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The Holistic Assessment and care Planning in Partnership Intervention Study [HAPPI]: A Protocol for a feasibility, cluster randomised controlled trial

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Author Contributions

Criteria	Author Initials
Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;	HL;BK;JML;SC;KS
Involved in drafting the manuscript or revising it critically for important intellectual content;	HL;BK;JML;SC;KS
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	HL;BK;JML;SC;KS
Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.	HL;BK;JML;SC;KS

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Conflict of Interest statement

No conflict of interest has been declared by the authors.

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Abstract

Aim

During an initial phase of this research, an e-Delphi survey was conducted to gain consensus among stakeholders on the components of a nurse-led assessment and care planning intervention for older people who live with frailty in primary care. This feasibility randomised controlled trial (fRCT) will test the proposed intervention and its implementation and determine methods for the design of a conclusive randomised controlled trial.

Methods

The fRCT, with embedded qualitative study, aims to recruit 60 participants. Moderately and severely frail older people will be identified using the electronic frailty index (eFI) and the intervention will be delivered by senior community nurses. The control participants will receive usual primary care for frailty. The study is funded by the National Institute of Health Research (NIHR) (funding granted in May 2016, ref: ICA-CDRF-2016-02-018) and received NHS and University Ethical approval in 2018.

Discussion

There is evidence that the delivery of complex interventions for community-dwelling older people can reduce care home and hospital admissions and falls, there is less evidence for the benefit of any specific type or intensity of intervention or the additional benefits of targeting the frail population. This trial will determine feasibility of the intervention, define recruitment and retention parameters and trial logistics and decide outcome measures.

Impact

This study aims to address the limitations of current research by using a systematic method of frailty diagnosis and participant identification, trialling implementation of a person-centred intervention and testing of feasibility parameters.

Trial registration number: ISRCTN: 74345449

Key Words

older people, frailty, primary care, nursing, assessment, holistic intervention

1. Introduction

Frailty is a multifactorial clinical syndrome associated with ageing. It is caused by incremental damage to body cells and systems as individuals age (Rockwood and Mitnitski 2007, Cesari et al. 2013). Although its specific pathophysiology is not fully understood, it is known to follow similar mechanisms to sarcopenia (muscle weakness), malnutrition and is underpinned by de-regulation of inflammatory processes (Cesari et al. 2014, Jeejeebhoy 2012, Li et al. 2011). Although associated with older age, frailty can be distinguished from the effects of natural ageing. Frailty manifests when multiple body systems fail, the more systems that fail, the more likely it is that the person will become frail (Morley et al. 2013, Clegg et al. 2013). As people age, there is a loss of physiological reserve in all body systems, however, there is an intrinsic reserve buffer which enables homeostasis to be maintained and good function preserved. Once this threshold is breached then frailty will result with repair mechanisms no longer able to maintain homeostasis (Lang et al. 2009). Other independent risk factors for frailty development include loneliness (Gale et al. 2018), deprivation (Hoogendijk et al. 2014), depression (Vaughan et al. 2015), low physical activity and polypharmacy (Heuberger 2011).

Given the multifactorial nature of frailty, an effective intervention should address relevant risk factors using a holistic, multi-dimensional approach. This approach is the founding principle of a comprehensive geriatric assessment (CGA) which is described as the

management and treatment for prevention of deterioration in frailty (Gladman 2016). The British Geriatrics Society describe CGA as:

“a multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of a frail older person to develop a coordinated and integrated individualised care plan for treatment and long-term follow up in partnership with the patient and carers”

(British Geriatrics Society 2014).

This approach is part of routine care and well evidenced in the acute hospital setting in the speciality of geriatric medicine, but not well established in other healthcare settings such as primary care. To meet the challenges of the increasingly frail and older population and to provide proactive, holistic care close to home, there is a need for a standardised intervention that can be implemented in primary care, which provides value for money, is not time consuming and has a high level of sensitivity to enable primary care resource to be targeted at patients who will most benefit from the intervention. If a primary care led standardised intervention is to become a reality, the burden of completion and effect on patient outcomes require further research as to the feasibility, acceptability, effectiveness and scalability. Informed by the existing literature and patient and public engagement (PPI), a primary care intervention that contains cost and clinically effective components of the acute CGA framework was developed.

An e-Delphi survey was conducted to gain consensus among stakeholders on the components of the intervention. After mapping the components, a new intervention was developed including a conversation guide and assessment pack to structure the intervention to be tested

in a feasibility randomised controlled trial (fRCT). This paper presents the study protocol of the fRCT.

1.1 Background

There is increasing evidence that, using a person-centred approach, frailty can be managed as a long-term condition with early identification, diagnosis and effective management to improve outcomes, prevent or delay deterioration and reduce health and social care costs (De Lepeleire et al. 2009, Lee et al. 2015). Although they advocate the management of frailty in primary care settings De Lepeleire et al acknowledge that the identification of frailty and its application to clinical practice in this area are under-developed. Given its high prevalence, frailty management is likely to become the remit of primary care in the future. However, there may be insufficient capacity and lack of appropriate skills and knowledge in primary care settings to adequately manage numbers of frail patients. If an achievable, proactive model of care is developed, primary care is the ideal setting to implement a more person-centred approach because of the integrated nature of primary and community care and the opportunities to interact with patients in their home environment (Beswick et al. 2008).

In 2014 the British Geriatrics Society (BGS) suggested that a primary care led ‘holistic review’ by a GP or specialist nurse may enable more frail older people to access services out of hospital. However, as previously discussed, it is not clear whether the acute hospital CGA framework is immediately transferable. The BGS have suggested other considerations that are missing from the traditional CGA framework, such as treatment escalation and advanced care planning (British Geriatrics Society 2014). These considerations would appear to be highly relevant as part of a CGA intervention delivered in a primary care setting where the

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clinician has a more long-term and person-centred relationship with the patient. A recent review of person-centred care concluded that while there is no universal definition of the concept, there are well recognised behaviours displayed by nurses that promote person-centeredness, such as engaging with the patient as a partner and shared decision making (Sharma et al. 2016). These behaviours and their foundation in nurses' approaches to care would appear to make nurses appropriate clinicians to carry out CGA/holistic review in a primary care setting.

2. The Study

2.1 Aim and Objectives

The aim of this fRCT with an embedded qualitative study is to determine the feasibility of delivering the Holistic Assessment and care Planning Intervention (HAPPI) in primary care to older people with frailty and determine methods for the design of a conclusive randomised controlled trial (RCT). Detailed objectives of the trial are described in Table1.

2.2 Methodology

The trial will be a cluster randomised, controlled feasibility trial with an embedded qualitative study aiming to recruit 60 participants from six general practices. Cluster randomisation with the general practice as the unit of randomisation has been proposed to reduce contamination between control and intervention groups which may lead to biased estimates of effect size in the main trial. Three general practices will be allocated to the intervention and three to the control arm of the study, so that patients of individual general practices will either receive the intervention or usual primary care. As the HAPPI is an intervention that aims to have an impact on staff expertise, awareness and clinical practice, it

is important to ensure separation of the control and intervention groups in this way. Fig 1 shows the flow diagram of the study design.

2.2.1 Study Setting and General Practice Eligibility

Six general practices will be recruited to the study. The following factors will be used to determine suitability of practices to participate in this study:

- a. The practice uses the electronic frailty index (eFI) to identify their moderately and severely frail population
- b. The practice is willing to fulfil the requirements of the study relating to screening, recruitment and provision of outcome data
- c. There is at least one senior community nurse attached to the practice who is willing to deliver the HAPPI intervention

General practices registering an interest in the trial will be invited to complete a feasibility questionnaire to assess their suitability which will be checked by the Chief Investigator.

Reasons for non-selection of practices will be fully documented to inform feasibility objectives.

2.2.2 Recruitment

Under the terms of the NHS England General Practice Contract (NHS 2017), practices are required to identify moderately or severely frail patients aged 65 years and over in their practice population. Practices use an appropriate evidenced based tool such as the electronic frailty index (eFI) (Clegg et al. 2016). The eFI is a computerised algorithm that is integrated into most general practice electronic clinical records and is used to identify and grade severity

of frailty using a cumulative deficit model based on several variables that including clinical indicators, long-term conditions, disabilities and abnormal test results (Clegg et al. 2016).

To generate a list of the moderately and severely frail patients, a practice administrator will run the eFI as a database search and this will classify the entire practice population into fit, mildly frail, moderately frail and severely frail people. The output from the eFI, combined with the application of the trial inclusion/exclusion criteria, will identify initial potential participants for the trial.

Potential participants will be eligible for the study provided they are:

- a. Aged 65 years and over
- b. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36)
- c. Frailty confirmed by PRISMA7 instrument
- d. Able to give informed consent
- e. Living in own home/supported living accommodation

Patients in receipt of palliative care with limited life expectancy, those who lack mental capacity to give informed consent or if they are already on the caseload of a senior community nurse will be excluded from the study.

90 potential participants will be randomly sampled from the eFI list, 45 in the moderate and 45 in the severely frail categories. If there are less than 45 in either category, then sampling will not occur and all patients go forward for eligibility checking. The eFI is a population risk stratification tool and cannot confer clinical diagnosis, therefore, a further step is required to make a diagnosis of frailty and confirm eligibility. Frailty diagnosis will be confirmed by the completion of the PRISMA7 questionnaire (Raiche et al. 2008). An invitation to participate in the trial and PRISMA7 will be sent to the 90 people. Names of interested patients who meet PRISMA7 criteria will be passed to the research team who will make contact. An appointment will be made for a visit at home or in the general practice to provide choice and minimise participant burden. During this consultation, the participant will be given the opportunity to ask further questions about the study before consent is obtained and baseline assessments carried out.

2.2.3 The Intervention

Participants in the intervention group (n=30) will receive the HAPPI intervention delivered by a senior community nurse who has received training in delivering the intervention. Senior community nurses are experienced nurses with advanced assessment and prescribing skills, the required skills set to deliver the assessment and care planning intervention. They are attached to individual general practices and employed by the community services NHS Trust. To ensure a standardised approach, training will be given prior to delivering the intervention using a training package delivered by face-to-face training by the Chief Investigator.

A conversation guide, assessment pack and personalised support plan template have been developed to support delivery of the intervention and ensure treatment fidelity by detailing the content of the intervention and how it should be delivered. The intervention will be delivered at home and it is expected that it will consist of one assessment visit and up to six care planning visits conducted over a maximum of 12 weeks. For the purpose of the trial, the minimum “dose” of the intervention will be defined as one assessment visit and at least two care planning visits. Documentation of the intervention, including assessment, support plan and evidence of any referrals, will be recorded using a standardised template, which will be stored in the clinical record.

2.2.4 Control

Participants in the control group (N=30) will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice (British Geriatrics Society 2014). This may include the management of long-term conditions, referrals to other services, prescribing of medications and routine vaccinations. As part of the feasibility trial, components of usual care will be captured to standardise for the future definitive RCT.

2.2.5 Outcomes

The primary outcomes relate to feasibility of the intervention, feasibility of conducting the trial and assessing different potential primary and secondary outcomes of the future trial and are summarised in Table 2. All potential clinician and participant-reported primary and secondary outcome measures will be collected at baseline (following randomisation and consent), three months (post intervention) and six months post intervention.

The Medical Research Council guidance (Craig et al. 2008) highlights the need to explain causative mechanisms and describe contextual factors associated with variation in outcomes.

Process evaluation will form part of feasibility assessment. This highlights the importance of capturing fidelity, which includes assessing whether the intervention was delivered in the correct dose/quantity and to the expected number of participants.

Fidelity will be measured in a variety of ways; nurses delivering the intervention will receive standardised training and use a conversation guide, assessment pack and personalised support plan template as a framework for the intervention. They will record the completed components of the intervention, any adverse events related to the intervention and an independent assessor (Academic Supervisors) will observe 10% of interventions across all GP practices using a fidelity checklist.

2.2.6 Data Collection and Storage

Data will be collected through the completion of case report forms consisting of three sections relating to intervention delivery, participant outcome measures and data from the clinical record. In addition, a screening log will be completed by the general practice, detailing numbers of participants screened, those eligible, responses to recruitment letters and those who progress to consent or decline to participate.

A customised database will be used for data entry and double entered data compared for discrepancies. Anonymised data will be securely stored for ten years after the completion of the trial in accordance with University policy. The Sponsor will be responsible for archiving all trial data following submission of the end of study report. In data gained from interviews

all participants will be anonymised and pseudonyms used to demonstrate different participants' experiences.

2.2.7 Data Analysis

As a feasibility study, a formal sample size calculation based on considerations of power is not appropriate (Thabane et al. 2010). This study is not powered to detect clinically meaningful between-group differences in a primary outcome. One of the aims of the study is to provide accurate approximations of recruitment and follow-up rates, as well as provide estimates of the variability of the proposed primary and secondary outcomes to inform sample size calculations for the planned definitive trial. There is no consensus on the recommended number of participants required for a feasibility study, with suggested numbers ranging from 20-70 or more participants when the planned primary outcome is of a continuous nature. (Whitehead et al. 2016). Therefore, this feasibility study aims to recruit 60 participants in total.

Participants will be recruited from a minimum of six general practices, with a total practice population of 491,000. The planned recruitment period is 6 months and over this period, across the practices, it is anticipated that following initial screening (eFI), approximately 9000 (1500 per practice) potential participants will be identified and from these 540 (90 per practice) sampled for second screening (PRISMA7) and eligibility. Following second screening, it is estimated that around 30% of eligible participants will consent to participate. The follow-up rate is estimated to be 70%, which would provide follow-up outcome data on a minimum of 42 participants across both allocated groups and three sites.

As a feasibility study it would be inappropriate to test treatment effects, therefore the statistical analyses will be descriptive in design (Thabane et al. 2010). The statistical analysis plan will conform to guidance related to statistical analysis plans (Gamble et al. 2017) and take into consideration the CONSORT updated guidelines for reporting feasibility and pilot trials (Eldridge et al. 2016) and also give consideration to the CONSORT Patient-Reported Outcome (PRO) extension: Health and Quality of Life Outcomes (Calvert et al. 2013) and CONSORT Statement for Randomised Trials of Non-pharmacologic Treatments (Boutron et al. 2017). All analyses and data summaries will be conducted on the intention-to-treat (ITT) population which is defined as all participants randomised regardless of non-compliance with the protocol or withdrawal from the study. Participants will be analysed according to the intervention they received.

The aim of the analysis is to assess the feasibility of the intervention, the feasibility of a full definitive trial and summarise potential primary and secondary outcome measures. A summary of the planned statistical analysis methods is presented in Table 3.

2.3 Embedded Qualitative Study

This component of the trial explores the experiences of the study participants, their carers, and clinicians who will deliver the intervention and general practice staff who facilitate recruitment and eligibility screening. The aim is to generate recommendations and address unknowns including experiences of recruitment, retention, practical implementation and further refinement of the intervention and outcome measures for the design of the future RCT.

2.3.1 Methodology

A qualitative study will be conducted using a phenomenological approach. The research team will conduct in-depth semi-structured interviews to gain insight into their experiences in participating in the study from participants, carers, community nurses and practice administrators.

2.3.2 Sampling

A sample of participants will be invited for interview based on severity of frailty (equal numbers across moderate and severe). Half the sample of participants and carers will be interviewed at three months post-randomisation and half at six months to gain insight at each stage of the trial. Senior community nurses who delivered the intervention will be approached for interview and practice administrators who conducted screening and recruitment procedures. Maximum sample numbers are described below but if saturation is reached prior to these numbers, no further interviews will be conducted. The following purposive sample size is anticipated:

- A maximum of six study participants (four from the intervention arm, two from the control arm of the RCT).
- Four carers of study participants (two intervention arm, two control arm of the RCT).
- Two people who declined to participate at the outset and two people who withdrew from the study before completion.
- A maximum of six senior community nurses who delivered the intervention.
- Four general practice administrators who implemented recruitment and eligibility screening procedures

It is understood that it might be ethically challenging to recruit to the qualitative study once a participant has declined the feasibility RCT. However, the importance of including these people is to explore their reasons for declining participation or withdrawal to use these data to inform the larger study protocol and maximise recruitment and retention.

2.3.4 Qualitative Data Collection

In-depth semi-structured interviews will be undertaken using an interview protocol and topic guide which comprises of open questions relating to structure, process and outcome of the trial. For clinicians, topics will include situations they found interesting with regard to implementation of the HAPPI intervention and any challenges with regard to its delivery.

Interviews with practice administrators will explore their experiences of the identification, screening and recruitment procedures. For patients and carers topics will include their experiences of the HAPPI intervention, participating in the trial and completing outcome measures questionnaires. All interviews will be audio recorded and transcribed verbatim.

Interviews with patients and carers will be conducted at the patient's own home following an informal format, to assist in helping participants to share their experiences and allay any concerns that they are being too critical. Interviews with community nurses and practice administrators will be conducted at their local work base. It will be re-iterated that all data will be anonymised and that interviewers are interested in all participants' views and opinions and will not make judgements.

2.3.5 Decliner and Withdrawal Interviews

Up to two people who declined to participate at the outset will be interviewed and another two people will be interviewed if there are participants who withdraw once consented into the trial. At the time they decline to participate in the study, or withdraw, they will be asked once only if they would be willing to share their reasons why they declined in a brief interview. They will be informed that the researchers would find any reasons they had for declining useful for developing this and future research. They will be clearly informed that this is entirely optional, and they do not have to share their reasons. If they consent, they will be given an option to be interviewed alone or with their significant other. The aim is to explore their feelings about this feasibility study and reasons for declining or withdrawing to inform and optimise recruitment/retention for the remainder of the trial and subsequent main study.

Data collection will occur within three days of declining or withdrawal.

2.3.6 Qualitative Data Analysis

Qualitative study results will be reported using the COREQ checklist for interviews and focus groups (Tong et al. 2007). Thematic analysis will be used to analyse the data. This method includes a strategy for identifying themes and subthemes (Braun and Clarke 2006). The interview transcripts will be uploaded to the qualitative analysis program NVivo. The first analysis step will involve two researchers becoming familiar with the narratives by reading the transcripts independently. In the next step, two researchers will independently code the text by allocating the text fragments to codes. The codes will be formulated from the text fragments and will possibly be revised during the process of reading the transcripts. Two researchers will then discuss the results of the individual codes and try to reach consensus. After this, the codes will be reviewed, and themes will be formulated.

2.3.7 Qualitative data presentation

Demographic data items will be presented using descriptive statistics. Meaningful text fragments will be determined, as will codes (sub-themes) and themes related to the trial objectives. Data extracts will be accompanied by extracts from the transcripts to elaborate why the extract is interesting as part of analysis.

2.4 Ethical Considerations

This study protocol was approved on 16th October 2018 by the National Health Service Research Ethics Committee (REC reference:18/LO/1354; IRAS project ID: 229210) and the University Research Ethics Committee on 14th November 2018 (Reference Number: 18/19-1027).

Protection of participants and researchers from harm is paramount. The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Policy Framework for Health and Social Care Research.

2.5 Consent, confidentiality and data protection

All eligible people who have agreed to be approached by completion of the recruitment invitation letter will be given verbal and written information about the study. Information will be provided in an appropriate form, for example a supported conversation around written material (a patient information sheet) to maximise understanding of what is being asked of them and to support them to make decisions. The patient information sheet is available in large print if required. People will be informed that their care will not be affected in any way by their decision to take part or not.

People willing to take part in the trial will be invited to provide confirmation of informed consent to undergo baseline and follow-up assessments and data collection and permission to access to patient's medical and social care records will be sought. If the person has capacity to consent but cannot sign the consent form, this will be indicated on the consent form by the assessor.

Data will be collected and stored in accordance with the Data Protection Act 1998/General Data Protection Regulation 2018. All paper documents will be stored immediately after use securely in the Site File at each site separate from study data. All computerised data will be stored on a password protected device. After completion of the trial these will be accessible for the purposes of monitoring and auditing via the Sponsor who will be storing the anonymised data for ten years. All identifiable data will be destroyed as soon as the trial has ended, and participants have been sent a summary of the results.

3. Discussion

Research into the management of frailty as a long-term condition and specifically in primary care is high priority for policy makers nationally and internationally. This study aims to test the feasibility of a uniquely person-centred approach to assessment and care planning led by nurses in partnership with patients and their carers. Testing feasibility is one of the key principles of developing a complex intervention (Moore et al. 2015) to assess acceptability and develop important parameters for a definitive trial. Research suggests that this preparatory work is often not undertaken fully leading to errors in design of full trials (Eldridge et al. 2004) and that interventions that would have made a difference fail due to challenges of delivery, implementation and compliance (Bower et al. 2007, Prescott et al. 1999).

There is some evidence that the delivery of complex interventions for older people at home can reduce care home and hospital admissions and falls, however, less is known about the benefit of any specific type or intensity of intervention (Beswick et al. 2008). In addition, Beswick's systematic review notes that there was a lack of identification and recruitment of frail older people to studies and, therefore, we do not yet understand the additional benefits of targeting the frail population.

The nursing contribution to the management of frailty is poorly developed with few well-designed studies assessing nurse-led interventions showing mixed results, again with very few focussing on targeting the frail population. Few studies have specified the content of the intervention and the competencies required by clinicians delivering the intervention (Gardner et al. 2017, Jovicic et al. 2015). One study has shown that nurses may be the most appropriate clinician to deliver a primary care-led intervention, but highlighted the issue of lack of treatment fidelity and identification of the most frail (Godwin et al. 2016).

4. Conclusion

This study aims to increase the evidence and to address the limitations of current research. This will be achieved by the use of a systematic method of frailty diagnosis and participant identification, implementation and testing of the acceptability of a uniquely person-centred intervention which is not prescribed or regimented but developed iteratively based on the needs and aspirations of the frail older person. It will enable testing of feasibility parameters to maximise success of a future definitive trial by exploring the views of all major stakeholders including participants, carers and clinicians.

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Table 1: Trial Objectives

Objectives a-h will be met within the feasibility randomised controlled trial:

- a. To assess compliance with the HAPPI intervention.
- b. To verify that proposed outcome measurement and follow-up schedules are feasible to collect.
- c. To determine achievable targets for recruitment and follow-up rates.
- d. To evaluate method of recruitment using the electronic frailty index (eFI).
- e. To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial. Outcome measures to be evaluated have been taken from the ICHOM Older Persons Reference Guide (Akpan et al. 2018).
- f. To calculate standard deviation of the outcome measures to estimate sample size for the definitive trial.
- g. To assess availability of clinical data and time needed to collect and analyse data required for numeric outcome measures.
- h. To explore factors that will enable future economic evaluation alongside the main trial.

Objectives i-l will be met within the embedded qualitative study:

- i. To explore the acceptability of the intervention to patients, carers and clinicians in primary care.
- j. To identify barriers to delivery of the HAPPI intervention e.g. any operational difficulties.
- k. To evaluate clinicians' willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised.
- l. To explore the acceptability of trial processes and collection of outcome measures to participants.

Table 2: Trial Outcome Measures

Feasibility of the Intervention	
a.	Numbers of completed HAPPI intervention conversation guides and personalised care plan templates
b.	Assess degree of contamination by number of staff moving between intervention and control practices
Feasibility of Conducting the Trial	
c.	Number of GP practices expressing an interest in participating
d.	Number of GP practices screened for selection and reasons for non-selection
e.	Number of GP practices withdrawing from the study, timing and reason for withdrawal
f.	Number of GP practices failing to progress through implementation milestones and reasons for failure
g.	Number of GP practices withdrawing during the implementation and delivery phases
h.	Numbers of participants screened as eligible, recruited, consented and followed up
i.	Numbers of participants identified using the electronic frailty index (eFI)
j.	Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up
Potential Primary and Secondary Outcomes	
k.	Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals
l.	Numbers of missing items for each potential primary and secondary outcome at each time-point
m.	Estimation of the feasibility of collecting data to estimate cost-effectiveness; EQ-5D-5L; add-on for economic evaluation.
n.	Assessment of the following outcome measure instruments: <ul style="list-style-type: none">• Review of usual care practice, using a clinical note review of control participants• Level of care at home received measured by participant self-reporting• Polypharmacy – number of medications prescribed and participant perception of adverse effects

- Accepted Article
- Number of falls measured by participant self-reporting
 - Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale
 - Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36)
 - Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire
 - Mortality; date and cause of death obtained from the clinical record
 - Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record

Table 3: Statistical Analysis Methods

<p>Measuring feasibility of the trial will include:</p> <ul style="list-style-type: none">• CONSORT diagram• timing of follow-up assessments (i.e. where they within a reasonable time frame)• time taken to recruit sites/participants• balance of baseline characteristics by allocation group• number of research assessors who became unblinded• movement between practices (although potentially this may not be representative of the country)
<p>Feasibility of the intervention will include:</p> <ul style="list-style-type: none">• numbers who complied• how much participants complied with intervention (i.e. one assessment and at least two care planning visits)
<p>Potential primary/secondary outcomes assessment will include:</p> <ul style="list-style-type: none">• summary statistics difference between baseline and follow-up visits• completeness of data (missing completely and missing items).

Figure 1: Flow diagram of the trial design

