), and health promotion interventions may be more effective with less frail populations (17, 18). This forms a good rationale to target a new health promotion intervention at those with mild frailty, aiming to delay/slow decline, maintain independence and 'compress morbidity' into the final stages of life (19).

Home-based interventions, largely based upon comprehensive geriatric assessment, typically by nurses, seem promising in frailer older people, with reported beneficial effects on mortality, functioning and emergency department admissions (20-22). However, these can be expensive, resource intensive (requiring specialist input) and difficult to deliver at scale. In current NHS practice, case management approaches focus on high risk groups (e.g. moderate-severe frailty) identifying deficits/problems with signposting and follow-up to address these. Designed in response to service needs, the opportunities to promote ongoing behaviour change can be missed or given a lower priority. Older people themselves tend to view successful ageing as including both biomedical (physical, mental and cognitive) and psycho-social components (23), such as meaningfully connecting to the world they live in. Their key priority is maintaining their independence (24). While health and social care professionals are mindful of psycho-social factors and context, they often lack resources, time, techniques, and/or skills to be able to directly address these.

Systematic reviews in our previous developmental work found that little was known about effective or cost-effective interventions for those with mild frailty (25). Interventions for frail older people often lacked a clear theoretical basis, rigorous development or stakeholder input (26). Other studies have shown some promising multi-domain interventions in different populations/settings, particularly those including an exercise component, however with mixed findings and limited data on cost-effectiveness (15, 27-32). Current healthcare for this group includes few 'upstream' approaches (33), with a lack of evidence based health promotion approaches that are both feasible to deliver in the NHS and its partners and acceptable to older people (25).

Our previous development study, following MRC guidelines (34), resulted in a complex evidence and theory-based multi-domain health promotion intervention delivered over six months. This was developed in partnership with stakeholders and based on behaviour change principles (35) (for more information see Section 7.1). We conducted a feasibility Randomised Controlled Trial (RCT) with older people with mild frailty individually randomised to our HomeHealth intervention or 'Treatment as Usual' (TAU) recruited from four diverse General Practices in Camden, London and Hertfordshire. The study was highly successful: we recruited to target (n=51/50), in less time than anticipated (4.5months, not 6) with 96% retention at 6 months (36). There was no evidence of control group contamination, supporting our individually randomised approach, and minimal missing data (<1%). The intervention was well-received and delivered at modest cost (£307/patient). Our process evaluation demonstrated through interviews, questionnaires and process data that the intervention was feasible to deliver and acceptable to participants, with few suggested improvements. Fidelity (delivery as planned) was 77%, with a 91.3% appointment attendance rate. We found significantly better functioning (Barthel Index; +1.68, p=0.004), grip strength (+6.48kg, p=0.02), reduced psychological distress (GHQ-12; -3.92, p=0.01) and increased capability-adjusted life years (+0.017, p=0.03) at 6 months compared to TAU, with no differences in other outcomes. NHS and carer-support costs were variable, but overall lower in the intervention arm. We concluded that this model should be tested in a definitive trial with multiple sites and longer follow up. This trial therefore aims to assess the clinical and cost-effectiveness of the HomeHealth intervention for older people with mild frailty compared to TAU.

Currently, there are recommended interventions in primary care for those who are moderately or severely frail, but no standard of care exists for mildly frail groups. Within our feasibility trial, the TAU group attended routine GP and practice nurse appointments, but had minimal use of other services that might be relevant for this population e.g. falls prevention classes. All sites have agreed that they do not plan to change services for people with mild frailty in the next three years. Our comparator for this trial is therefore TAU. Within the trial, it is impossible to blind participants as to whether or not they are receiving the service as it can be clearly differentiated from TAU. The trial will therefore be single blind (blinded outcome assessors).

5.1 ASSESSMENT AND MANAGEMENT OF RISK

We do not consider this trial to be high risk. The study personnel and co-investigators will ensure that the study is conducted in line with NHS and professional ethical and research governance guidelines. Training and regular supervision will be provided to researchers on study procedures by the CI, PIs and trial manager. Training and central supervision will also be provided to support workers delivering the intervention.

Lone working: Researchers 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
Researchers will offer participants the option of remote follow up assessments. Researchers will carry mobile phones and they will be able to contact the CI or trial manager during work hours and out of hours. Researchers will contact a member of the study team if they are not returning to the office after

an assessment. The study team will have addresses, phone numbers and next of kin details of all researchers. Support workers will follow lone working guidelines at their employing institution.

Confidentiality: All members of the research team will have undertaken and will provide certification for Good Clinical Practice, information governance and data protection training.

For baseline and outcome assessments, electronic and/or paper CRFs will be collected. Self-report questionnaires will be posted back to the research team if completed remotely. For the process evaluation, paper and electronic data will be collected. CRFs, intervention process data (e.g. fidelity checklist) and audio transcripts will be pseudonymised, labelled by participant ID and initials. Paper and audio recorded intervention and assessment data will be stored securely during transfer and will be transferred to the appropriate site secure storage as soon as feasible. Any videoconferencing for remote assessments or intervention delivery will be conducted over a secure platform. Intervention process and interview data will be stored separately to CRFs. Audio data will be uploaded as quickly as feasible to a secure folder and the recording deleted from the recorder. Sensitive personal data will be stored in the UCL Data Safe Haven or locked filing cabinets with limited access; pseudonymised data will be stored in separate locked filing cabinets or password protected folders with limited access to only authorised personnel.

If participants disclose information to a RA leading them to believe that the participant or others are at significant risk, the researcher will discuss it with the site PI and/or the trial's Clinical Safety lead and if appropriate, will seek consent from the participant to contact the participant's GP or a local safeguarding service as appropriate. If participants disclose information to a support worker leading us to believe that they or others are at significant risk, they will contact their clinical supervisor in the first instance and will seek consent to contact the participant's GP or a local safeguarding service as appropriate, and will also inform the study team (CI, Clinical Safety Lead and site PI).

Lack of intervention fidelity: The intervention is manualised. Support workers will receive five days initial interactive case-based and skills focused training. Core training will be supplemented by other mandatory training (e.g. adult safeguarding, information governance) and one day 'top-up' training in exercise, nutrition and behaviour change 2-3 months after starting intervention delivery. Support workers will receive 2 weekly group supervision, with one-to-one supervision as needed. Ongoing supervision and support by telephone or videoconferencing from experts in behaviour change, communication skills, exercise, nutrition and mood will also be available to support workers. We will document fidelity within the process evaluation through audio-recording appointments and checking 10% of participants' appointments against a checklist from our feasibility trial.

Trial conduct: The trial will be overseen by a Trial Steering Committee (see Section 13), and supported by Priment CTU. Priment CTU will support and provide expertise in trial methodology, conduct, management, safety reporting, quality assurance monitoring Priment will also support the trial database development and will develop and implement the statistical and economic analysis plans and will lead on the health economic and statistical analysis. There will be regular team meetings in place and email

or phone communication as needed. The research team will keep in regular contact with the sites. As this is a single-blind study, there is a small risk that assessors may become unmasked. We will minimise this risk by asking the assessors to remind participants at each stage that they must not reveal their treatment arm allocation to their assessor. Assessors will be blinded to the arm allocation within the Sealed Envelope database via their access role. If an assessor does become unmasked, the study team will record this and ask an alternative assessor to complete future outcome measures for that participant. At the end of assessment for each participant the assessor will record which study group they believe the participant has been allocated to in order to verify blinding.

The table below summarises the risks and mitigations of all tests above standard care that are being performed:

Name of Intervention/ Assessments/ design and Methods/ trial Population	**Potential risk**	**Risk Management**
Gait speed measurement, weight measurement, height measurement	Falls risk	This will only be carried out if a face-to-face assessment is possible and it is optional for the participants. Researcher will be trained and will take care with the participant. Participants are not likely to be high risk (high risk participants are likely to be moderately frail and so will be excluded from the trial)
MoCA	Risk of participant distress or concern if failing some items	Researcher will make it clear to participants that this is not a diagnostic test for dementia, will not disclose total score and will signpost participant to consult their GP if they have further concerns
Managing red flags	Managing red flags such as marked weight loss or very distressed on GHQ12	Researcher or support worker will discuss any red flags with the CI, site PI or Clinical Safety Lead and if appropriate, will seek consent to inform the participant's GP or a local safeguarding service.
Covid-19 transmission	Risk of transmission between research team and participants, and HomeHealth workers and participants	A decision making flow chart has been developed to put in place contingency plans regarding remote assessments and intervention delivery in accordance with the current risk level. Implementation of contingency plans will be assessed on an ongoing basis and light of any national changes, and will subject to approval by the TSC and funder.

6 OBJECTIVES

Primary: Test the clinical effectiveness of HomeHealth in maintaining independence in a randomised controlled trial (RCT).

Secondary:

1. Determine the cost-effectiveness of HomeHealth.
2. Quantify the cost/savings of HomeHealth to different health and social care providers.
3. Explore the context, mechanisms and impact of the intervention for different populations (age, gender, deprivation, ethnicity, rurality) and barriers and levers to implementation at scale in an embedded mixed-methods process evaluation and impact stream.

7 TRIAL DESIGN

7.1 OVERALL DESIGN

Single-blind two-arm individually randomised trial comparing the HomeHealth intervention to TAU in older people with mild frailty. Participants will receive the individualised, multi-domain behaviour change intervention in six sessions over six months. Data will be collected at baseline, six months and 12 months by blinded outcome assessors. Participants will be additionally consented to be approached for longer-term (post-trial) follow-up using routinely collected data from NHS and local authority social care.

8 INTERVENTION AND CONTROL

'HomeHealth' is an individualised multi-domain behaviour change intervention based upon evidence and theory, which has been co-designed with stakeholders (see Appendix 2 for logic model). It was developed and tested in an initial feasibility study (34). Participants are initially offered up to six individual one-to-one sessions with a support worker over six months, and where needs are more complex more sessions (up to maximum 12) can be offered within this period. Complex needs may include situations such as participants with a combination of complex physical, cognitive and mental health needs who may need extra support or carer involvement to develop achievable goals and overcome barriers, or where new needs or events arise during the intervention period (e.g. a hospital admission or fall) which may require re-setting goals or further support to overcome any associated setbacks. The first session will be face-to-face where possible, in accordance with current Government guidelines and using any personal protective equipment or social distancing measures in line with current guidance, with subsequent sessions delivered face to face, by videoconferencing or by telephone according to participants' needs. If it is not possible to deliver the intervention face-to-face, potential participants will be offered the opportunity to defer enrolment in the trial until a later date or carry out all sessions by videoconferencing or telephone. If the participant does not have a device to undertake videoconferencing but would like to use this method, we will provide them with an internet-enabled study funded tablet to encourage participation, and the support worker will provide support with any technical issues. The number, duration and contact type of sessions attended by each

intervention participant will be documented and summarised in the embedded process evaluation. The impact of remote delivery will also be explored. At least three intervention sessions will be considered a minimum dosage.

Core domains covered by the intervention include mobility (physical activity, exercise and falls prevention), under-nutrition or risk of malnutrition, mood (depression/anxiety) and social engagement, with the potential for participants to include additional goals (e.g. modifying their home environment). In each session, participants set and address self-directed independence and wellbeing goals, supported by a HomeHealth support worker through education, skills-training, overcoming barriers, providing feedback, maximising motivation, coping with setbacks and promoting habit formation. The support worker undertakes an initial behavioural assessment, considering the participant's capability, opportunity and motivation to change and their overall outcomes goals are broken down into behavioural goals and 'SMART' objectives (Specific, Measureable, Achievable, Realistic, Timely). This assessment can include strategies to compensate for common problems causing barriers to change in this population e.g. fatigue, urinary incontinence. The support is individually tailored, and for frailer individuals or those with cognitive impairment this may include involving another person (e.g. family member or friend), or providing practical support to overcome barriers, such as technology or provision of aids. Baseline function (capability) is taken into account – for example the exercise/physical activity programme (exercises and intensity) will be tailored to ability and falls risk. Subsequent sessions then include reviewing goals and progress, addressing problem solving, coping with setbacks and low motivation, modifying or developing new goals as needed, forming an action plan and maintaining behavioural changes.

The service is delivered by a trained support worker who has experience working with older people, but without specialist qualifications. They are based within either primary care or community/voluntary sector teams working with older people. There will be some local variation in this, but providers may be voluntary sector (e.g. Age UK) or within a Community Multi-Disciplinary Team (MDT) providing services for older people with frailty within local areas. Where appropriate support workers will encourage or enable participants to access local services, e.g. falls prevention schemes, psychological therapies, hearing/low vision aids, continence services, transport, dieticians, memory clinics, debt/housing/benefits advice, etc.

The control group will receive Treatment As Usual (TAU), as currently there is no standard of care delivered specifically for a mildly frail population. In our feasibility study, this included usual GP and practice nurse appointments, with some participants using secondary care services. Few accessed other health promotion services that might be suitable for this population, e.g. falls prevention classes.

8.1 CONCOMITANT MEDICATION

There are no inclusion or exclusion criteria based on concomitant medication, as these are unlikely to confound the results of the trial. All medications taken during the trial period by participants will be

collected in a CRF retrospectively from their medical notes by a RA. All other interventions received e.g. physiotherapy, psychological therapy, will be collected by participant self-report using a modified Client Services Receipt Inventory.

8.2 POST-TRIAL INTERVENTION ARRANGEMENTS

The intervention is carried out for a six month period per participant, and therefore there are no arrangements to continue the trial intervention after the ending of the trial. Throughout the study, we will work with an implementation group to develop a strategy for if and how the intervention should be more widely implemented if effective.

9 SELECTION OF PARTICIPANTS

9.1 ELIGIBILITY OF TRIAL PARTICIPANTS

9.1.1 TRIAL PARTICIPANT INCLUSION CRITERIA

- Older people aged 65+
- Registered with a general practice within the participating site area
- Scoring as '5. Mildly frail' on the Rockwood Clinical Frailty Scale
- Community-dwelling (including extra care housing)
- Life expectancy of >6 months
- Capacity to consent to participate

People with dementia will not be excluded from the study, providing they fit the above criteria.

9.1.2 TRIAL PARTICIPANT EXCLUSION CRITERIA

- Care home residents
- Those with moderate to severe frailty (6-9 on Rockwood Clinical Frailty Scale (CFS)) or not frail (1-4 CFS)
- Receiving palliative care
- Already case managed
- Lack capacity to consent

9.2 RECRUITMENT

We will recruit older people with mild frailty registered with a General Practice within three geographically, ethnically and socially diverse areas; Camden Clinical Commissioning Group (CCG) (London), Airedale, Wharfedale & Craven CCG (West Yorkshire) and East & North Hertfordshire CCG. We anticipate recruiting 6-9 General Practices per area, that will represent diverse neighbourhoods (e.g. rural areas, areas with high deprivation, and high proprtions of black and minority ethnic (BAME) populations). Recruitment is outlined in a flow chart in Appendix 3. Practices will conduct list searches

using the electronic frailty index (eFI) (37), which classifies patients into those with mild, moderate and severe frailty. We will exclude those who are robust or with severe frailty. Practices will review the list of those identified with mild or moderate frailty (the eFI is known to be over-sensitive in comparison to clinical judgement). Clinicians within the practices will be asked to use their existing knowledge of patients or medical records and the Clinical Frailty Scale (CFS) criteria to exclude those known to be very fit – managing well (categories 1-3), and those known to be clearly moderately frail or worse (category 6 or more), plus those who meet the additional exclusion criteria. Practices will then send postal invitations to those who are potentially eligible (i.e. with initial mild or moderate frailty on the eFI and either unknown/uncertain frailty status (using the CFS with existing knowledge) or who are considered 'vulnerable' or mildly frail (categories 4 or 5)). Postal invitation packs will include an invitation letter, a leaflet about the study, a leaflet about the HomeHealth service and a reply slip. Invitation letters and leaflets include a series of questions on frailty symptoms (e.g. weakness, excessive tiredness, feeling it is taking longer/more difficult to do things) to allow for self-identification. Those who positively self-identify as potentially eligible and are interested in participating will be asked to return the reply slip to the RA at each site.

In addition, health and social care professionals including GPs, practice nurses/health care assistants, community teams, social workers and care navigators and those working in the voluntary sector (e.g. Age UK, local support groups) will be able to refer people they judge as potentially eligible (having mild frailty) directly. Older people or carers can also self-refer for inclusion screening from posters and/or leaflets that will be distributed in community venues, such as GP waiting rooms, community pharmacies, sheltered or extra care housing facilities, libraries, day centres, lunch clubs, carer centres and faith groups. We will publicise the study in these facilities, including outreach work including giving talks in venues that are likely to have eligible people attending, with a particular focus on those who may not participate through contact via their GP (e.g. BAME groups, in more deprived areas etc). We will also recruit virtually through relevant community groups such as local Age UK groups, Univeristy of the Third Age and older people's forums, through asking them to circulate study leaflets to members. Those who express an interest will contact the research team at their site or at the central UCL site directly for screening.

The RA at each site will conduct telephone screening using the study inclusion and exclusion criteria, and if the person is eligible, send a copy of the participant information sheet (PIS) with an appointment letter confirming the time of the baseline assessment (which will be at least 24 hours after planned receipt of the PIS). At baseline assessment the RA will confirm eligibility, check the participant has read the PIS and ask if they have any questions, and seek informed consent prior to undertaking assessments. Researchers will keep screening logs on all participants expressing an interest, including numbers who refused participation, numbers ineligible and reasons for ineligibility.

Process evaluation

For the process evaluation, existing participants in the intervention arm who have completed the final outcome assessment will be sent an invitation to participate in an interview by an unblinded RA. We will aim to recruit approximately 20 participants receiving the service (including carers where they have been involved), purposively sampled according to intervention appointment attendance, area type

(rural, urban), remote vs face-to-face service delivery, deprivation, ethnicity and baseline functioning. Participants will also be sampled for maximum diversity according to age, gender and sexuality, choice of goal type and recruited earlier/later in the study. Separate consent will be sought for participating in an interview. Service providers, managers and supervisors (approximately 10) will also be recruited for interviews about experiences of delivering the service. Around 10 other stakeholders (e.g. GPs, other relevant team members) will also be recruited for a telephone interview.

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

1. Been confirmed by the Sponsor (or its delegated representative) by providing green light, and
2. Been issued an 'NHS permission letter'.

9.3 INFORMED CONSENT PROCEDURE

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 responsibility for seeking informed consent will be delegated by the CI/PI to Research Associates based at each site, as will be indicated on the Staff Signature and Delegation of Tasks. We will not include any participants who we believe lack capacity to decide whether or not to take part in the study. Those participants who agree to take part will have their capacity assessed before written informed consent is obtained. This assessment will be carried out by the Investigator or persons delegated by the Investigator, who will all be trained to assess capacity. If the person has capacity they will then be given a consent form to sign. If the person no longer has capacity to consent to participate, they will not be invited to take part. Assessment of capacity will be documented. We will abide by the Mental Capacity Act (England and Wales) (2005) throughout. All Research Assistants will have undertaken GCP and Mental Capacity Act training and will be suitably trained and qualified to assess capacity to consent prior to seeking consent. People interested in taking part in the study will have at least 24 hours to read the Participant Information Sheet (PIS), which they will receive by post after expressing an interest, screening positively and booking a baseline assessment. Informed consent (see attached Consent Form) will be sought face-to-face at the participant's home prior to baseline assessment if possible. If this is not possible, a consent form will be completed by the person at home (with assistance from a researcher to complete if needed), either written and returned by post or completed digitally and emailed to the research team. If neither of these methods are possible audio recorded verbal consent will be sought and a transcript sent to the participant. If on paper, the participant will sign two copies of the consent form, and will retain one whilst the other will be filed in the site trial file. Prior to seeking the consent, the person will be given an explanation of the study by the Investigator or designated individual (including potential risks and benefits, that they are under no obligation to take part and can withdraw at any time without giving a reason) and the opportunity to ask any questions. A copy of the signed consent form will also be posted to their GP practice to be filed in the participant's medical notes. 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. Some items on the consent form (including agreeing for appointments to be audio-recorded, agreeing to be approached for a process evaluation interview and agreeing to be approached for further research including 24 month follow up contact) will not be compulsory to participate in the trial. These are clearly indicated.

The PIS and consent form will be reviewed and updated if necessary throughout the trial (e.g. where new assessments are required or additional safety information becomes available) and participants will be re-consented if appropriate.

If a participant loses capacity during the trial, we will retain them in the trial if they have a personal or nominated consultee that can support them during the assessments and they consented to this at baseline. If they do not, we will withdraw them from the trial but retain their data up to that point unless otherwise requested. This is outlined in the consent form.

10 TRIAL PROCEDURES

10.1 PRE-TREATMENT ASSESSMENTS

Participants will be screened by a RA over the telephone on expressing an interest, who will ask a series of structured screening questions about symptoms of frailty and need for support with instrumental and basic activities of daily living. People who meet the criteria (Rockwood Clinical Frailty Scale score 5 Mild Frailty: reporting one or more symptoms of frailty and requiring support for one or more instrumental activities of daily living, but not receiving help for a basic activity of daily living) will be invited to a face-to-face appointment at the person's home or to take part in a virtual assessment (telephone or video conferencing) at which the researcher will seek informed consent and undertake a baseline assessment. A screening log will be used to document those screened, those excluded and reasons for exclusion.

The RA will then seek informed consent and undertake a baseline assessment, either face-to-face (if possible) or by telephone/video conferencing. If potential participants have hearing impairment, they will be asked if they would like copies of the questionnaires to be posted to them to refer to during the assessment, or to arrange it at a time when friend or relative could be there in person to support them. RAs will be trained in clear communication. The baseline assessment will consist of all instruments listed in the Schedule of Assessments in Appendix 1, including the primary and secondary outcome assessments, demographics and a number of baseline characteristics that will not be assessed as outcomes (e.g. cognition, lifestyle factors). The baseline assessment is estimated to take 50-155 minutes, which was acceptable to feasibility trial participants with minimal missing data.

If it is not possible to screen the person over the phone or their frailty status remains uncertain, the RA will ask the same screening questions in person and observe their functional status (e.g. gait, use of aids) to reach a frailty categorisation. If the person screens as mildly frail then consent for participation will be sought, and if the person consents, a baseline assessment will be undertaken.

10.2 RANDOMISATION PROCEDURES

Randomisation will be 1:1, stratified by site, and will be carried out independently using the remote computerised web-based application Sealed Envelope, provided by Priment CTU. It will be set up, tested and validated following Priment SOPs. Participant randomisation will be undertaken by site staff if there is sufficient capacity for unblinded staff to perform this, otherwise this will be undertaken centrally by unblinded staff (e.g. administrators, process evaluation RA). Staff will enter screening details online to randomise the participants. Randomisation will be undertaken after consent has been taken and a baseline assessment completed. A Trial Participant Enrolment log will be stored securely at each site in the site file, with access restricted to the research team. If the participant is randomised to the intervention group, the site PI or administrator will inform the HomeHealth support worker delivering the intervention at the appropriate site to pass on the participant's details. The support worker will then contact the person directly to arrange a time for an initial appointment. Those randomised to the control group will be informed by another central or site member of staff who can remain unblinded. The Data Management Plan will specify which trial staff are blinded.

10.3 SUBSEQUENT ASSESSMENTS AND PROCEDURES

10.3.1 VISIT SCHEDULE AND ASSESSMENTS

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

Outcome assessments

A RA will carry out the outcome assessments at 6 months and 12 months post-randomisation, as outlined in Appendix 1 Schedule of Assessments. Outcome assessments will be carried out face-to-face, by videoconferencing or by telephone depending upon current guidance in relation to Covid-19 and the participant's preference. Self-report questionnaires (containing some of the outcome measurements) will be offered to participants to complete at home either by weblink or on paper and posted back to the research team, with telephone support from a RA if needed. If participants have hearing impairment, they will be asked if they would like copies of all questionnaires to be posted to them to refer to during the assessment, or to arrange it at a time when friend or relative could be there in person to support them. The RA will be blind to arm allocation, and will ask participants not to disclose whether they have received the HomeHealth service at the start of all contacts. Outcome assessments are estimated to take 40-150 minutes, which was acceptable to participants in our feasibility trial.

Within six months following the participant's 12 month visit, an RA will collect data from their primary care medical notes. Data will include primary and secondary healthcare usage, medications and comorbidities (see Appendix 1). If an AE or SAE is detected (e.g. an A&E attendance) during the follow up period, this will be recorded separately in the site AE log or corresponding CRF.

Process evaluation

Intervention data: For each client, service providers will record the following data as the intervention progresses: number of appointments attended, modality and duration, technical issues with remote delivery, reasons for non-attendance; goals set by participant (coded into mobility, psychosocial,

nutrition or other); progress towards achieving goals at each appointment; fidelity checklists after each appointment; and audio recording all intervention appointments (10% of individuals will be randomly selected and their appointments audio-files transcribed for fidelity checking).

Evaluation interviews: A sample of approximately 20 intervention participants will also be invited to participate in an interview about their experiences. Participants are consented in the main trial consent form for further contact to be invited to participate in the process evaluation. Consent will be sought separately for this part of the study by an unblinded RA, who will not be involved in the intervention delivery. One interview will be carried out remotely or in the person's home, depending on participant preference and current Covid-19 guidance. This will explore their experiences of receiving the service, experiences of remote delivery in light of a national pandemic, their choice of goals, experiences of behaviour change and barriers and facilitators to engaging with the service.

As part of the process evaluation, all service providers, managers and supervisors will be invited to participate in a face to face, video or telephone interview regarding their experiences of delivering the service, factors influencing this, training and supervision and barriers and facilitators to participant engagement. We will also interview up to 10 other stakeholders such as GPs, practice nurses and other relevant team members by telephone to understand their perceptions of the service, the extent to which HomeHealth has been integrated into practice processes and barriers and facilitators to commissioning and implementation.

Long term follow up

Participants will be consented to be approached for further research, including long term follow up (24 months).

10.4 CLINICAL PROCEDURES

No further procedures will be carried out above those described in 10.3.1 and in Appendix 1.

10.5 ASSESSMENT OF TRIAL INTERVENTION COMPLIANCE

Attendance at sessions will be documented by the HomeHealth support worker. Attending at least 3 sessions will be considered compliance with minimum dosage.

10.6 DISCONTINUATION/WITHDRAWAL OF PARTICIPANTS

Participants may discontinue the intervention sessions or withdraw from the project. If a participant expresses their wish to withdraw from trial treatment, sites will explain the importance of remaining on trial follow-up and seek permission to contact for assessments and for use of routine follow-up data to be used for trial purposes. Although we will stress that participants can withdraw at any time without giving a reason, we shall retain any assessments that have been collected to that point and we shall maintain contact unless told otherwise. Service use data and routine data such as mortality from

medical notes will also be collected for the duration of the trial, unless the participant specifically requests these not be collected, as outlined in the information sheet and consent form. If the participant becomes acutely unwell, they will be contacted at a later date to see if they wish to continue participation. Participants will be consented at baseline to opt to continue with the study if they lose capacity during the study period and they have a personal/nominated consultee to support them in ongoing participation and completion of outcome measures. If a person who had capacity at the start of the study loses capacity and a personal/nominated consultee is not identified they will be excluded from the study.

Withdrawal will be recorded explicitly in the CRF and a copy of this will be sent to the participating practice to file in their medical notes. The participant may withhold their reason for withdrawal however, if the participant gives a reason for their withdrawal, this should be recorded. Participant mortality and cause of death will be recorded as a study endpoint in the CRF. If a participant moves to a care home they will be retained in the trial and undertake outcome assessments unless they choose to withdraw.

Loss to follow-up

If a participant moves from the area, every effort will be made for the participant to be followed up, either by that site or at another participating trial site (if a new site they will to take over the responsibility for the participant). If a participant is lost to follow-up at a site every effort will be made to contact the participant's GP to obtain information on the participant's status.

10.7 REPLACEMENTS

Withdrawn participants will not be replaced.

10.8 STOPPING RULES

The trial may be stopped before completion for the following reasons:

- On the recommendation of the TSC
- On the recommendation of the Sponsor and CI

10.9 DEFINITION OF END OF TRIAL

The expected duration of the trial is 2 years from recruitment of the first participant.

The end of trial is the date of the last home visit of the last participant.

The end of the process evaluation will be the final interview with any stakeholder (participant, service provider etc).

11 RECORDING AND REPORTING OF ADVERSE EVENTS AND REACTIONS

Collection, recording and reporting of adverse events (including serious and non-serious events and reactions) to the Sponsor will be completed according to Priment pharmacovigilance SOPs.

11.1 DEFINITIONS for AE

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant administered a treatment/intervetnion and which does not necessarily have a causal relationship with the treatment/intervention. *Therefore an AE can be any unfavourable or unintended change in the structure (signs), function (symptoms) or chemistry (laboratory data) in a participant to whom a procedural intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention.*
Serious Adverse Event (SAE), Serious Adverse Reaction (SAR) or Unexpected Serious Adverse Reaction	Any adverse event that: 1. results in death, 2. is life-threatening*, 3. requires hospitalisation or prolongation of existing hospitalisation**, 4. results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect
Serious Adverse Reaction	Any SAE that is 1. Related to the trial intervention AND 2. Expected (listed in the protocol as an expected side effect of the intervention)
*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. ** Hospitalisation is defined as an inpatient admission, regardless of length of stay. **Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.**	
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Any SAE that is deemed to be 1. Related to the trial intervention AND 2. Unexpected (not listed in the protocol as an expected side effect of the intervention)
Important Medical Event	These events may jeopardise the participant or may require an intervention to prevent one of the above characteristics/consequences. Such events should also be considered 'serious'.

11.2 RECORDING ADVERSE EVENTS

All adverse events will be recorded by RAs in the source documents from randomisation intervention until the participant completes the trial. Participants will be asked open-ended questions at each outcome assessment regarding whether they have experienced any adverse events, and will also be asked to contact the research team if they experience an adverse event throughout the trial. If an AE is detected by a HomeHealth support worker, they will ask the participant to contact the research team to report it. Adverse events such as hospitalisations will also be documented if recorded as part of service use on the CSRI. Adverse events will be recorded at site with clinical symptoms and accompanied with a simple, brief description of the event, including dates as appropriate. Serious adverse events will be recorded in the CRF.

11.3 EXPECTED SIDE EFFECTS

This is a low risk intervention and we envision few side effects, although it is possible that the following adverse events may occur due to the intervention:

- Falls may occur in this population, both related (e.g. during exercises, during social visits encouraged through the intervention) and unrelated to the intervention. All falls will be followed up and documented with details and relatedness to the intervention will be assessed by the site PI or Clinical Safety Lead.
- Delayed appropriate care (e.g. if the support worker misses a red flag symptom)
- Other mild adverse events, e.g. increasing exercise may cause increased pain or fatigue, or participants may become distressed from not meeting behaviour change goals or discussing sensitive issues.

As this is a population who are mildly frail, the following may occur but are unlikely to be related to the intervention:

- Falls (when assessed as unrelated to the intervention)
- Illness or severe illness requiring hospitalisation
- Death
- Loss of capacity or decline in cognition
- Worsening physical functioning

SAEs which fall into these categories and so are assessed as unrelated to the intervention will not be reported to the Sponsor.

11.4 ASSESSMENTS OF SERIOUS ADVERSE EVENTS

Each adverse event will be assessed by either the CI, site PI or other designated individual to determine severity.

11.5 RELATED EVENTS

Each serious adverse event will be assessed by either the CI, site PI or other designated individual to determine if the event is related to the intervention and if the event is expected. The assessment of the relationship between adverse events and the administration of the intervention is a decision based on all available information at the time of the completion of the case report forms (CRFs). If the event is a result of the administration of any of the research procedures then it will be classed as related.

11.6 EXPECTED EVENTS

If the event has been listed in the protocol (section 11.3) as an expected side effect of the intervention then the event will be classed as expected. If the event is not listed then it will be classed as unexpected.

11.7 PROCEDURES FOR RECORDING AND REPORTING SERIOUS ADVERSE EVENTS AND SUSPECTED UNEXPECTED SERIOUS ADVERSE EVENTS

All serious adverse events will be recorded in the CRF and the GP will be notified of self-reported SAEs to record in the electronic medical records. All SAEs (except those specified in section 11.3 as not requiring reporting to the Sponsor), must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will review and assess causality and severity. The form will be preferably emailed to primentsafety@ucl.ac.uk within 24 hours of his / her becoming aware of the event, with the Sponsor informed within 5 working days. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible. All SAEs will be recorded from when the participant is randomised until the date of their final outcome assessment.

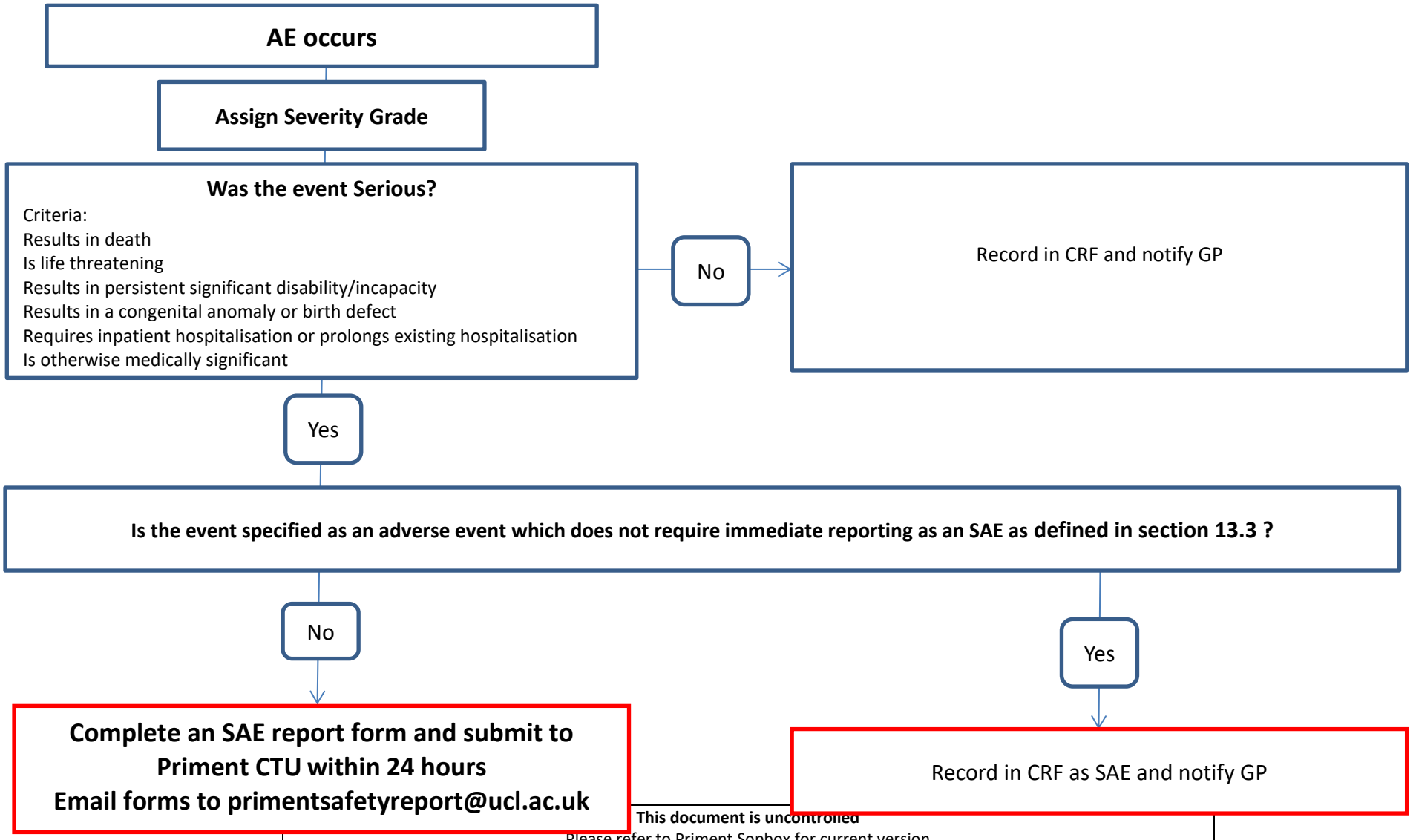
The RA or intervention provider who detects a serious adverse event will complete the Serious Adverse Event CRF and send it to the site PI/or delegated individual for review and assessment of causality and severity. Participants will be followed up if necessary for SAEs related to the intervention and follow up forms will be clearly marked and emailed to Priment as more information becomes available. SUSARs will be reported to the Sponsor within 24 working hours of the CI or delegated individual becoming aware of the event. Site PIs will be informed of any updates on safety through email. The trial is single blind (outcome assessors only) so no unblinding measures will be required.

Where the event is unexpected and thought to be related to the intervention, it is a SUSAR and this must be reported by the Investigator to the Health Research Authority within 15 days. SUSARs that are fatal or life-threatening must be notified to REC within 7 days after the Chief Investigator has learned of them.

Completed SAE forms (for those related to the intervention) must be sent within 24 hours of becoming aware of the event to Priment CTU
Email forms to primentsafetyreport@ucl.ac.uk

The reporting of adverse events to the ethics committee and Sponsor will be completed according to Priment non-CTIMP safety management SOP or to any other specific requirements if the Sponsor of the trial is not UCL.

Flow Chart for SAE reporting



11.8 NOTIFICATION OF DEATHS

Only deaths that are assessed to be related to the Intervention will be reported to the Sponsor. This report will be immediate.

11.9 REPORTING URGENT SAFETY MEASURES AND OTHER SAFETY EVENTS

If any urgent safety measures are taken, the CI/ PI shall immediately notify Priment of this measures, and in any event no later than 3 calendar days from the date the measures are taken. Written notification will be submitted within 3 calendar days to the relevant REC as in line with Priment SOP on Urgent Safety Measures.

11.10 NOTIFICATION OF SERIOUS BREACHES TO GCP AND/OR THE PROTOCOL

A "serious breach" is a breach which is likely to effect to a significant degree –

1. the safety or physical or mental integrity of the participants of the trial; or
2. the scientific value of the trial.

The Sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of –

1. the conditions and principles of GCP in connection with that trial; or
2. the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of the breach.

PRM-SOP-006 Non Compliance To Study Protocol,Regulatory Requirements and Serious breaches of GCP or trial protocol will be followed.

11.11 REPORTING INCIDENTS INVOLVING A MEDICAL DEVICE(S)

n/a

12 DATA MANAGEMENT

12.1 DATA COLLECTION TOOLS AND SOURCE DOCUMENT IDENTIFICATION

Baseline and outcome data will be collected from participants using electronic or paper CRFs. If paper, the paper CRF will act as the source document and data will be entered inot the electronic database. If data are directly entered electronically, the electronic CRF will act as source document with a copy stored locally at site. An RA will extract and transcribe primary care medical notes source document data into the electronic CRF following the participant's completion of the trial.

A trial specific data management plan will be created which will outline how data will be handled before, during and after the trial. It will include all aspects of data management from the creation of databases and case report forms, the collection and cleaning of data, and the extraction and lock of the trial database.

It will be the responsibility of the CI to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection, handling and entering data on the study database. All personnel will be given training on the database and randomisation system prior to including those who have access to the trial database.

12.2 DATA COLLECTION AND HANDLING

All data will be collected and handled in accordance with the General Data Protection Regulation and Priment Data Handling SOP. Trial specific arrangements will be detailed in the data management plan. The CRFs will not bear the participant's name or other personal identifiable data. The participant's initials and trial identification number will be used for identification and this will be clearly explained to the patient in the PIS.

Copies of consent forms and other identifiable data will be stored separately in locked filing cabinets in a secure location with limited access. Any digital identifiable data (e.g. audio recorded consent) will be stored in the UCL Data Safe Haven.

Audio data from intervention sessions and interviews will be recorded using an encrypted audio recorder. Files will be transferred between professional transcription services (TP transcription, University Transcription and/or Devon Transcription) and UCL via a secure server hosted by the transcription service. A confidentiality agreement will be put in place between the transcription service and UCL. Audio files will be anonymised and stored securely in the Data Safe Haven at UCL. Transcripts will be pseudonymised and stored in separate folders to the audio files on password-protected computers at UCL and will only be accessible to those authorised to use the files.

The patient data collected in this trial will not 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 patients' consent.

12.3 TRIAL DATABASE

The CRFs will be entered into a web-based clinical data management system, Red Pill, provided by Sealed Envelope through Priment. Sealed Envelope has been assessed by Priment to ensure that adequate processes are in place and are being followed for quality management, software development and security. There will be an agreement in place between the Sponsor and Sealed Envelope to ensure compliance and agreement with clinical trial regulations and data protection laws. Priment SOPs 18 Validating Sealed Envelope Systems and 20 Change Control for Sealed Envelope Systems will be followed to set up and manage changes to the trial database. At the end of the trial, prior to analysis, Priment SOP Database Lock, Unlock and Closure will be followed.

12.4 DATA OWNERSHIP

At the end of the trial the data belongs to University College London.

13 STATISTICAL CONSIDERATIONS

13.1 OUTCOMES

13.1.1 PRIMARY OUTCOMES

The primary outcome is the Modified Barthel Index (BI) (38) at 12 months. This is a widely used, validated measure of physical functioning and ability to undertake basic Activities of Daily Living (ADLs), and a key outcome measure in frailty trials (39). The BI is an interviewer-administered continuous scale from 0-100, where 100 reflects completely independent functioning. It will be assessed at baseline, 6 months and 12 months. Telephone assessment is also valid and reliable compared to face-to-face assessment (40).

13.1.2 SECONDARY OUTCOMES

Our secondary outcomes reflect other important intervention outcomes and/or potential mechanisms of effect, including:

- Instrumental ADLs (Nottingham Extended Activities of Daily Living (41-43))
- Fried Frailty Phenotype score (44) to assess for progression of frailty, including the following components:
    - Gait speed, self-reported according to Op het Vald's (2018) questionnaire (45) If possible, we will carry out face-to-face physical gait speed assessment (m/s) (46) in a subsample of trial participants to confirm the validity of the self-report measure in our population with mild frailty .
    - Grip strength, self-reported according to Op het Vald's (2018) questionnaire (45)). If possible, we will carry out face-to-face grip strength assessment using a dynamometer (kg, highest score out of three trials) (47) in a subsample of trial participants to confirm the validity of the self-report measure in our population with mild frailty .
    - Physical activity (International Physical Activity Questionnaire-Elderly (48)), quantified according to the IPAQ-E guidelines (49).
    - Exhaustion (exhaustion questions from 7-item Centre for Epidemiological Studies Depression Scale "7. I felt that everything I did was an effort," "20. I could not get going.") (44)
    - Weight loss (weight loss question from the Mini-Nutritional Assessment Short Form (50))
- Quality of life and Quality-adjusted Life Years (EQ-5D-5L (51, 52))
- Capability and Capability-adjusted Life Years (ICECAP-O (53))
- Wellbeing (Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (54))
- Psychological distress (General Health Questionnaire-12 (55))
- Loneliness (University of California, Los Angeles 3-item loneliness scale (56))

- Cognition (Montreal Cognitive Assessment (MoCA) (57) or telephone MoCA (remote items only) (58, 59)
- Falls (using the ProFANE consensus definition(60))
- Mortality
- Carer burden (61)

Health economic data: Healthcare and additional services (e.g. voluntary sector and social care) utilisation will be collected using a Client Services Receipt Inventory (CSRI) at 0, 6 and 12 months, modified for the population in our feasibility study to include the range of services they may use (e.g. podiatry, hearing aids, dental care, physiotherapy, exercise classes, day care etc). We will additionally ask about unpaid and paid (state and out-of-pocket) carer time for specific activities of daily living, using an adapted iMTA Valuation of Informal Care Questionnaire (iVICQ) (61). This will be costed as the cost of face to face care worker time if funded by a LA to reflect the fact that if this care were to be reduced it is likely to be unpaid carers that would need to take over this caring role, and vice versa.

Healthcare resource use (contacts, hospitalisations, medications, etc) will be additionally extracted from patient medical records. Resource use will be costed using nationally published sources ((PSSRU(62), NHS Reference Costs (63) and BNF (64)). The cost of the intervention including staff training, administration, supervision and delivery will be included in the costs of the intervention group.

Process evaluation: Qualitative and fidelity process evaluation data will be collected by an independent RA or after the last outcome assessment has been completed, to avoid unblinding of outcome assessments. For efficiency, the process evaluation will begin alongside the main trial, although feedback will not be given to service providers or other team members until trial completion. The following data will be collected:

Qualitative Interviews: We will conduct audio-recorded semi-structured qualitative interviews with participants receiving the service, service providers and other stakeholders, based on topic guides developed with public and patient involvement and engagement (PPIE) representatives and stakeholders from our impact group. We will explore the impact of remotely delivering the intervention in the time of Covid-19 and its impact upon participant and provider experiences.

Trial process data: Service providers will record the following data for each client:

a. Number of appointments attended, modality, technical issues experienced if delivering remotely, duration, reasons for non-attendance.
b. Goals set by participant (coded into mobility, psychosocial, nutrition or other)
c. Progress towards achieving goals, through provider ratings. Providers will rate progress towards outcome goals at the end of the study using goal attainment scaling on a scale of -2 (much less than expected progress) to +2 (much more than expected progress) (65) and progress towards SMART goals at each appointment using a 0 (not achieved) to 2 (fully achieved or exceeded) as in the feasibility study.

d. Fidelity (behaviour change technique (BCT)) checklists after each appointment (based on those used in the feasibility trial)
e. Audio recording all intervention appointments. 10% of individuals will be randomly selected and their appointments audio-files transcribed for fidelity checking.

Trial data: The process evaluation will utilise trial data, including demographic data to assess reach and outcome data (gait speed, weight, depressive symptoms, functioning) to explore mechanisms of impact.

13.2 SAMPLE SIZE AND RECRUITMENT

13.2.1 SAMPLE SIZE CALCULATION

We have calculated the sample size using the Minimal Clinically Important Difference (MCID) for the Modified Barthel Index (BI) at 12 months (1.85) (66). We anticipate average functioning to decline over time without intervention in those with mild frailty; in our feasibility study scores declined by >1 point in 6 months in the control arm, and improved in our intervention arm (36). If this decline is prevented, we would therefore expect a larger difference at 12 months than observed at 6 months in our feasibility study. The standard deviation (SD) was 3 for the BI in our feasibility RCT. This has been reported in other studies (27), but larger SDs have been reported in other settings in frail populations (28, 31). We have therefore conservatively assumed an SD of 5 for our full trial, which would require 308 people (154 per group), with 90% power and 5% significance level. Whilst attrition was minimal (6%) at 6 months in our feasibility study, other studies have had higher attrition rates with longer follow-up(15).

We anticipate that clustering by therapist will be minimal and non-significant. No trials in those with mild frailty have reported therapist clustering (intraclass correlation coefficients (ICCs)), only clustering by GP practice in cluster RCTs in older community-based general populations (67). Unpublished data from a PhD studying therapist effects in a secondary analysis of a cluster exercise trial in older people (68) suggested no significant clustering by therapist (ICC 0.01, P=0.54), so we have not inflated for therapist clustering.

Based on these estimates, a sample size of 386 people (193 per arm) is required to provide 90% power at the 5% significance level to detect an MCID of 1.85-points in the BI, assuming a 20% attrition rate at 12 months.

13.2.2 PLANNED RECRUITMENT RATE

In our feasibility trial 33% of those we sent postal invitations to responded, and 26% of these (8% of those invited by post) were enrolled in the RCT. The majority 57/72 (79%) of those that were assessed but were not recruited were ineligible as they were 'too fit' (vulnerable or managing well), a further 5/72 (7%) were too frail and 10/72 (14%) declined. It is also anticipated that many of those who did not respond to the initial postal invitation would also be ineligible as too fit, as we requested only those with evident symptoms of mild frailty to respond. In our feasibility study one researcher recruited 20 people/month across 4 practices in 2 sites (London, Hertfordshire) once recruitment was established. There was a large potentially eligible pool of participants in each practice, and therefore in larger practices we only invited a random sample of 100-150 people from 260+ possible participants. We successfully recruited above

target in less time than anticipated. Researchers based across our 3 sites could therefore recruit 386 participants over 12 months (15 per month for the first 3 months while the service is established, followed by 37-38 per month or 12-13 per site per month for the subsequent 9 months), allowing for leave, unforeseen events, and time to screen and conduct outcome assessments. Three CCGs have already agreed to participate (Camden; East and North Herts; Airedale, Wharfedale & Craven), each with a large pool of potential practices.

The first 6 months of recruitment will form our internal pilot, to further test trial recruitment procedures, with the following stop/go progression criteria at 6 months:

Progression Criteria	**Red**	**Amber**	**Green**
Trial recruitment	<50	≥50-99	≥100%
Recruitment rate/CCG site/ month (Set-up phase: months 0-3))	≤2	3-4	≥5
Recruitment rate/CCG site/month (Maintenance phase: months 3-6)	≤7	8-11	≥12
Number of sites opened	0-1	2	≥3
Total number of participants recruited	<80	80-159	160

We will monitor our recruitment rate/site/month very closely and act early to put in place contingency measures if levels are less than 'amber' (e.g. expand to further study sites/participant identification cnetres, implement more intensive community engagement).

13.3 STATISTICAL ANALYSIS PLAN

Priment Statistics SOP will be followed. A statistical analysis plan will be developed by the trial statistician a priori and will be reviewed and signed off by the Trial Steering Committee. All analyses will be by intention to treat. Missing data were low in the feasibility study and will not be imputed. Variables at all time points will be summarized by randomised group.

13.3.1 SUMMARY OF BASELINE DATA AND FLOW OF PARTICIPANTS

Participants' baseline characteristics using appropriate summary statistics (mean and SD, median and interquartile range or proportions)by randomised group will be computed. A CONSORT diagram (http://www.consort-statement.org/) will be used to describe the flow of participants through the trial.

13.3.2 PRIMARY OUTCOME ANALYSIS

The primary outcome (Barthel Index (BI) score at 12 months) will be analysed using linear regression. This model will control for baseline BI score and site (the stratification variable). Assumptions will be checked and appropriate transformations or analogous models will be used if the assumptions of linear

models are violated. The ICC will be reported. The primary outcome analysis will be independently verified by an appropriately experienced statistician. If any issues arise during confirmatory analyses, the two statisticians will meet to agree on a course of action, and this will be documented.

13.3.3 SECONDARY OUTCOME ANALYSIS

Secondary outcomes, including The Nottingham Extended Activities of Daily Living, Fried Frailty Phenotype score (components: gait speed, grip strength, physical activity (IPAQ), exhaustion, weight loss), gait speed, grip strength, IPAQ, wellbeing (WEMWBS), psychological distress (GHQ-12) and cognition (MoCA) at 6 and 12 months will be analysed using similar models to the primary outcome, controlling for outcome baseline score and site. Binary outcomes (falls, death and exhaustion) will be analysed using logistic regression. These will be reported descriptively if there are too few events to perform statistical modelling.

13.3.4 SENSITIVITY AND OTHER PLANNED ANALYSES

We will examine baseline predictors of missingness for the primary outcome and include any significant predictors of missingness in a supportive analysis to restore the missing at random assumption using a similar model to the primary analysis. All analyses will be complete case. There are few gains to multiple imputation in RCTs, therefore this will not be used (69, 70). We will perform a complier average causal effects (CACE) analysis after unblinding using a threshold dosage of 3+ sessions for compliance to determine the average treatment effect of participants who would have adhered to the protocol regardless of how they were randomised. Other supportive analyses will be discussed with the trial team and included in the detailed statistical analysis plan, which will be written before comparative analysis.

13.3.5 HEALTH ECONOMIC ANALYSIS

A health economic analysis plan will be developed by the trial health economist a priori and will be reviewed and signed off by the Trial Steering Committee within the statistical analysis plan.

We will calculate the mean incremental cost per quality adjusted life year gained (QALYs) using EQ-5D-5L and the relevant UK tariff and Years of Full Capability (YFC) using ICECAP-O and its respective tariff for the duration of the trial and report this from cost perspectives of the NHS and personal and social care services (PSS). A secondary analysis will also report the incremental cost per QALY and YFC gained from a wider cost perspective to capture the impact on carers and any patient/carer out of pocket costs for health and social care. QALYs will be calculated from the EQ-5D-5L as the area under the curve adjusting for baseline(71) with site as a fixed effect and a random effect for therapist clustering in line with the statistical analysis plan. YFC will be calculated in line with the most up to date guidance (72). Means and 95% confidence intervals will be based on bootstrapped results. The difference in total cost at 12 months will be adjusted using baseline values (73) in line with the statistical analysis plan.

We will report descriptive statistics for the EQ-5D-5L, ICECAP-O, QALYs and YFC, resource use and costs. Cost-effectiveness acceptability curves and cost-effectiveness planes will be reported from i) health and PSS cost perspective and ii) a wider cost perspective using bootstrapped results as defined above to represent the probability that the intervention is cost-effective compared to TAU for a range of values of willingness to pay for a QALY gained and YFC. Seemingly unrelated regression will be used to account for the correlation between costs and QALYs/YFC. We will conduct and report a range of sensitivity analyses for any assumptions. We will work with the statistician on handling missing data, likely to be complete case analysis adjusting for predictors of missingness.

Budget impact analysis: We will develop a tool for use by commissioners for them to assess the yearly costs to their budget of implementation of HomeHealth based on a range of different commissioning models. For example, if this was to be implemented in primary care this would contain NHS costs each year over 5 years and would demonstrate the cost of implementation compared to potential cost savings in primary and secondary care. As there is little long-term data for similar interventions and populations to base assumptions on effectiveness over time, we will explore alternative scenarios. This will include assuming constant effectiveness of the intervention over five years, initial further gains (in year 1-2, if care home transitions and hospital admissions are avoided) followed by a depreciation in effect, and a slow decline in effectiveness over time. We will further include the impact of assumptions about the grade of staff delivering the intervention, cost of training and the patient case load taking into account the size and composition of the relevant local population. It would also include scenarios modelling the potential cost to the NHS if aspects of the intervention were commissioned by a third sector organisation, or the impact on local authorities if this was to be commissioned as part of social care.

13.3.6 PROCESS EVAUATON ANALYSIS

Qualitative data: Interviews will be transcribed and entered into qualitative software. We will undertake a thematic analysis including searches for disconfirming evidence (36). All transcripts will be read by at least three team members, with a thematic framework developed independently and refined in team discussions (which will include PPIE members). Analysis will continue alongside data collection in order to inform future interviews. Themes will be derived inductively to explore intervention fidelity and mechanisms of impact in relation to contextual factors. We will explore how and why participants choose certain goals, their experiences of remote delivery in the context of a national pandemic and how these might impact upon outcomes. Data from providers and stakeholders will be mapped against constructs from Normalisation Process Theory (NPT) (74) to identify facilitators and barriers to implementation within newly evolving integrated care systems. Interpretations will be agreed in multi-disciplinary team discussions (qualitative sub-group, including PPIE members) with a particular focus on how contextual factors such as Covid-19, rurality, age, gender, ethnicity, sexuality, socio-economic status, health literacy, degree of impairment, co-morbidities and provider differences might influence service delivery, fidelity, impact and implementation.

Quantitative data: Trial process and outcome data will be used to assess intervention reach, fidelity and dose and explore mechanisms of impact. The statistical analyses will be conducted once the main trial outcomes have been completed and the statistician has been unblinded.

1) *Reach:* Demographic data will be compared descriptively to Office of National Statistics area level census data (75), and CCG/LA (Joint Strategic Needs Assessment, JSNA) and practice-level data where available to determine whether any populations are under-represented in those recruited to the trial and receiving the intervention. We will compare percentage recruited from typically underserved older populations (e.g. BME groups, low socioeconomic status, oldest age groups, those living alone) to data in each area. We will also explore differences in engagement with the intervention (goal progress, receiving a minimum dose and use of remote intervention delivery) according to these populations.
2) *Fidelity:* Two independent researchers will apply fidelity checklists (for core BCTs delivered, based on those used in our feasibility trial) to transcribed audio-recordings of intervention appointments for 10% of intervention participants (n=18). Inter-rater agreement will be calculated using kappa statistics and disagreements will be resolved through discussion. Researcher ratings will be compared to service provider ratings using appointment fidelity checklists.
3) *Dose:* Descriptive statistics will be calculated for: Number and percentage of appointments attended, average duration, number and percentage attending the minimum dose of appointments (>=3) to the intervention overall and per area/service provider.
4) *Mechanisms of impact:* Types of goals set (mobility, nutrition, psychosocial, other) will be summarised across all intervention arm participants and by key socio-demographic characteristics. Mean service provider rated goal attainment scale score will be calculated using established methods (65) overall and by goal type and key socio-demographic characteristics.

We will carry out three statistical analyses to explore hypothesised mechanisms:

i. To determine whether those who get a 'therapeutic dose' of the intervention (defined as attending ≥3 appointments) have higher BI scores than those who do not, number of sessions attended will be dichotomised into those attending ≥3 sessions or not. Those in the TAU group will be coded <3 sessions. This will be analysed using linear regression with an interaction between sessions attended and randomised group, and baseline BI score.

ii. We will assess whether choice of goal (mobility, psychosocial, nutrition or other) is associated with differential effects on BI scores. Similar analyses will be conducted as in i) above; this time with an interaction between goal (mobility yes/no), nutrition (yes/no) and social network/psychological wellbeing (yes/no) and randomised group. Modelling will be undertaken separately for each goal. Additionally, if there are sufficient numbers for each goal type, we will explore if there are effects on the most related secondary outcome to assess if specific behavioural targets show more potential for effectiveness (using an interaction term as previously described). This will include mobility (gait speed and IPAQ score), nutrition (weight) and psychosocial (psychological distress and loneliness).

iii. As goal setting is a key component of the HomeHealth service, we will explore whether overall progress towards meeting goals (quantified using goal attainment scaling) is associated with greater impact on ADL functioning (BI). We will model the BI with an interaction between

randomised group and mean progress towards goals. In the TAU group, this will be set at 0 as there were no goals set, so no progress will be made.

13.4 INTERIM ANALYSIS

This trial is low risk and therefore an interim analysis will not be undertaken. An internal pilot (see section 13.2.2) will be used to test recruitment rates.

13.5 OTHER STATISTICAL CONSIDERATIONS

Priment Statistics SOP will be followed. Any alterations to the Statistical Analysis Plan will be documented with the appropriate version control. Changes made after database lock will be clearly identified as post hoc in reports and publications in which they are included, with their rationale outlined.

14 RECORD KEEPING AND ARCHIVING

At the end of the trial, all essential documentation will be archived securely by the CI and trial sites for a minimum of 5 years from the declaration of end of trial.

Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether the site complied with the principles of Good Clinical Practice and all applicable regulatory requirements.

The Sponsor will notify sites when trial documentation can be archived. All archived documents must continue to be available for inspection by appropriate authorities upon request.

15 OVERSIGHT COMMITTEES

The HomeHealth RCT will have a Trial Management Group (TMG), a Trial Steering Group (TSC), a Data Safety and Monitoring Board and an Impact group.

15.1 TRIAL MANAGEMENT GROUP (TMG)

The TMG will include the CI, co-applicants (including site PIs), Trial Manager, Trial Co-ordinator, Priment Operations manager, statistician and/or health economist. The TMG will meet monthly (face to face or by teleconference) throughout the study to oversee the day-to-day study progress. Other members will also join the core team meetings as needed for relevant components of the study. The TMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. A TMG charter will be in place to detail arrangements and frequency of meetings.

15.2 TRIAL STEERING COMMITTEE (TSC)

There will be an Independent Trial Steering Committee (TSC) as per NIHR guidelines including an independent Chair, at least two further trials experts, an independent statistician and PPIE members. The TSC will meet 6 monthly throughout the trial to provide guidance and oversight of the study

progression. 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. The terms of reference for this group will follow the NIHR standard terms of reference for TSCs. A TSC charter will be in place to detail arrangements and frequency of meetings.

15.3 DATA SAFETY AND MONITORING BOARD

A Data Monitoring and Ethics Committee will be set up for this study. They will meet at least annually. The role of the DMEC is to provide independent advice on data and safety aspects of the trial. Meetings of the Committee will be held at least annually to review trial progress, or as necessary to address any issues. The DMEC is advisory to the TSC and can recommend premature closure of the trial to the TSC.

The DMEC terms of reference will detail arrangements on timing, reviews and board members.

15.4 IMPACT GROUP

The trial staff will establish an Impact group. The Impact group will meet twice in the first year, once in year 2 and twice in year 3 to consider and support implementation plans. This will be attended by the CI, Clinical Safety Monitoring Lead and the Trial Manager. It will consist of representatives from policy, commissioning (CCGs or Local Authorities), practice, the voluntary sector and three Patient and Public Involvement and Engagement (PPIE) members.

16 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s)/ institution(s) will permit trial-related monitoring, audits, REC review, and regulatory inspection(s), providing direct access to source data/documents. Trial participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical/case notes/source documents.

17 ETHICS AND REGULATORY REQUIREMENTS

Priment will ensure that the trial protocol, participant information sheet, consent form, GP letter and submitted supporting documents have been approved by the HRA and an 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).

Before any site can enrol participants into the trial, the CI/PI or designee will apply for local confirmation of capacity and capability. It is the responsibility of the CI/PI or designee at each site to ensure that all subsequent amendments gain the necessary approvals. This does not affect the individual clinician's responsibility to take immediate action if thought necessary to protect the health and interest of individual patients (see section for reporting urgent safety measures).

Within 90 days after the end of the trial, the CI/Priment will ensure that the main REC are 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.

The CI will supply Priment with a summary report of the clinical trial, which will then be submitted to the main REC within 1 year after the end of the trial.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The CI will prepare the APR.

The CI will supply the Sponsor with a report of the clinical trial and a copy of the report will be submitted to the main REC, within 1 year after the end of the trial.

17.1 PATIENT AND PUBLIC INVOLVEMENT (PPIE)

Three PPIE representatives (Jane Hopkins, Rekha Elaswarapu and Maggie Kirby Barr) contributed to the proposal and will be closely involved throughout all aspects of the study. They will assist in developing recruitment materials, identifying appropriate non-NHS channels for recruitment (e.g. local community groups), provide ongoing monitoring from a PPI perspective, provide input on topic guides for the process evaluation, sit on the Impact Group and provide input on methods of dissemination. One PPIE member (JH) will be the PPIE lead and was a co-applicant on the grant. She will provide expert input to the TMG, advise the team on PPIE aspects, support PPIE members and contribute to the process evaluation qualitative sub-group. Three further independent PPI representatives will be recruited for the Trial Steering Group.

18 MONITORING REQUIREMENTS FOR THE TRIAL

The Sponsor will determine the appropriate level and nature of monitoring required for the trial. Risk will be assessed on an ongoing basis and adjustments made accordingly.

The degree of monitoring will be proportionate to the objective, purpose, phase, design, size, complexity, blinding, 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.

19 FINANCE

This RCT has been funded by the NIHR Health Technology Assessment (NIHR128334).

Professor Claire Goodman is a NIHR Senior Investigator. Professor Dawn Skelton is a Director of Later Life Training Ltd, a not for profit Company that delivers training to health and fitness professionals working in

exercise with older people. This includes training in the Otago Exercises (which form part of the exercise intervention in HomeHealth). All other co-applicants declare no conflict of interest.

20 INSURANCE

University College London holds insurance against claims from participants for injury caused by their participation in the clinical 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 an NHS organisation or an organisation contracted to the NHS, the NHS organisation or organisation contracted to the NHS continues to have a duty of care to the participant of the trial. University College London does not accept liability for any breach in the NHS organisation's duty of care, or any negligence on the part of NHS organisation employees. This applies whether the organisation is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical 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.

NHS organisations or organisations contracted to the NHS selected to participate in this clinical trial shall provide clinical 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.

21 PUBLICATION POLICY

We will disseminate our findings in peer reviewed journals and at international conferences. We will present findings in appropriate local forums for health and social care professionals; participants who have indicated they are interested in the results will be sent a summary of the findings. All NIHR-funded primary research studies are required to register in an appropriate registry. The NIHR's registry of choice is the International Standard Randomised Controlled Trial Number Register (ISRCTN). Registry information on ISCTRN will be updated regularly as appropriate and in line with instructions from the relevant NIHR secretariat/monitoring team and ISRCTN. The results of the trial will be disseminated on ISRCTN in line with NIHR transparency policy.

UCL publication policy is as follows:

All co-applicants will be listed on the main study papers. Authorship for any supplementary 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.

The study co-applicants have all contributed to the conception and design of the study, thereby meeting criteria (a). Within the Trial Management Group we will discuss the most useful ways in which to disseminate our findings.

All conference posters and presentations will acknowledge the National Institute for Health Research (NIHR) Health Technology Assessment as the funder. We will NIHR HTA guidance on branding and notification of publications.

22 DATA SHARING POLICY

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Access to the quantitative datasets generated and/or analysed during the current study will be included in the subsequent results publication, where they can be sufficiently de-identified for data-sharing and conform to ethics and data governance requirements. The primary qualitative data will not be shared as it is not possible to de-identify this data sufficiently and retain the integrity of the data.

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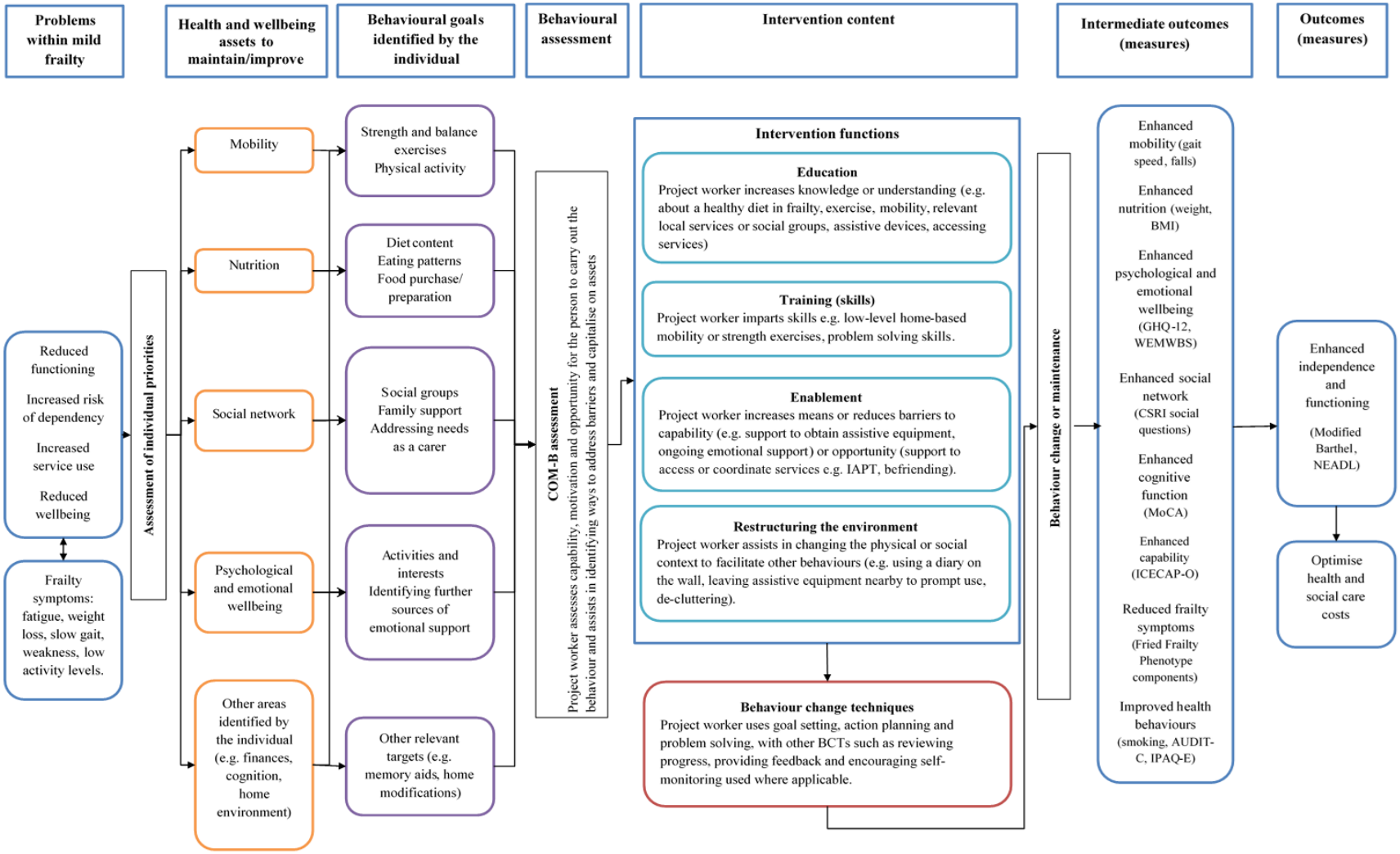
APPENDIX 1 – SCHEDULE OF ASSESSMENTS

	Screening (1)	Screening (2)	Baseline assessment[1]	Intervention	Post-Intervention	Final assessment	Medical notes extraction	Process evaluation (sample of intervention participants only)
Visit No:	Telephone	1	1		2	3	n/a	4
		0 months (immediately prior to baseline assessment)	0 Month	0-6 months	6 Month	12 Month (final outcome assessment)	Covering period of -6 to 12 months	
Window of flexibility for timing of visits:				n/a	-2 to +4 weeks	-2 to +4 weeks	Within 6 months of final assessment	Within 6 months of final assessment
Eligibility confirmation	X	X						
Informed Consent			X					X
Demographics			X					
Alcohol (AUDIT-C)			X					
Smoking			X					
Comorbidities							X	
Deprivation (Local area Index of Multiple Deprivation based on postcode)			X					
Covid-19 status			X		X	X		
Modified Barthel Index			X		X	X		
Nottingham Extended Activities of Daily Living			X		X	X		
Gait speed			X		X	X		
Grip strength			X		X	X		

Physical activity			X		X	X		
BMI (weight, height)			X		X	X		
Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)			X		X	X		
Euro-Qol 5D-5L			X		X	X		
ICECAP-O			X		X	X		
12-item General Health Questionnaire			X		X	X		
UCLA 3-item			X		X	X		
Montreal Cognitive Assessment			X		X	X		
Falls (ProFANE consensus criteria)			X		X	X		
Mortality					X	X		
Carer burden			X		X	X		
Client Services Receipt Inventory			X		X	X		
Healthcare resource use							X	
Randomisation			X					
Adverse Events review			X		X	X	X	
Concomitant Medication review							X	
Process evaluation interview								X
Process evaluation intervention data				X				

[1]Randomisation can be carried out up to four weeks after a baseline assessment

APPENDIX 2 – INTERVENTION LOGIC MODEL



APPENDIX 3 – RECRUITMENT FLOW CHART