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The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
21/11/2018

Overall study status
Completed

Last Edited
03/04/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Frailty can be a distressing but not inevitable part of getting older. People who are frail may feel more tired and weak than normal, have trouble getting around, lose weight and feel that they are slowing down. Frailty progresses over a period of 5-15 years and may lead to losing independence, hospital admissions and moving to a care home.
Previous research has suggested that it may be possible to support older people to manage frailty like any other long-term condition. If recognised early, care and support can be provided that may delay or prevent negative effects of frailty so that older people can retain their independence and quality of life. To do this, people need effective support at home from health services such as their GP, community and practice nurses.
Once people are aged 80 years and over, between a quarter and a half will show some of the signs of frailty. Therefore, it is important that we understand the causes and how best to manage the condition for the future. Like many long-term conditions, frailty cannot be cured, so we need to understand how to empower people to live well with it.
This research aims to explore how people can be best supported at home and how community nurses could work to provide individualised support. We want to explore if we can improve outcomes for patients enabling them to live at home, improve wellbeing, prevent falls and reduce the need for unplanned hospital care.

Who can participate?
Adults aged 65 years or older who have moderate or severe frailty and live in their own home or in supported living accomodation

What does the study involve?
The first part of the study will include a survey of an expert group of nurses to explore their views of elements of care for frail older people in the community. This will enable development of a care plan based on the individual needs of people that can be used by nurses in partnership with patients and their carers. In the second part of the study, a small trial will be undertaken to test this new care plan, including frailty assessment and evaluation, to see if it is practical and achievable. In this part of the study, there will be a group of patients who receive the new care

plan and a group who will receive care as usual.
In the final part of the study, the experiences of participating in the trial will be explored with frail patients, carers and nurses. The information gathered during the proposed project will be used to inform a future larger clinical trial to ensure the methods we used are fit for purpose.

What are the possible benefits and risks of participating?
Participants in intervention group may benefit from visits and support from a nurse in addition to your normal care and support; however, we cannot guarantee any specific benefits from this. Participating in research does deliver wider benefits to society and others with a similar condition and will help us to determine how best to support people in the future.
There are no known risks to participants taking part in this study. Participants will be asked to give up some of their time to participate in the study, which may be inconvenient.

Where is the study run from?
Cornwall Partnership NHS Foundation Trust and 6 other practices in Cornwall, UK

When is the study starting and how long is it expected to run for?
May 2018 to April 2021

Who is funding the study?
NIHR Trainees Co-ordinating Centre (TCC) (UK)

Who is the main contact?
Helen Lyndon
helen.lyndon@plymouth.ac.uk

Study website
https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-pla

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34936

Study information

Scientific Title
The Holistic Assessment and care Planning in Partnership Intervention (HAPPI) Study: A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care

Acronym
HAPPI

Study objectives
There is no formal hypothesis as this is a feasibility study. The primary aim of this cluster randomised, controlled feasibility study of a nurse-led Holistic Assessment and care Planning in Partnership Intervention (HAPPI) is to determine the feasibility of delivering the intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Giles and Camberwell Research Ethics Committee, London, 16/10/2018, 18/LO/1354

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Frailty in older people

Interventions
We aim to recruit 60 participants from general practices in Cornwall. Cluster randomisation will be used. Half of the general practices will be allocated to the intervention and half to the control arm of the study, so that patients of individual practices will either receive the intervention or usual primary care. Community Matrons (CMs) in the area under study will deliver the intervention. They are attached to specific general practices and so individual CMs would only visit participants in the control or the intervention group, never both. As the HAPPI is an intervention that aims to impact on staff skills, knowledge and clinical practice, it is important to ensure separation of the control and intervention groups in this way.

Once informed consent or consultee agreement has been received, baseline assessment of outcome measures will be undertaken with the participants. All baseline assessments will be carried out in one session and at the same time as consent is obtained to minimise burden of multiple contacts for participants. They will be undertaken by the CI or authorised delegate (RAs). Consent and baseline outcome measures will be collected in the participant's place of residence and it is estimated that this consent and data collection visit will be approximately 60 minutes duration. Support and additional time/visit will be offered to participants who may need suffer fatigue, cognitive impairment etc. As a feasibility study, any difficulties will be noted and adjustment made to the design of the main trial.
The assessor will record the results of the baseline assessments on the case report form (CRF) and enter the results into a secure password protected web-based system. This will generate an email for the community matron who will be carrying out the intervention informing that he/she can contact the participant and arrange the first visit in accordance with the intervention guide.

Participants in the intervention group will receive the HAPPI intervention delivered by a CM who has received training in delivering the intervention. In Cornwall, CMs are experienced nurses with advanced assessment and prescribing skills and, therefore have the required skills set to deliver the assessment and care planning intervention. CMs are attached to individual general practices and employed by the community services NHS Trust (Cornwall Foundation NHS Trust). In order 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 CI.
The holistic assessment and care planning intervention (HAPPI) will encompass the following key principles that make the intervention unique and different to current care for this population:
1. The person will not be referred in crisis (as in current CM practice) but will be approached proactively following identification using the eFI and PRISMA7 screening tool.
2. The CM will visit without first gaining any past medical history or other information about the person's health from the general practice record and initiate an "unbiased, open dialogue" with the person. Any issues/problems/deficits will be generated from this dialogue and the assessment and care-planning intervention will develop from this point.
3. There will be an ongoing development and review of a support plan in partnership with the person and carer (if appropriate).
4. Outcome measures will focus on responsiveness to change/completeness of the intervention and discharge plans; what is different after the intervention is complete.
5. The intervention will be based on a "conversation guide" rather than a prescriptive assessment template. Assessment tools will be available to be used if they are appropriate for

that person's needs/problems.
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 carried out in the participant's 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 document/computerised template, which will be stored at in the clinical record at the Community Matron's base with a copy in the electronic general practice clinical record.

Participants in the control group will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice. This may include the management of various 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 in order to standardise for the future definitive RCT using a standardised template.

All potential clinician and self-reported primary and secondary outcome measures will be collected at baseline (following randomisation), three months (post intervention) and six months. As a feasibility trial, process evaluation is a key part of the intervention development process to enable conclusions to be drawn about the strengths and weaknesses of a trial.

This study also has an embedded qualitative component. This component of the trial explores the experiences of the study participants, their carers and the experiences of the clinicians who have delivered the intervention and GP practice staff who facilitated 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 randomised controlled trial.
In-depth semi-structured interviews will be undertaken by the CI, which will last approximately 40 minutes. An interview protocol and topic guide will comprise questions relating to structure, process and outcome of the trial. The topic guide will not be exhaustive, with flexibility to offer space and the opportunity for participants to raise other issues which they might consider pertinent. All interviews will be audio recorded for their entire duration and transcribed verbatim by the CI or delegated staff. Interviews for patients and carers will be conducted at the patient's own home following an informal format, which it is envisaged will assist in creating a situation in which experiences will be openly shared, without participants fearing they are being too critical. Interviews for the community matrons will be conducted at their local work base or other CFT premises. All respondents will be assured of the anonymity of the data and that the interviews are intended to be non-judgemental.
In particular, the CMs will be asked to describe, discuss and elaborate on the situations they found interesting and challenging with regard to implementation of the HAPPI intervention with patients, and the situations they found interesting and challenging with regard to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service.
The GPs will be asked to describe the situations they found interesting and challenging with regard to the identification, screening and recruitment procedures.
In particular, the participants will be asked to describe, discuss and elaborate on the situations that they found interesting and challenging with regard to receiving the HAPPI intervention or usual care, the situation that they found interesting and challenging with regard to the completion of each of the questionnaires and the experience of participating in the trial

Intervention Type
Other

Primary outcome measure
1. Feasibility of the intervention, assessed using the following after 3 and 6 months:
1.1. Numbers of completed HAPPI intervention conversation guides and personalised care plan templates
1.2. Degree of contamination by number of staff moving between intervention and control practices
2. Feasibility of conducting the trial, assessed using the following after 3 and 6 months:
2.1. Number of GP practices expressing an interest in participating
2.2. Number of GP practices screened for selection and reasons for non-selection
2.3. Number of GP practices withdrawing from the study, timing and reason for withdrawal
2.4. Number of GP practices failing to progress through implementation milestones and reasons for failure
2.5. Number of GP practices withdrawing during the implementation and delivery phases
2.6. Numbers of participants screened as eligible, recruited, consented and followed up
2.7. Numbers of participants identified using the electronic frailty index (eFI)
2.8. Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up
3. Assessment of different potential and secondary outcomes of the future trial, assessed at the baseline and after 3 and 6 months:
3.1. Numbers of potential primary and secondary outcome measures completed
3.2. Numbers of missing items for each potential primary and secondary outcome
3.3. Estimation of the feasibility of collecting data to estimate cost-effectiveness (EQ-5D-5L, add-on for economic evaluation)
3.4. Assessment of the following outcome measure instruments:
3.4.1. Review of usual care practice, using a clinical note review of control participants
3.4.2. Level of care at home received measured by participant self-reporting
3.4.3. Polypharmacy – number of medications prescribed and participant perception of adverse effects
3.4.4. Number of falls measured by participant self-reporting
3.4.5. Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale
3.4.6. 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)
3.4.7. Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire
3.4.8. Mortality; date and cause of death obtained from the clinical record
3.4.9. Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record

Secondary outcome measures
Functional ability, assessed using the following at the baseline and after 3 and 6 months:
1. Barthel Index
2. 36-item Short Form Survey (SF-36)

Overall study start date
01/05/2018

Completion date

30/04/2021

Eligibility

Key inclusion criteria
1. Aged 65 years and over
2. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI >0.36)
3. Frailty confirmed by PRISMA7 instrument
4. Able to give informed consent
5. Living in own home or supported living accommodation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
56

Key exclusion criteria
1. Fit or mildly frail (eFI 0.13 – 0.24)
2. In receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy
3. Already on the caseload of a Community Matron

Date of first enrolment
01/12/2018

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cornwall Partnership NHS Foundation Trust
Head Office

Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
The Alverton Practice
7 Alverton Terrace
Penzance
United Kingdom
TR18 4JH

Study participating centre
Carn To Coast Health Centres
Station Road
Pool
United Kingdom
TR15 3DU

Study participating centre
St Austell Healthcare
1 Wheal Northey
St Austell
United Kingdom
PL25 3EF

Study participating centre
The Roseland Surgeries
Gerrans Hill Surgery
Portscatho
United Kingdom
TR2 5EE

Study participating centre
The Three Spires Medical Practice
Truro Health Park
Infirmary Hill

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United Kingdom
TR1 2JA

Study participating centre
The Clays Practice
Victoria Road
Roche
St Austell
United Kingdom
PL268JF

Sponsor information

Organisation
Plymouth University

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Sponsor type
University/education

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: ICA-CDRF-2016-02-018

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal in April 2022

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Chief Investigator, Helen Lyndon at helen.lyndon@plymouth.ac.uk. Individual participant data that underlie the results will be made available (following de-identification) on a controlled access basis, subject to data sharing agreements.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/11/2019	15/08/2022	Yes	No
Results article		31/03/2023	03/04/2023	Yes	No
HRA research summary			28/06/2023	No	No