



Home-based health promotion for vulnerable older people

RESEARCH PROTOCOL

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3. Abbreviations

BMI	Body Mass Index
BP	Blood Pressure
CCG	Clinical Commissioning Group
CI	Chief Investigator
CSRI	Client Services Receipt Inventory
CTU	Clinical Trials Unit
CVD	Cardiovascular Disease
EQ-5D	standardised instrument for use as a measure of health outcome
FTE	Full Time Equivalent
GCP	Good Clinical Practice
GHQ	General Health Questionnaire
GP	General Practitioner
ICECAP-O	ICEpop CAPability measure for Older people
IPAQ	International Physical Activity Questionnaires
KCL	King's College London
LH&WBS	Local Health & Well-Being Boards
MeSH	Medical Subject Headings
MoCA	Montreal Cognitive Assessment
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NoCLoR	North Central London Research Consortium
NRES	National Research Ethics Service
PCRN	Primary Care Research Network
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Personal and Social Services
QALY	Quality Adjusted Life Year
QOF	Quality Of Life
RA	Research Assistant
RCGP	Royal College of General Practitioners
RCT	Randomised Controlled Trial
SOP	Standard Operating Procedure

S-WEMWBS Short Warwick-Edinburgh Mental Well-Being Scale
 UCL University College London
 WISH study Wellbeing Interventions for Social and Health Needs study

4. Study synopsis

Title	Home-Based Health Promotion for Older People with Early Frailty
Methodology	Qualitative (interviews and focus groups) and quantitative (RCT)
Research Sites	University College London (in collaboration with King’s College London, University of Hertfordshire, and St George’s University of London)
Objectives/Aims	To develop and test feasibility/acceptability and costs of a home-based health promotion intervention for older people with early frailty
Research Plan	<ol style="list-style-type: none"> 1. <u>Evidence synthesis</u>: systematic reviews 2. <u>Qualitative study</u>: Interviews with older people with early frailty and focus groups with carers, home care workers, and community health professionals 3. <u>Development and manualisation of an intervention</u>: use of co-design methodology and stakeholder panel meetings 4. <u>Feasibility study</u>: Randomised Controlled Trial
Number of Participants	10 older people with early frailty for interviews 40 carers, home care workers, and community health professionals for focus groups 50 older people with early frailty for feasibility study
Main Inclusion Criteria	Aged 65 or over; score as ‘pre-frail’; community-dwelling; life expectancy >6 months; capacity to consent to participation
Analysis	For the qualitative study thematic analysis will be undertaken. For the feasibility study, analysis will be mainly descriptive of the recruitment, participant characteristics, baseline and outcome variables, loss to follow-up and adverse events.

Proposed Start Date	01/09/2014
Proposed End Date	28/02/2017
Study Duration	30 months

5. Summary of research

Background and rationale: Meeting the needs of the growing number of older people with complex problems is a great challenge for the NHS and social care. Health promotion has the potential to make a difference, and is a government priority. Interventions have focused on those with highest levels of need/frailty, and show potential to alter behaviours, promote independent living and reduce hospitalisation¹⁻⁵. However, current models are expensive, with some disappointing outcomes^{1,6,7}, with little compelling evidence of cost-effectiveness⁸. There is evidence that the most frail (typically targeted by current case management services) may benefit least³, and there are no health prevention interventions in widespread use that have been specifically developed for a population with early frailty or the 'pre-frail'.

Aim: To develop and test feasibility/acceptability and costs of a home-based health promotion intervention for older people with early frailty.

Methods:

Design: Evidence synthesis, qualitative study, development of intervention, feasibility of a complex intervention.

Setting: Community (home) based, in London & Hertfordshire.

Target population: Older people 65+ years with early frailty (mild or 'pre-frail')⁹.

Exclusion criteria: Those in care homes, on GP palliative care register, who lack capacity to consent, already case managed (e.g. by community matrons).

Evidence synthesis: We will review previous research to identify what has worked, for whom and why. We will update systematic reviews of trials and assess the behavioural techniques that appear most effective for promoting health within the home for frail older people, and the theory that underpins these interventions. We will systematically review the literature for evidence (trials, observational and qualitative) for health promotion for those with early stage or pre-frailty, focusing on identifying active components and theory, and conduct a rapid appraisal and synthesis of the policy context. We will use Cochrane methods for trials¹⁰ and NICE/SCIE methods to synthesise heterogeneous literature¹¹⁻¹³.

Qualitative work: We will build on our current work, where we have already interviewed 52 older people and professionals from the NHS, local government and the voluntary sector as part of our MRC funded study on health promotion in older people. We will supplement this with further interviews of older people unable or virtually unable to leave their home (under-represented in our existing study) and conduct focus groups with carers, home care workers and community based health professionals (community nurses, physiotherapists, occupational therapists and health trainers). Interviews/focus groups will explore views towards existing methods of health promotion, benefits and barriers to health promotion in older people, and views on content and delivery of a new health promotion approach. Interviews/focus groups will be recorded, transcribed and analysed thematically using a constant comparative approach.

Intervention development: Using a co-design approach successful in previous work we will convene panels of older people/carers and multi-disciplinary stakeholders/experts to develop the intervention. Using the MRC Complex intervention model¹⁴ we will develop/manualise the intervention, and synthesise evidence

from the reviews, theory and qualitative findings. The intervention will be delivered by health professionals at home for older people with early frailty, and will include use of theory-based behaviour change techniques.

Feasibility study: We will conduct a feasibility study with randomisation with older people in the target population registered with 4 General Practices in 2 different locations. General Practices will identify individuals receiving home visits and invite them to take part. Those eligible will be randomised to receive the intervention or treatment as usual. Intervention visits will be recorded and assessed for content/fidelity.

All people taking part will get a letter with a booklet listing local services/contacts that may be useful to them. Participants will be followed up for six months.

Outcomes: A theory-based intervention tested for acceptability/feasibility in community settings. Data on patient recruitment/willingness to be randomised, attrition, acceptability of assessments and potential outcomes for an RCT: quality of life (EQ-5D^{15,16}); functioning (modified Barthel^{17, 18}); frailty (Frailty Index^{9,19}); mobility (gait speed^{20,21}); grip strength²²; well-being (S-WEMWBS²³); psychological distress (GHQ-12²⁴); uptake preventative interventions; CVD risk factors (Body Mass Index (BMI), physical activity-IPAQ²⁵, smoking, alcohol-AUDIT-C²⁶), falls; medication use; Cognition (MoCA²⁷) service utilisation (NHS/social care, CSRI²⁸); costs (health and social care, out of pocket expenses, cost to carer); quality adjusted life years (QALYs); Capability Adjusted Life Years (ICECAP-O²⁹); mortality.

Sample size: To test feasibility we will identify 12-13 eligible older people per GP practice, in 2 practices per locality (target: 50 participants). This was feasible in our previous work.

Management: The project will be led by UCL, with monthly meetings with the core team (co-investigators), overseen by a multi-disciplinary advisory group meeting 6 monthly. Key project milestones:

Month

0-6: Evidence searching/extraction/coding; focus groups, in-depth interviews.

6-12: Evidence synthesis, qualitative analysis, develop/manualise intervention with panels, ethics/governance amendments

12-18: Site initiation for feasibility study, training intervention delivery.

Recruit participants (8-10/m over 6m); deliver intervention; baseline, 3m assessments.

18-24: 3m & 6m follow-up participants, process evaluation.

24-30: Complete final follow-up & process evaluation, feasibility study analysis, economic analysis, refine manual, final report, dissemination, plan main RCT

Expertise: We are a strong multi-disciplinary team experienced in systematic reviews, behaviour change, qualitative studies and trials, and engagement with older people. We have particular expertise in developing, delivering and evaluating complex interventions for older people in community settings.

Impact: This research will identify key components of effective home-based behaviour change interventions for older people and test a new approach where the NHS can be pro-active in improving the health and wellbeing for older people with early frailty who find it difficult to leave their homes.

6. Background and rationale

Healthy ageing interventions have focused on those with highest levels of need/frailty, and show potential to alter behaviours, promote independent living and reduce hospitalisation¹⁻⁵. However, while there have been several systematic reviews and trials in this field¹⁻⁵, it is unclear which intervention components contribute to effectiveness¹. Within the NHS, case management for older people focusses on high users of hospital care and not those likely to benefit from early interventions to promote health. Current models led by community matrons are expensive to deliver, with limited evidence on cost-effectiveness¹, and some disappointing outcomes⁶⁻⁸, including little evidence of a reduction in unplanned hospital admissions⁷. This may be as targeting only the highest risk group to reduce hospital admissions is setting an impossible task:

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“by concentrating just on the 0.5% at highest risk of admission, more than the total number of admissions in this group would need to be avoided (107.5%)”⁶. As most admissions arise from lower risk patients, then arguably the greatest effect on admissions will be made by reducing risk factors in the whole population, supporting widening interventions to pre frail groups. Whilst the quantitative findings on case management have been disappointing⁵⁻⁸, the qualitative evidence is consistent about its value to older people in providing continuity of care and resources to deal with inevitable challenges³⁰⁻³².

Alternative lower cost intervention models have been introduced and widely implemented successfully elsewhere in the NHS, such as a stepped care model for psychological therapies for depression/anxiety³³ using lower paid, less experienced graduate mental health workers. Health Trainers³⁴ are now being

employed widely in primary care organisations, at low cost (typically band 3 Agenda for Change) and with basic training on delivering behaviour change interventions for healthier lifestyles and address health inequalities³⁵⁻³⁷. While reported to be well received, evaluation of Health Trainers has been in the main qualitative or observational, with no study of their cost effectiveness^{36,37} and no observational studies or RCTs to our knowledge on cost-effectiveness of working on behaviour change with older people with early frailty.

Few health promotion services and less research are targeted at the early frailty ('pre-frail') population. Early stage frailty is common, with a prevalence of 44% in older people³⁸ and is associated with 2.5 times the risk of move to care homes³⁹. A spiral of worsening frailty has been identified with increasing disability, risk of admission and mortality⁴⁰⁻⁴². Past trials suggest the most frail benefit least from interventions³ and some health promotion interventions e.g. exercise programmes have shown positive effects in the pre-frail and harmful effects (increased falls) in the frail⁴³. There is a good rationale therefore to target a new health promotion intervention at those with early frailty, aiming to delay/slow decline, maintain independence and 'compress morbidity' into the final stages of life⁴⁴.

In current NHS practice, case management approaches are predominantly used that identify a high risk group (e.g. established frailty, or frequent hospital admissions) and focus on identifying deficits and signposting, engagement and active follow-up. Designed in response to service needs, the opportunities to promote on-going behaviour change can be missed. Older people themselves tend to have a broad view of successful aging, which includes both physical and importantly psycho-social aspects⁴⁵. Both within the health service and in related health research, a biomedical perspective on successful ageing predominates, with a focus on the prevention of disease and risk reduction⁴⁶, and while primary care health professionals are mindful of psycho-social factors and context, often lack resources, techniques and/or skills to address these directly.

Several relevant theoretical and methodological advances can be drawn on to develop a new approach to health promotion for older people with early frailty, that is orientated to the values and perspectives of older people. This includes theories and models of successful ageing and what this means⁴⁶⁻⁵⁰, and a framework for categorising the determinants of behaviour so as to permit theory- and evidence-based selection of appropriate intervention approaches and specific behaviour change techniques⁵¹. The theoretical basis and behavioural techniques employed in past interventions are not well-described, and there is a need to systematically review this to understand the basis of effective interventions for this population. Relatively simple behavioural techniques have the potential to benefit older people, and a health professional could feasibly be trained to deliver these techniques effectively. For example, home-based Problem Solving Therapy, can improve depression symptoms^{52,53}, personalised advice on physical activity, can increase engagement in activity⁵⁴, and simple advice to integrate low-level balance and strength activities into everyday routines can reduce falls⁵⁵. Some simple brief interventions such as a single 'preventative' home visit, or 4 weekly 'senior meetings' have also shown promise⁵⁶. Sarcopenia (age-related loss of muscle mass, strength and function) is a key feature of frailty in older people and a major determinant of adverse health outcomes such as functional limitations and disability⁵⁷. Resistance training, management of weight loss, adequate protein and energy intake are plausible strategies for the management of sarcopenia, with additional potential gain from correcting Vitamin D deficiency⁵⁸. The critical role of micronutrients in frailty suggests the need to improve the quality of food eaten by older people, not just the quantity⁵⁹. There is thus a range of evidence and theory on which to base a new intervention, and which it is important to understand and synthesise.

We have some evidence on how older people view successful ageing⁴⁵, but less research has linked this to define the 'active ingredients' and optimal delivery of a complex intervention to promote well-being. Qualitative work that explores this with older people, their carers, and health professionals is important. A new intervention is needed that is theory-based, rigorously developed using MRC guidance¹⁶, and uses a development process with strong older people and stakeholder involvement, so that a new intervention is grounded in real life experiences and is acceptable and feasible to deliver in the NHS and its partners.

Evidence explaining why this research is needed now

Healthy ageing is an increasingly important public health issue; in the UK the numbers living over 85 years are projected to rise from 1.4 million today, to 3 million by 2050⁶⁰. The 'compression of morbidity'⁴⁴ into the last stages of life is key to maintaining quality of life, independence and contain health and social care costs. For healthy ageing to be meaningful for older people there is a need to recognise that ageing of itself is not a linear process of progressive decline⁶¹, and interventions are needed that can optimise function, interrupt the disablement process and address accumulating deficits at stages when they are still tractable. Developing a new intervention, targeted specifically at those with early frailty, would be an important step towards this, with much potential gain. Current NHS care for this group is predominately reactive to needs that arise, and we know little about the best evidence based health promotion approaches that are both acceptable for older people and feasible to deliver in the NHS. Interventions that support healthy ageing for the recently retired are unlikely to reflect the priorities and interests of those who are significantly older. Health promotion for older people has been acknowledged as a government priority in England⁶², and with demographic changes this would be expected to increase in future. The outputs from this research are therefore anticipated to have a sustained impact for the NHS and social care, as well as addressing the heterogeneity of experience and need of older people and their families.

This research contains four components, all of which will contribute significantly to knowledge and practice in this field. 1) From the systematic reviews, identifying the behaviour change techniques and theories associated with intervention effectiveness, comprising the probable 'active ingredients' of the intervention, represents an advance in knowledge of not only what works and to what extent, but also why it works. 2) Qualitative work that further explores what is needed in effective health promotion for this population and why, from the perspectives of older people, their carers, and health and care professionals is important to inform both new interventions, and provide added value to developments in services that already exist (e.g. case management and reablement services). Insights from this work and the review phase will enhance the likelihood that future interventions will be effective and responsive to the needs of older adults with early frailty. 3) To ensure the work is both grounded in real life experiences, is context sensitive and is acceptable/feasible to deliver in the NHS a new intervention will be developed using co-design methods with older people, carers, health and care professionals and experts. Co-design is a technique adopted from product development⁶³ which has tangible benefits in developing or redesigning health services⁶⁴⁻⁶⁷. 4) Feasibility testing of this new intervention is important to evaluate both acceptability and appropriateness for patients in the NHS, and to collect data that will inform the design of a future trial. Ultimately if a future trial demonstrates clinical and cost-effectiveness of the new intervention in its aims of reducing morbidity and improving quality of life and independence for older people, then it will provide important information for the commissioners of health promotion services for older people within the NHS and integrated services.

Health promotion interventions aimed at older people have been introduced in the NHS on the basis of very limited evidence, from the 75 & over checks introduced in 1990 to the launch of community matrons in 2008, and have had limited impact, at great cost. Recent government policy is calling for an expanded role of primary care in health promotion for vulnerable older people⁶². This needs to have a strong evidence base of cost-effectiveness to be sustained long-term. This study will create costed models of interventions, in readiness for a definitive trial, but also of use to current commissioning processes.

7. Aims and objectives

Aim: To develop and test feasibility/acceptability of a new home-based intervention to promote health and well-being of older people with early frailty.

Objectives:

- 1) Systematically review and synthesise evidence for home-based health promotion interventions, including Randomised Controlled Trials (RCTs), observational and qualitative studies. We will update existing systematic reviews of RCTs, and conduct reviews and further meta-analysis if indicated. We

will apply a coding framework and conduct meta-syntheses where appropriate, addressing the questions:

- a. Which behaviour change techniques have been used in effective interventions?
 - b. Which (if any) age/population-specific or other theory has been used to develop interventions?
 - c. What is the evidence of acceptability, appropriateness and value of different types of interventions for early frailty from perspectives of older people, carers and professionals?
 - d. How do policy and practice in the health and social care system address health promotion with older people with early frailty?
- 2) Explore current approaches, facilitating and hindering factors to health promotion, strategies for engaging older people from 'under-served' groups and key components for a new home-based health promotion intervention for older people with early frailty in terms of effectiveness, acceptability and feasibility using in-depth interviews with older people, and focus groups with carers, home care workers and community health professionals.
 - 3) Develop and manualise a new health promotion intervention for older people with early frailty using co-design methodology with older people, carers, health/care professionals, and experts in behaviour change and healthy ageing.
 - 4) Test acceptability and feasibility for delivery in the NHS and for a full-scale RCT with participants recruited from 4 general practices in two diverse localities, London and Hertfordshire. This will include testing recruitment, attrition, feasibility of individual randomisation for a future RCT, feasibility/acceptability of study procedures, and suitability of outcome measures.
 - 5) Determine the costs of delivering the intervention, and test the feasibility of calculating the incremental mean cost per QALY gained of the intervention compared to control i.e. the cost-effectiveness, for a full RCT from a health and social care perspective and from a societal perspective.
 - 6) Assess the feasibility of conducting a budget impact analysis, scaling up to Clinical Commissioning Group level, estimating where monetary costs and benefits will fall, for the NHS (e.g hospitalisation) and Local Authority (e.g personal budgets/reablement).

This plan uses the MRC model¹⁴ to develop a new complex intervention integrating existing evidence, relevant theories and a co-design development process involving the public and front-line health/care professionals to develop and manualise a new health promotion intervention, tailored for delivery at home to people with early frailty. We will test feasibility to recruit and randomise individuals for an RCT, and whether the intervention is acceptable and feasible to deliver in the NHS. We will determine intervention costs and potential effect sizes across a range of outcomes to inform a future RCT. We assess the feasibility of conducting a budget impact analysis to inform current debates amongst commissioners on how to provide and fund care at home and the feasibility of a cost-effectiveness analysis in the full RCT.

8. Research plan

Design: This research study incorporates four stages:

- 1) Evidence synthesis:** systematic review of behavioural techniques, theoretical underpinning of effective interventions in RCTs; systematic review of qualitative and observational research for potential 'active ingredients' of effective interventions for people with early frailty; policy review.
- 2) Qualitative study:** in-depth interviews with older people with early frailty and focus groups with carers, home care workers and community health professionals.
- 3) Development and manualisation of an intervention** using co-design methodology and a series of stakeholder panel meetings, hosted by Age UK London, KCL and UCL.
- 4) Feasibility study** with 50 people recruited from 4 General Practices in London and Hertfordshire individually randomised to the intervention and treatment as usual.

The intervention will be the first of its kind specifically developed for home-based health promotion for older

people with early frailty. We will engage with key organisations and representatives throughout the process, including older people with early frailty, carers, home care workers, community health professionals, primary care health professionals, adult social care, public health, voluntary sector (Age UK) and public representative organisations (Healthwatch), commissioners/policy makers (Clinical Commissioning Groups CCGs, Local Health and Well-being boards LH&WBs) and experts in ageing and behaviour change. The research team itself is a strong multi-disciplinary team from a range of backgrounds including clinical (primary care and nursing), social care and social policy, health psychology, health economics and statistics supported by collaborators experts in health psychology/behaviour change, health economics, the voluntary sector, CCGs, LH&WBs and 3 experienced PPI representatives. We have substantial experience in research including systematic reviews, behaviour change, qualitative studies, health economics and trials of complex interventions. We have particular expertise in developing, delivering and evaluating complex interventions for older people in community settings.

9. Health technologies being assessed

This study's aim is to develop, manualise and feasibility test a new health technology. The intervention development will follow MRC guidance for the development of complex interventions¹⁴. Components of the intervention will be clearly specified following the development stage including the evidence review and empirical qualitative study of 'active ingredients' of effective interventions, and the intervention delivery defined by the co-design process. It will be based on a theoretical framework, including an assets-based approach^{68,69} and the Baltes' model of selective optimisation and compensation (see description below)⁵⁰. The theoretical framework underpinning past effective interventions determined by our evidence review will also be considered. Components are likely to include initial assets/risk profile; the older person identifying and selecting life goals to optimise; behavioural techniques to optimise these goals, promoting coping and the maintenance of function; development of compensatory mechanisms to address deficits. The behavioural techniques used will be those demonstrating the best evidence of effectiveness with this population in the evidence review, or if a lack of evidence for those with early frailty, then effective techniques with other similar populations. The intervention could include an assets based approach^{68,69} identifying what older people are able to do and wish to continue, with the older person setting goals, problem-solving^{52,53} to support optimisation of these goals and behaviour change, and sign-posting/facilitation of use of services to aid compensatory mechanisms, such as mobility aids, technology, or low vision services. For example, an asset might be identified that the older person can still get a taxi to visit their daughter/grandchildren, although this is becoming increasingly difficult with tiredness/weakness (a feature of frailty) and concerns about occasional urinary incontinence. In order to preserve this asset, the intervention might include advice and goal setting on physical activity/resistance training and diet to increase strength, a problem solving approach to support change/coping and signposting on provision of incontinence pads as a compensatory mechanism.

We will provide a translator for participants unable to speak/understand English and will be sensitive to older people's communication needs more generally. Intervention delivery will be specified in the co-design development process, but is anticipated to be of low-moderate intensity, with an initial assessment visit at home, followed by up to a maximum of 6 further home-visits or telephone contacts tailored to the individual. The 'person-specification' and related training requirements of the health professional delivering the intervention will be agreed in the co-design process, and will include training in the use behavioural techniques for health promotion in older people. The right skill-mix of the individual will be considered alongside cost to the NHS for intervention delivery. Currently in the NHS Health Trainers deliver behaviour change interventions at relatively low cost, and are widely available across England and may be a suitable option with specific training³⁴⁻³⁷.

10. Theoretical/conceptual framework

A number of theories of successful ageing are important to consider in the development of a new

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intervention for those with early frailty. Early important theories include activity theory and disengagement theory, where social engagement and activity is considered vital for successful ageing to occur^{47,48,70}. Whilst not the central underpinning theory for our approach, these theories have relevance in broadening the

scope of an intervention beyond a bio-medical model of disease prevention and reduction of disability. For older people the concept of resilience is also considered by many to be key, variously defined as the “dynamic process encompassing positive adaption within the context of significant adversity”⁷¹. An application of resilience theory seen in Baltes’ model of successful aging based on ‘selective optimisation and compensation’ is particularly relevant for an intervention for older people who are starting to become frail and face changes or adversity which require adaptation⁵⁰. Use of this model for our intervention would involve, for example, the selection of new or transformed goals in life by the older person, which are then optimised using changes in behaviours, and compensatory mechanisms are identified and promoted to tackle deficits. An intervention based on resilience theory might also focus on the development of resiliency traits, such as self-efficacy⁴⁹ and draw on past experiences of loss and coping⁷². A further key concept underlying our intervention is the use of an assets-based model that would focus on identifying and maintaining what people are still able to do to prevent a decline into increasing frailty^{68,69}. More widely used deficits models (identifying problems and needs to be addressed) tend to define individuals in negative terms, disregarding what is positive and works well. In contrast an ‘assets’ model would accentuate positive capability to identify problems and activate solutions. Assets models focus on promoting salutogenic resources that promote self esteem, self-efficacy, problem-solving and coping abilities, leading potentially to less dependency on professional services. This has particular relevance for those with early frailty, who are facing some problems, for example with fatigue and weakness, but still have a reserve of function and capabilities that it is important to identify and maintain.

11. Target population

Older people 65+ years with early frailty in receipt of community health services/visited at home by a health professional in the previous 6 months.

Inclusion/Exclusion Criteria

Inclusion criteria: Registered with one of participating General Practices; aged 65 or more; score as ‘mild frailty’ on the Clinical Frailty Scale⁷²; community-dwelling (including people living in extra care housing); life expectancy > 6months; capacity to consent to participate in this research (including those with dementia or communication difficulties who retain capacity to consent). We will include participants who are not able to communicate in English, if they can provide informed consent, assisted if needed by a translator.

Exclusion criteria: Those living in care homes (likely to have established frailty); on GP palliative care register; those who lack capacity to consent (e.g. advanced dementia); those already case managed (e.g. by community matrons, some reablement schemes).

Setting/context:

Participants will be community dwelling and recruited through General Practices in Hertfordshire and the London Borough of Camden.

12. Search strategy

Systematic reviews:

We will use Cochrane systematic review methods¹⁰, and identify components associated with effectiveness; what works, for whom, why? We will write and publish a formal protocol for the reviews. For the qualitative and policy review we will additionally be guided by the methods developed by the Social Care Institute for Excellence¹¹ and National Centre for Clinical Excellence (NICE)^{12,13} for synthesis of heterogenous literature for NICE Public Health guidance. We do not aim to replicate other recent systematic reviews of RCTs, such as Tappenden et al¹ but will update this review with any trials published since March 2011, broaden the scope to include trials of interventions delivered by any health professional at home (not restricted to nurses) and focus specifically on identifying components within interventions associated with effectiveness. In addition we will conduct a systematic review of qualitative studies focusing on defining active ingredients and the acceptability and feasibility of different modes of intervention delivery for older people. This will include i)

any linked qualitative studies to the RCTs identified and ii) qualitative studies of older people with early or pre-frailty and their perspectives of health promotion and behaviour change interventions.

Studies of home-based interventions will be identified via a systematic database search for the period 1990 to present of MEDLINE, MEDLINE in Process & Other Non-Indexed Citations, EMBASE, Science Citation Index Expanded (SCIE), Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCRCT), Cochrane Effective Practice and Organisation of Care Group (EPOC), PsycINFO, Health

Technology Assessment (HTA) database, NHS Health Economic Evaluation Database (NHS EED), Health Economics Evaluations Database (HEED), Database of Abstracts of Reviews of Effects (DARE), Cumulative Index to Nursing and Allied Health Literature (CINAHL); Evidence for Policy and Practice Information Centre Register of Health Promotion and Public Health Research (BiblioMap), Sociological Abstracts (SocAbs), Applied Social Sciences Index and Abstracts (ASSIA), Health Development Agency Register (Health Promis), Index to Theses. Completed and unpublished studies will be identified through searches in the HTA database, the UK Clinical Research Network (CRN) Portfolio Database and ClinicalTrials.gov. Leading researchers in the field will be contacted to help identify unpublished research or work in press. Intervention descriptions will be obtained from published journal papers and unpublished materials (protocols, manuals) requested from corresponding authors. Preliminary searching will begin with a strategy based on keyword/index (MESH) terms. In addition 'lateral searching' techniques will be used including checking reference lists of relevant papers, using the 'Cited by' option on Web of Science, Google Scholar and Scopus, and the 'Related articles' option on PubMed and Web of Science.

In addition to the above databases we will conduct a rapid appraisal of the policy context, searching national, local government and local health care provider and commissioning groups websites, and other relevant resources e.g. Health Promotion and Public Health Research (BiblioMap), addressing the context issues in introducing and sustaining innovation in health care. This search will use key words derived from the study objectives. Key people in central, regional and local government organisations will be contacted to assist in the identification of relevant documents, as well as leading figures in national level voluntary and professional organisations.

13. Sampling

Qualitative study:

In depth interviews: We will use data from our current study (MRC funded WISH Study) of interviews with 52 older people and stakeholders from the NHS (GPs and practice nurses), local government (adult social care, housing and transport), public health/commissioning, the voluntary sector (local AgeUK, U3A, and other smaller organisation representatives) which explore approaches to health promotion for older people, barriers/facilitating factors and views on content/delivery of health promotion for older people. In addition we will supplement this with up to 10 interviews on home-based health promotion with older people who are unable to leave their homes, who are not well-represented in our current study. We will sample for maximum diversity with respect to age, gender, socio-economic status and ethnicity and aim to achieve saturation on main themes. Participants will be identified from General Practices in North and Central London/Hertfordshire.

Focus groups: In order to explore further key stakeholder perspectives on health promotion interventions for older people with early frailty we will conduct 4 focus groups with 1) carers of people with early frailty, 2) home care workers and 3) two groups with community health professionals (district nurses, community occupational therapists, community physiotherapists, Health Trainers and community matrons), with up to 8-10 participants in each group. Carers will be

identified through participating General Practices and carers' groups/organisations. Carers will be given an option of attending a focus group or of having a one-to-one interview in their home if more appropriate (e.g. if they are a carer of an older person who is already being interviewed at home). Home care workers will be identified and invited through their employers (with whom we have good contacts) and representative organisations e.g. Hertfordshire Care Providers Association, and community health professionals through our collaborators in Camden and Hertfordshire Clinical Commissioning Groups, and community health service providers.

Feasibility study:

Sampling strategy: We will select 2 practices each in our 2 study areas (London Borough of Camden and Hertfordshire) to ensure a diverse representation of older people living in urban, suburban, and rural communities and from diverse socio-economic and ethnic backgrounds. The London Borough of Camden has a very socially and ethnically diverse population, while there are higher proportions of older people (and very old people) in Hertfordshire with differences in access to health, transport and other services. Participants will be identified through database searches of GP lists of registered patients over 65, excluding those with recorded exclusion criteria (e.g. those on the GP palliative care register). These lists will be further screened by participating GPs for eligibility criteria and exclusions removed. Remaining participants will be approached by letter by their GP with a study information leaflet. A telephone reminder will be made to non-responders by a member of the practice team. Those expressing an interest will be contacted by the research nurse for initial telephone eligibility screening. GPs will also be able to refer people opportunistically to the study, e.g. those they are visiting/have visited at home recently who did not meet criteria for existing frailty services. Potentially eligible participants (from telephone screening or GP referral) will then be visited at home to discuss participation, gain informed consent, full baseline assessment, and subsequent web-based randomisation.

Sample size, recruitment and retention: For the feasibility study we aim to recruit 50 people, 12-13 each from 4 General Practices. This number was selected as a sufficient number to test the feasibility/ acceptability of the intervention and pilot the study process, recruitment, randomisation and retention for a full RCT, and a realistic number to recruit per practice and deliver the intervention in the short time frame available for the feasibility study. Assuming an average of 600 people aged over 65 per study practice (based on our previous studies with this age group in our study settings), a prevalence of 41% of 'pre-frailty'³⁸ would lead to a population of 246 before exclusions. Assuming (on best estimates) 30 of these are excluded, and 20% have been visited at home in the last 6 months⁷³ by a health professional (including GPs, Out of Hours services, nurses, health care assistants, physiotherapist, occupational therapist or other community health professional) our eligible population would be 43 people. Assuming a conservative recruitment rate of 30% of eligible people, we could recruit 13 people per practice. In our past experience in previous studies on health promotion in the 65+ population (the WISH study) our attrition (including deaths) over 3 months was 10% and over 6 months 23%. Part of the purpose of the feasibility study is to assess if all of these assumptions are correct, as there is no data available (apart from community prevalence) that are specific to an older population with early frailty with which to base these assumptions. If our eligibility or recruitment rate is much lower than anticipated we would be able to extend our study to include further GP practices.

14. Data collection

Systematic reviews:

Research studies identified by the systematic searches will be grouped into RCTs/systematic reviews of RCTs and qualitative, observational and quasi-experimental studies. Identified abstracts and items will be screened against the agreed inclusion and exclusion criteria by two researchers. Full

text copies will be retrieved, read for those meeting the criteria or are ambiguous. Documents and data will be managed through bibliographic software and electronic spreadsheets. Data extraction formats will be developed for each of the types of evidence (e.g. RCT, qualitative) and relevant to the research questions. Quality assessments will be made of research studies according to the type of evidence, using Cochrane methods¹⁰ for RCTs and SCIE/NICE methods¹¹⁻¹³ for the qualitative studies.

Qualitative study:

Topic guides will be developed for in-depth interviews with older people and focus groups based on the literature review findings and findings from our current WISH qualitative study. They will explore attitudes towards health promotion and behaviour change for older people with early frailty, experiences of behaviour change attempts, barriers and facilitating factors, and views on the content and delivery of a home-based health promotion intervention (e.g. who should deliver it, what it should contain, how often etc). In depth interviews with older people will be conducted in participants' homes, and be recorded and transcribed verbatim. Focus groups will be conducted in an accessible local venue with an experienced facilitator from the research team and an observer present recording field notes, and will be recorded and transcribed verbatim. Refreshments will be available and travel costs met.

Intervention development:

The intervention will be informed by insights from the systematic review and the qualitative study. The systematic review will extract components found to be associated with effective previous interventions, while the qualitative study will identify the needs of the target population within which intervention content must be contextualised. Hence, our intervention will marry a top-down, theory-driven approach with a bottom-up, experiential approach. The research team will synthesise inputs from the two evidence sources in an integrative review using thematic analysis⁷⁴ so as to develop an intervention that uses components previously found (via the systematic review) to be associated with effectiveness, as framed by the needs of the target population (as identified via the interviews and focus groups).

The research team's initial ideas for the intervention, as informed by the reviews and qualitative work, will be used as a basis for discussion among the research team and the co-designers. The co-design development panels will be presented with a summary of the evidence and the research team's views on the intervention content, theory and behaviour change techniques, based on this evidence. The co-designers' expert knowledge and interpretation of the available evidence and experiences will be used to inform the most appropriate intervention delivery method and to tailor the intervention to those people with early frailty. This is important as we anticipate that much of the RCT evidence will relate to older populations more broadly. These discussions will inform refinement of the intervention, while retaining the key intervention components (identified in the systematic reviews) and addressing the needs identified (via qualitative review and interviews/focus groups). The research team would lead on developing the intervention based on these discussions. Each refinement of the intervention would be discussed with co-designers, such that multiple iterations of the intervention may be proposed. The final version will be approved by the research team and co-designers and at this point we will proceed to the feasibility study.

Feasibility study:

We will randomise individual participants to intervention or treatment as usual (TAU) arms to assess willingness to be randomised and check for contamination with patients in the same practice. We have full support of PRIMENT CTU, including a randomisation service, SOPs, database and quality assurance. We will use an independent web-based randomisation service through PRIMENT CTU. The researcher conducting outcome assessments will be blind to treatment group. Data will be collected at baseline, 3 months and 6 months.

Outcome measures: Potential outcomes for a main RCT including: quality of life (EQ-5D)^{15,16}, functioning (modified Barthel)^{17,18}, frailty (Frailty Index of cumulative deficits^{9,19}), mobility (gait speed)^{20,21}, grip strength²², well-being (Warwick-Edinburgh Mental Well-being Scale)²³, psychological distress (GHQ-12)²⁴, CVD risk factors (BMI, physical activity- IPAQ²⁵, smoking, alcohol AUDIT-C²⁶), medication use, cognitive function (MoCA²⁷) service use (Modified Client Services Receipt Inventory-CSRI)²⁸, QALYs, Capability (ICECAP-O²⁹); mortality. Resource use will be costed using national reference costs.

Process evaluation: We will collect data on eligibility, uptake/recruitment and non-respondents where possible at each stage, and adherence, attrition/losses to follow-up and document these in a CONSORT flow diagram⁷⁵. Intervention appointments will be audio-recorded and a random sample of 10% checked for fidelity to the intervention. We will conduct a process evaluation with questionnaires for all feasibility study participants and semi-structured interviews with a purposive sample of up to 15 participants receiving the intervention, sampled from those with good/poor adherence/outcome from the intervention.

15. Data analysis

Systematic reviews:

Interventions identified from the searches of RCTs will be coded according to seven dimensions: intervention content (behaviour change techniques, theory-base, intervention function), format (methods of intervention administration), setting (where and when delivered), recipient (population characteristics), intensity (number of patient contacts), duration, and fidelity⁷⁶. Intervention content will be described using a

taxonomy of 93 discrete behaviour change techniques⁷⁷, a 19-item coding scheme to assess the extent to which theory has been used in the design of the intervention⁷⁸, and a set of nine items which specify the overarching function served by the intervention (e.g. to impart skills, to educate, to persuade, etc)⁵¹. Coding schemes for other dimensions will be developed inductively, iteratively and concurrently with the coding process, to ensure all possible elements contributing to effectiveness are extracted. This process will allow for the systematic identification of common and replicable elements of effective interventions; what works, for whom, and why? Insights from the coding process will be used as an evidence base to inform the content and theoretical basis of our intervention. If sufficient data are available, formal meta-analyses will be conducted of all interventions combined, with subgroup analyses to test whether effectiveness and between-study heterogeneity vary according to the presence versus absence of discrete elements of each of the seven coded dimensions. Should meta-analysis be unfeasible due to lack of data, the relationship between intervention components and effectiveness will be explored by tabulating the presence of each coded component in effective versus ineffective interventions. Reporting will follow PRISMA guidelines for RCTs and meta-analysis⁷⁹. The review of the qualitative studies will consider first issues of validity and reliability⁸⁰ and then use techniques of meta-ethnography⁸¹ to identify recurring explanatory concepts contributing to judgements of appropriateness, acceptability, efficiency and effectiveness of interventions from a variety of perspectives including the older people. The policy review will use documentary analysis methods⁸² successfully used in other NIHR funded studies, focusing on policy relevant to those with early or pre-frailty, and factors that might affect widespread implementation of a successful intervention. A narrative review will be presented of the qualitative evidence and the policy review^{83,84}.

Qualitative study:

A thematic analysis will be undertaken identifying key emergent themes and their meaning. Transcripts will be reviewed independently by members of the research team and analysed using a constant comparative approach⁸⁵ including searches for disconfirming evidence. This involves dividing each interview into units, identifying each discrete area through extracting significant statements

and highlighting of text in the transcripts. The units are then grouped into categories and coded based on similarities and differences. Data will be inputted into a qualitative software package NVivo⁸⁶ and coded using this framework. After further reflection in comparing and integrating the units, they will be categorised into themes and typologies will be developed. The clusters of themes and typologies will then be referred back to the original descriptions for validation. The overall interpretation of meaning and explanations will be developed and their implications considered for the intervention development, with input from the entire research team including collaborators and PPI representatives. We will use adaptive theorising⁸⁷ where we consider the interpretation in relation to our theoretical framework and existing theory/models of successful ageing⁴⁶⁻⁵⁰.

Feasibility study:

As a feasibility study, our analysis will be mainly descriptive of the recruitment, participant characteristics, baseline and outcome variables, loss to follow-up and adverse events. We will provide confidence intervals for comparisons of outcome variables between groups and estimates of their standard deviations. These will assist in choice of principal outcome variable(s) and calculating power/sample size for a full trial. We will report findings using CONSORT guidance and flowchart⁷⁵.

Health Economic Analysis:

We will assess the feasibility of conducting a cost-effectiveness analysis of the intervention compared to treatment as usual alongside a full RCT. We will calculate the mean incremental cost per quality adjusted life year gained (QALY) for the duration of the trial and report this from the cost perspective of the NHS and personal and social services (PSS). A secondary analysis will also report the incremental cost per QALY gained from a societal perspective to capture the impact on carers and any patient out of pocket costs for health and social care. Health and social care resource use, out of pocket expenses and carer impact will be collected in the intervention and control group for the duration of the trial using a modified version of the client services receipt inventory (CSRI)³⁰. We will assess the feasibility of collecting some health care resource use, primarily primary and secondary care NHS contacts, from patient records. Resource use will be costed using published national reference costs and data published by the Personal Social Services Research Unit. The cost per patient of the intervention including staff salaries and oncology costs, travel costs, consumables, estates and training will be calculated. QALYs will be calculated from the EQ-5D and the UK algorithm for calculating utility scores. We will calculate the area under the curve of the intervention versus the control group for the 6 month duration of the trial, adjusting for baseline differences in utility score. Confidence intervals will be constructed using non-parametric bootstrapping and a cost-effectiveness acceptability curve will be reported. One and two way deterministic sensitivity analyses will also be conducted for any key assumptions made. Given the importance of this issue to commissioners, we will assess the feasibility of conducting a budget impact analysis for the NHS and Local Government to reflect the cost of the intervention for their population alongside any cost savings that could be realised for that organisation.

Process Evaluation:

We will conduct a descriptive analysis of quantitative questionnaire data on the acceptability/satisfaction with the intervention components, and a thematic analysis of the open questions on the questionnaires and interview data using the process described above in the qualitative study analysis section.

16. Success criteria

For a feasibility study it is important to define success criteria a priori that will determine whether it is appropriate to progress to a full evaluation. For the purposes of this study in a population with early frailty we would define this as

- 1) A recruitment rate of a minimum of 70% of our target of 50 people within 6 months.

- 2) A retention rate of 80% at 6 months (excluding those with outcomes we are measuring as part of the study i.e. deaths).
- 3) A positive evaluation of feasibility and acceptability to older people/the NHS in the process evaluation.
- 4) On analyses of the candidate primary outcomes there is at least no difference between the two arms (ie. no negative effects).

17. Barriers/risks

We will create and monitor a risk register throughout the study. We have identified the following potential risks:

1) *Lack of evidence specific to population.*

We will address this by including studies where those with early frailty have been included as a sub-population, e.g. RCTs of home-based interventions with a broader older population. If the range of

relevant behavioural techniques used is limited, we will also draw on evidence/theory from other relevant populations/settings.

2) *Poorly developed intervention*

We have put in considerable efforts to engage with a wide range of stakeholders/older people to develop the intervention, which would be based on a sound theory/evidence base. We will ensure a good representation of sectors and diverse populations in the development process.

3) *Lack of local engagement* We have had considerable enthusiasm from CCGs/clinicians we have consulted with in the development of this protocol. There is a widespread recognition of the importance of this work. The workload for practices/community health services is small, as patient identification centres only. We have good working relationships with our Primary Care Research networks and NoCLoR to help recruit practices if needed.

4) *Recruitment*

A potential concern is the identification of an eligible population with early frailty who are willing to participate in a RCT of a new intervention. We have been conservative in our estimates and have the capacity to extend to further practices if needed. Testing the recruitment process is an important output from the study.

5) *Workforce capacity to deliver the intervention*

This is a low risk in a small study with only 25 people receiving the intervention.

6) *Harms from intervention*

There are low risks of harm e.g. falls in people becoming more active, or increased carer burden in supporting the participant to make changes. We will highlight these in seeking informed consent and develop a system to identify and act on these if they occur.

7) *Attrition/serious adverse events*

With this population we would expect a higher rate of hospitalisation, inter-current illness, moves into residential care and mortality, impacting on attrition. We will report adverse events, monitor for capacity to consent with deteriorating health, and continue to follow-up where possible if the participant moves.

8) *Delivering on time*

This will be a tightly run study to keep to schedule with multiple components in 30months. We are an experienced, dedicated team that has delivered on other similar studies in short time frames. We have set a later start date (Sept 2014) in order to have all NRES, local governance, NIHR Clinical Research Network portfolio, Service Support Costs approvals in place before we start. We

are already engaged with our study sites, and have had interest in participation from several GP practices.

18. Plan of investigation and timetable

The project plan and key milestones are indicated in the project timetable below.

Month	Task
Sept – Nov 2014	Evidence searching/extraction systematic reviews Engage stakeholders, finalise study site recruitment Focus groups, in-depth interviews.
Dec - Feb 2015	Evidence review, quality assessments, coding, synthesis Complete in-depth interviews, focus groups, start qualitative analysis. Set up intervention development panels Interim Reporting
Mar - May 2015	Complete qualitative analysis Complete systematic reviews synthesis data Co-design development panels (May 2015) Draft papers systematic reviews/qualitative work
Jun - Aug 2015	Ethics substantial amendment feasibility study Recruit research nurse Manualise intervention Develop training programme Set up study sites feasibility study Set up database CRFs, randomisation service (via PRIMENT) Interim Reporting
Sept – Nov 2015	Complete feasibility study set up (Sept 2015) Training for people delivering intervention (Sept 2015) Begin recruit participants feasibility study (from Oct 2015) Baseline assessments Deliver intervention. Dissemination systematic reviews/qualitative work
Dec 2015 – Feb 2016	Continued recruitment participants feasibility study Deliver intervention 3 month follow-up assessments Interim Reporting
Mar – May 2016	Complete recruitment participants (by end Mar 2015) 3 & 6 month follow-up assessments Start process evaluation.
Jun – Aug 2016	Complete 3 month follow-up assessments (Jun 2015) 6 month follow-up assessments Process evaluation Interim reporting

Sept-Nov 2016	Complete 6 month follow-up (by end Sept 2015) Complete process evaluation Feasibility study analysis Economic analysis Draft papers
Dec – Feb 2017	Refine manual Final report Dissemination Plan main RCT (if applicable).

19. Project management

The project will be led and overseen by the CI, working closely with team members at other institutions and our collaborators at Age UK London who will be hosting and co-facilitating the intervention development process. We have a good track record of working closely and collaboratively together with coapplicants/collaborators at UCL, KCL, St Georges, University of Hertfordshire, PPI representatives, CCGs and AgeUK.

The core team (KW, KK and the Research Associate) will meet weekly, and the project management team (co-applicants) will meet monthly throughout the study to oversee the day-to-day study progress. Other members will join the core team meetings as needed for the relevant components of the study. The project management team will report to an Advisory group who will meet 5 times during the 30month study to provide expert advice and guidance and oversight of the study progression. This will adhere to NIHR guidance and include key members from the project management team, all of our collaborators including our 3 PPI representatives (MJ, SM, SM, SM-T, LS, TK, JB, KP, JH, RE, DL), an independent chair and statistician.

KW and KK will be involved in all aspects of the study as the CI and Senior Project/Trial Manager, co-ordinate the study, supervise the research associate/administrator and ensure timely progress and integration of the component parts. Each component of the study has nominated leads. BG will lead/supervise the systematic reviews of behavioural techniques and theory in interventions (with support from our collaborator MJ), VMD will lead/supervise the qualitative and policy systematic reviews. KK will lead the qualitative study and co-design development process, supervised by KW and supported by JM/CG/VMD/SI/BG. All project management team members will be involved in the co-design development process, definition and manualisation of the intervention, with input from our expert behaviour change collaborator MJ. KK will be the trial manager for the feasibility study supported by the PRIMENT Senior Trials Manager, and supervised by KW at UCL site and with CG as the Hertfordshire site lead. JW will supervise the PRIMENT trials statistician to conduct the analysis of the feasibility study, and RH will lead on the economic analysis (with support from our collaborator SM).

20. Approval by ethics committees

There are ethical issues as this project is with vulnerable older people, and we will seek NRES approval for the qualitative study, intervention development and feasibility study. Ethical issues will include assessing capacity to consent and ensuring fully informed consent, in particular for those with some impaired cognition or where English is a second language. We will provide translators and translated study materials where appropriate, and act in accordance with the Mental Capacity Act 2005 and Good Clinical Practice (GCP) guidance. There may be some small risks associated with the intervention, for example falls in someone who is increasing their activity levels as a result of the intervention, and these will be fully explained to participants prior to consent. We will

set up and maintain a risk register, and report any adverse events which may occur according to GCP guidance. If the researchers identify any participants where there are concerns about their welfare, such as adult safeguarding concerns, then this will be discussed with the CI (who is a practicing GP) and the appropriate services to support them would be informed (e.g. GP or adult services), with their consent unless there is very high level risk. We will request permission from participants for longer term follow-up using routinely collected data (e.g. their GP medical records, Hospital Episode Statistics and mortality).

The first year of the study will be busy in undertaking the systematic reviews and the qualitative study, and these and the intervention development work would need to be completed before final ethical approval is sought for the feasibility study. To avoid excessive delays in the progression from the intervention development to the feasibility study, we would seek ethical approval for the overall study prior to the start date of the grant, and submit a substantial amendment with the final version of the intervention before the feasibility study.

21. Patient and public involvement

Public and Patient Involvement (PPI) is a key part of this study, and three representatives, Kath Parson (Chief Executive, Older People's Advocacy Alliance), Jane Hopkins (Lewisham Pensioners' Association) and Rekha Elaswarapu (Dignity Adviser, Helping Hands Home Care, Ealing Healthwatch) have all contributed to this proposal and agreed to contribute to our Advisory group and multi-disciplinary intervention development panel. Our PPI representatives have been positive about the need for this research and the need for new approaches in health promotion for older people, and enthusiastic about our plans. We also invited comments from our voluntary sector collaborators at national Age UK and Age UK London (Samantha Mauger), and Age UK London has agreed to host and facilitate the older people/carer panels involved in the development of the intervention. We have strong relationships with Age UK London with a joint annual conference and open invitations to their members to take part in our dissemination activities.

There will be strong PPI involvement (older people and carers) throughout the study, in particular with the intervention development panels which will be undertaken using co-design methodology. Our 3 PPI representatives on our Advisory Group will advise on design, process and dissemination. We will also invite them to assist in analysis of qualitative data, which has worked well in previous studies. Research highlights that PPI is overrepresented by higher educated, more affluent and white people. To ensure representative and meaningful PPI we will recruit to the intervention development panels through participating practices in ethnically and socially diverse areas, our close collaboration with Age UK London and the PPI networks members of the team currently work with (e.g. UH Public Involvement in Research Group, Greater London Forum for Older People, King's College London SCWRU User and Carer Advisory Group). The local PPI networks and Age UK London have established mechanisms for supporting/training PPI representatives, which we will link with. Age UK London will host the PPI panels at accessible venues, e.g. an Age UK day centre, and can facilitate attendance/transport, so that we can engage with a population with early frailty who have difficulty leaving their home or accessing public transport.

22. Role of collaborators

We have a good support structure in place from a range of collaborators, as needed for a multi-faceted applied study developing a new health promotion intervention. Collaborators will be invited to attend our advisory group, and have been consulted in the development of this protocol. Clinical, voluntary sector, PPI representatives and topic experts will also be invited to contribute to the intervention development process.

Our collaborators include:

1. Professor Marie Johnson, Emeritus Professor of Health Psychology University of Aberdeen: Expert in behaviour change interventions. Will provide expert advice/support to BG and KW, in particular in the review of behaviour techniques, theory and intervention development.
2. Ms Samantha Mauger, Chief Executive, Age UK London/Health Watch: Voluntary sector perspectives, co-facilitate/host the intervention development panels, advice on dissemination to the public.
3. Professor Steve Morris, Professor of Health Economics, UCL: Expert in health economics, will provide advice where needed to RH in health economic analysis.
4. Dr Stuart Mackay Thomas, Frailty Lead Camden Clinical Commissioning Group (CCG), General Practitioner Hampstead Group Practice: Advice on NHS service perspectives intervention development, frailty expertise.
5. Dr Lance Saker, CCG Board Sponsor Frailty, Integrated Care Lead, advice on commissioning CCG perspectives and frailty services.
6. Dr Tony Kostick, Chair, East & North Hertfordshire CCG, Vice Chair, Hertfordshire Health & Wellbeing Board, advice on commissioning CCG and LH&WB perspectives.
7. Jacqui Bunce, Associate Director East & North Hertfordshire CCG, advice on commissioning perspectives.
8. Ms Kath Parson, Chief Executive, Older People's Advocacy Alliance: PPI representative
9. Jane Hopkins, Lewisham Pensioners' Association: PPI representative
10. Rekha Elaswarapu, Dignity Adviser, Helping Hands Home Care, Ealing Healthwatch: PPI representative.
11. Dr Dan Lee, Service Lead, Consultant Health Care for the Elderly, Royal Free NHS Trust: Advice on NHS perspectives (from Secondary Care), implementation of innovations in care for older people, frailty expertise.

23. Justification of support requested

We propose a 30 month study (with associated costs) and will deliver 4 major outputs: 1) comprehensive systematic literature reviews made accessible to professional readership by being written by an experienced team, including specification of behavioural techniques, theory, qualitative and policy reviews; 2) a large qualitative study combining findings from in-depth interviews with 62 older people and stakeholders and 4 focus groups; 3) co-design of a new manualised evidence and theory based health promotion intervention by older people, carers, professionals and experts; 4) a feasibility study with individual randomisation that will both assess acceptability and feasibility of the intervention within the NHS, and feasibility for a trial. Including testing of randomisation at this stage should enable us to proceed to a full RCT (with a pilot run-in phase, if this study is successful) and save additional costs from funding a separate pilot RCT through the NIHR. Our study will thus provide good value for money, as it will contribute substantively to the evidence base in this field, and provide a sound basis for the development of a new intervention deliverable across the whole NHS. There is a consensus for a need for a stronger evidence base and effective health promotion interventions for this growing population group that are often high users of NHS and social care services, with much potential for health gains, quality of life, and associated potential resulting savings.

The main costs will be staff costs, both co-applicant time and researcher time, costs for the involvement and support of PRIMENT Clinical Trials Unit in the feasibility study and costs for PPI involvement, collaborators, travel and dissemination.

Co-applicant time has been costed for the chief investigator and members of the team with complementary expertise, including a project manager, health psychologist, senior statistician,

health economist, trialists, qualitative experts, clinicians (General Practice and nursing), social care and social policy and experts in ageing. These have been detailed in the main application form. We have costed for a 60% FTE Research Associate (Grade 7 RA) for 30m supervised by an experienced project/trial manager (Grade 8, 60%FTE, funded as a co-applicant). The RA will undertake the systematic reviews (supervised by BG and VMD), contribute to the qualitative work, and assist with the feasibility study, conducting the outcome assessments at 3 months and 6 months across both sites (London and Hertfordshire). The senior project manager (KK) will lead on the qualitative work and co-design process, contribute to the systematic reviews and oversee the feasibility study. As the population has by definition difficulty leaving the home, all baseline and follow-up assessments would be conducted by home visits, which is resource intensive for RA time and travel costs. We have also costed a research nurse 80%FTE for 1 year for the feasibility study (to be split 40%FTE at each site) to assist with recruitment, screening for eligibility, baseline assessments and deliver the intervention at home to the 25 participants in the intervention arm. This person would not be conducting outcome assessments which would be the responsibility of the RA, who would be blinded to the intervention status. We have costed a small amount of time for a study administrator (Grade 6, 10%FTE) for 30m to undertake study related administrative tasks, such as minutes of meetings, maintaining a trial master file, documentation, invoicing and other administrative duties.

Collaboration with an accredited CTU is important so that we can ensure the feasibility study collects the information needed to inform a high quality full cost-effectiveness trial if the feasibility phase is successful. We have therefore included costs provided by PRIMENT CTU (limited to the feasibility phase of the study for 12m), including a database and data manager to develop and maintain the database, a senior trials coordinator to provide supervision/support, quality assurance (including checks of adherence to PRIMENT SOPs) and training for the trial manager, a PRIMENT statistician to undertake the feasibility study analysis and a web-based randomisation service.

As we are using a co-design methodology to develop the new intervention, adequate costs for PPI/Voluntary Sector involvement are important. These include payments using Involve rates for involvement of older people and carers on advisory groups, and for intervention development panels including costs of transport and payments for alternative care costs. We have also included consultancy costs for AgeUK London/HealthWatch involvement on our advisory group and to host/facilitate the intervention development panels and consultancy costs for our collaborator Professor Marie Johnson based in Aberdeen to advise and attend advisory group meetings.

We have included costs for the qualitative study transcribing, £10 vouchers for reimbursement for participants in the research, translation costs for translating study materials and costs for translators to attend interviews. Travel costs have been included for researchers for multiple assessments in people's homes and site visits, and for collaborators to attend advisory group meetings (including from Aberdeen) and experts to attend the intervention development panels. We have included project specific consumables costs to cover postage for recruitment to the study and reminders, and disseminate findings to participants, printing costs for study leaflets, the intervention manuals and study materials, posters for the study for each participating General Practice, mobile phone top-ups for researchers. We have costed for a laptop for the RA conducting assessments in homes and entering data directly onto our database, and a desk top computer and printer. Dissemination costs include attendance at the Society for Academic Primary Care's Conference and the British Geriatrics Society's conference (using their 2013 fees).

NHS Costs

Service support costs:

We anticipate a modest amount of service support costs for the NHS for practices in participation/ recruitment of participants. We have calculated these using current paycales and a

template for standard times for tasks provided by the Primary Care Research Network (PCRN)- Greater London and North Central London Research Consortium (NoCLoR).

Each practice will be recruiting 12-13 participants. We will require practices to help us identify suitable participants for the study meeting the study criteria. This will require practices performing electronic searches to identify a potential eligible population and remove those with exclusion criteria recorded, and then clinician(s) manually reviewing this to remove those with exclusion criteria not recorded. Practices would then write to participants informing them about the study and requesting their consent for approach by the research team. Practices could also opportunistically refer those they thought might be eligible, in which case time would be needed to explain the study and study information leaflet. Based on these tasks, and standard payscales above, and times for each task provided by the PCRN, we estimate service support costs to be £628 per general practice. For 4 General practices this would total £2,512.

Excess treatment costs:

These are difficult to determine in advance as we do not know the impact of this type of new intervention on NHS services. There may be excess treatment costs related to identification of new needs and an increased uptake of services as a result of the intervention, for example visits from General Practitioners to address needs that have been identified. From our past experience of work with this population, we do not anticipate this to be large, and we would anticipate that they would be mitigated in the medium term by reduced costs in other areas, for example, reduced rates of hospitalisation, a reduced need for more intensive rehabilitation or reablement services, or reduced adverse events that would need NHS resources, such as falls. In our previous similar studies with older people in primary care any additional treatment costs resulting from the identification of new needs and associated extra service utilisation have been accepted by participating practices and primary care trusts (now CCGs) as part of normal and appropriate clinical care, and has followed usual treatment/care pathways. We also cannot calculate intervention costs, as the intervention has not been developed, and components will be specified during the study. Costs will vary considerably depending on the person delivering intervention and length/frequency of contacts. We anticipate these being lower than costs for existing frailty services, for example if a Health Trainer model is used, Camden CCG estimated costs as £800 total for their site for Health Trainer time (at the top end of Agenda for Change Band 3) to attend 15 hours training and deliver the intervention to 13 people. In this study we will measure intervention costs and health and social care utilisation as an outcome, in order to estimate potential NHS excess treatment costs for a main RCT. Our partner CCGs have agreed to help us in estimating excess treatment costs resulting from this study, which will be important information for a future full-scale RCT.

24. Dissemination and projected outputs

Our findings will be disseminated widely to policy makers, practitioners, researchers and the public. Policy makers will include NHS England & Clinical Commissioning Groups (CCGs), Public Health England and Health and Well-being Boards, and those developing NICE's Public Health Guidance for delaying the onset of disability/frailty and NICE guidance on interventions to promote mental wellbeing and independence of older people. We would anticipate much interest, as many of these groups will be making difficult decisions regarding the commissioning of health promotion services. We have had substantial interest/engagement from our partner CCGs and LH&WB boards with the development of this proposal and with our current MRC LLHW research (The WISH study on health promotion for general older population, not home-based). These collaborations have meant that there has been an immediacy in dissemination of findings. For example, findings from the WISH study that were presented and discussed in stakeholder groups have already been included in partner organisations' strategic plans as supporting evidence.

Intensive case management type services used in the NHS have shown some disappointing outcomes, and the systematic review and qualitative/developmental work may yield important information for further development of these services. We will engage with professionals to ensure our findings are debated among frontline practitioners; in nursing through the Royal College of Nursing Older People's Forum and through the Anticipatory Care for Older People group within the Royal College of General Practitioners (RCGP) of which KW and SI are members. KW is an advisor for the NICE-led Quality and Outcomes Framework. We will discuss findings with home care provider organisations (e.g. UK Home Care Association), as their staff may be most closely in touch with older people unable to leave their own homes and who may need to support any home-based intervention. We will work with the main user/carers' organisations (e.g. Age UK, Healthwatch and Campaign to End Loneliness groups) to ensure that the recommendations we make fit with experiences and possibly inform their activities. Age UK has an established mechanism for the dissemination of new findings to their network of local branches and the public with which we have engaged in previous studies.

We will present our findings, and the methodological lessons learned, through publication in journals, to reach policy makers, and conference presentations in ageing, health services and primary and social care. We will publicise these through social media to achieve a wide reach. We will register the systematic reviews with PROSPERO.

The main outputs/impact of the research will be:

1. A systematic review and synthesis of the diverse evidence in this field. This will provide best evidence on secondary and tertiary prevention of disablement in early stage frailty. It will inform not only the new intervention we will develop, but also the development and commissioning of existing interventions in this field currently in use in the NHS, such as case management by community matrons. This will be an early output and impact from the research (in year 1) and the findings will be timely as Clinical Commissioning Groups and NHS England consider the on-going commissioning of these services within the NHS, and will inform the related NICE Quality Standards due for publication at that time.
2. A greater understanding of approaches to/increasing engagement with health promotion for older people who may find it difficult to access services available for the general population. This will have widespread applicability and will inform NICE Quality Standards and commissioning of health promotion services. This will also be an early output/impact with results reporting by 2015 and will be of interest to both NHS England and Public Health England/Health and Well-being Boards. It will also be relevant to public bodies' duties to promote equalities under the Equality Act 2010.
3. A new manualised evidence and theory based intervention to promote health and well-being for older people with early frailty ('pre-frail'), rigorously developed jointly with older people, carers, health and care professionals and experts in the field. Our project is designed to make the most of diversity of the study sites, where there are sizeable populations in one area of people who speak English as a second language.
4. The 'person specification' of the characteristics needed for the health professional delivering the intervention, and a manual for a training programme to deliver the intervention.
5. Feasibility, acceptability, recruitment, process and outcome data needed to design a high quality definitive cost-effectiveness RCT.
6. An approach to health promotion that focuses on the assets of this population, promotes patient and public involvement at the design stage of the intervention, shifts from deficit models of care and complements related work on long-term disease management e.g. Expert Patient Programme.
7. A contribution to the theory and evidence on how "healthy ageing" can be operationalised for older people living at home that are likely to be already in receipt of some services/family

support but are largely independent.

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