ISRCTN12363970 https://doi.org/10.1186/ISRCTN12363970

Personalised care planning for older people with frailty

Submission date 17/09/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/11/2018	**Overall study status** Completed	
Last Edited 09/11/2022	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims

Frailty is a condition of increased vulnerability to major changes in health as a result of seemingly small problems, such as an infection or new medication. It is common in older age, affecting around 10% of people aged over 65, and develops because as we get older our bodies change and can lose their inbuilt reserves, for example we lose muscle strength. People with frailty are at increased risk of falls, disability, loneliness, hospitalisation and care home admission. These problems can reduce quality of life and are costly for the NHS and social care. PCP is designed to improve self-management skills and improve wellbeing of older people with the support of their community. It also aims to improve coordination of GP, voluntary sector and social care services and increase the social networks of older people with frailty.

This study aims to test if it is possible to run a large trial to see if PCP can improve the quality of life of older people with frailty and provide value for money.

Who can participate?

People whose GP surgery is taking part in the study and have been identified from their records as someone who would be suitable

What does the study involve?

Researchers will contact all participants and visit them in their homes to ask them to complete questionnaires about general health, quality of life and day-to-day activities. All participants will asked to be complete the same questionnaires 6 and 12 months later.

GP practices will be randomly allocated to either the intervention group or the control group. If participants attend a GP practice in the intervention group, they will be contacted by the Age UK team to take part in a personalised care planning programme. If their GP practice is in the control group, participants will receive care as usual.

What are the possible benefits and risks of participating?

We hope this study could improve quality of life for older people in the future, but cannot say whether they will definitely see an improvement. If participants' GP practice is chosen for the intervention group, they may benefit personally by having a personalised care plan. Participants agreeing to complete questionnaires will mean giving up some of their time to do this.

There are no known risks to participants taking part in this study.

Where is the study run from?
The study is run from the Bradford Teaching Hospitals NHS Foundation Trust and the Clinical Trials Research Unit at the University of Leeds, and will take place in 8 GP practices in Bradford City and District (UK)

When is the study starting and how long is it expected to run for?
October 2017 to December 2020

Who is funding the study?
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?
Dr Andrew Clegg
PROSPER@leeds.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Catriona Parker

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)113 3439241
Prosper@leeds.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
245645

Protocol serial number
39073

Study information

Scientific Title
PROSPER: A feasibility cluster randomised controlled trial of PeRsOnaliSed care Planning for oldER people with frailty

Acronym
PROSPER

Study objectives
Personalised care planning (PCP) improves the self-management skills of older people with frailty and reduces health and social care costs, compared to usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber – Bradford Leeds Research Ethics Committee, 18/10/2018, 18/YH/0294

Primary study design
Interventional

Study design
Randomised; Both; Design type: Treatment, Complex Intervention, Qualitative

Study type(s)
Treatment

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

Interventions
This study is a cluster randomised controlled trial to test the feasibility of conducting a larger scale definitive cluster randomised trial. The PCP intervention will be applied across a whole 'cluster' rather than to individual participants within a general practice. Therefore to allow us to compare the PCP intervention to usual care, we need to randomly assign the whole cluster (GP practice) to either the intervention or control group. We need a control group to help us check that any differences seen are not due to chance.
The study aims to recruit 400 participants from 8 GP practices (approx 50 per practice) within Leeds and Bradford over a planned 12 month recruitment period. Clusters (GP practices) will be randomised on a 1:1 basis by a statistician at the Clinical Trials Research Unit (CTRU).
We will send out expressions of interest (EoI) to all GP surgeries in Leeds and Bradford to ask if they would like further information on the study. Sites (GP practices) expressing an interest will be asked to provide more detailed information by completing a site questionnaire. Suitable sites will be selected by the CI and trial management group (TMG). Consent for randomisation, training, intervention delivery (if allocated) and supporting recruitment will be taken at the practice level.
Potential participants will be identified from pre-defined searches of electronic primary care records based on age (over 65) and electronic Frailty Index (eFI). This eligibility list will be screened by a practice GP to ensure all eligibility criteria are met and the numbers on the list before and after screening recorded.
GP practices will be randomised to the intervention arm or usual care (control) arm and the lead GP at each practice informed of the allocation. Practice staff will send out invitation packs (containing participant & carer invitations and information sheets, reply form and pre-paid envelope) to patients on the eligibility list in a phased approach. If the participant hasn't responded within 14 days, a member of CRN/research staff will contact them by phone to confirm if they wish to participate or not.
A member of the CRN team/local researcher (who will not be aware of the allocated arm) will contact patients who indicated they would like to take part by telephone, to arrange a visit in their home to discuss the study further. If they are still willing to take part, the CRN/local

researcher will obtain written informed consent for data collection and linkage and complete a screening test to confirm eligibility to take part. If a participant is confirmed as eligible, the CRN /local researcher will ask some additional questions as part of baseline assessments. The CRN /local researcher will also ask the participant to identify a carer, if available, and obtain consent and collect some baseline assessments from the carer. There may be participants who are not able to consent for themselves. If the CRN/local researcher will assess if this is the case. If they cannot consent themselves, we will endeavour to use a consultee where possible. This could be a close friend or relative of the patient. Baseline data collection will involve the collection of the following demographics, contact details, living and carer arrangements, and questionnaires on healthcare resource use, self-management, health, quality of life, daily living, depression and loneliness. Carers will be asked to complete a questionnaire on quality of life.
For those clusters (practices) randomised to the PCP intervention, participants will be offered a PCP service from a trained Personal Independence Coordination (PIC) team from Age UK. PCP is planned to last for approximately 12 weeks, but this could be from 8 to 16 weeks depending on individual needs. The PIC team will meet with the participant in their own home and also have telephone/email contact.
Those clusters randomised to the control arm of the study will continue to deliver Treatment as Usual to patients.
Data will be collected from each participating site prior to recruitment, approximately halfway through recruitment and at the end of the intervention period to capture; site demographics, staffing and details regarding care offered to these patients. This will allow care in the control (usual care) arm to be described.
All participants and carers (regardless of intervention or control arm) will be sent a questionnaire booklet at 6 months and 12 months following baseline assessment. This data will be self-reported, with participants/carers either completing postal questionnaires, telephone assessments or completing questionnaires with local researcher support, dependent upon the participant's abilities.
Multiple sources of electronic health records will be accessed for this study. Participants will be specifically asked if they consent to allow access to their electronic health records and linkage to study data for this purpose. Data sources include health episodes statistics (HES) and death data from NHS Digital, and primary care data (e.g. medication, contacts) from GP data systems or Connected Health Cities type projects.
To help further understand how the intervention works in practice, researchers will also be observing delivery of the intervention, and performing interviews with staff, participants, and their carers in a sample of willing participants. This is called an embedded process evaluation.

Intervention Type
Other

Primary outcome(s)
Feasibility of the trial - a progression check 12 months after starting recruitment:
1. Recruitment, assessed by the mean number of participants registered per site at 12 months post-recruitment
2. Intervention delivery - the percentage of participants in the intervention arm receiving at least 2 intervention visits, assessed using case report form (CRF) return at 12 months post-recruitment
3. Follow-up - the percentage of participants returning a completed SF36 questionnaire 6 months post-registration

Key secondary outcome(s)
Feasibility of the trial, assessed 12 months post-recruitment using the following information:
1. Number of general practices expressing an interest in participating, number of practices

completing a site feasibility questionnaire (SFQ), method of initial contact and reasons for not returning SFQ
2. Number (%) of general practices screened, identified as eligible, and randomised, and reasons for non-selection
3. Number (%) of general practices completing the trial
4. Number (%) of and timing of general practice withdrawals from follow-up, reasons for withdrawal
5. Establish the extent to which blinding of practice staff and researchers to allocation can be maintained.
6. Number of patients screened for eligibility and number excluded
7. Number (%) of eligible participants consenting to participation in the trial
8. Number (%) of registered patients completing the trial
9. Number (%) of and timing of patient withdrawals and losses to follow-up, reasons for withdrawal
10. Mean and variability of self-reported patient outcome measures at baseline and 12 months
11. Mean and variability of SF-36 PCS and MCS scores and the corresponding derived SF-12 scores, the proposed primary outcome for the definitive RCT.
12. Clustering effect (ICC – intracluster correlation coefficient) and 95% CI relating to SF-36/SF-12
13. Difference (and 95% CI) in self-reported patient outcomes at 12 months between arms
14. Establishment of processes for successful collection of routine data, in particular primary care resource data, secondary care HES data and mortality data
15. Number (%) of participants with self-reported outcome data at each time point
16. Number (%) of participants for whom it was possible to collect routine data
17. Completion levels of self-reported questionnaires at each time point
18. Method used to collect on health resource use including primary care contacts, A&E attendances, unplanned admissions, hospital bed days, reason(s) for admission, outpatient attendances, care home admission, medications
19. Method used to collect mortality

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Patients
1. Aged 65 years or older
2. eFI (Electronic Frailty Index) score of 0.21 or above

GP Practice
1. Use any of the following electronic health care record systems: SystmOne, EMIS, Vision, Microtest
2. Within a reasonable geographical area to allow intervention team supervision
3. Have the structure and resources necessary and willing to deliver the intervention (eg MDT type meetings every 4-6 weeks)
4. Not have an existing or planned personalised care planning service with an element of targeting older people with frailty

Carers
1. Participant or their consultee has consented to the carer's involvement in the study
2. Has capacity to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
343

Key exclusion criteria
Participant:
1. Care home resident at the time of screening
2. Registered on the gold standards framework
3. Severe dementia (Montreal Cognitive Assessment score <10)

GP Practice:
1. Existing PCP service with an element of targeting older people with frailty and some overlap with Age UK model framework
2. Plans to implement a PCP service with an element of targeting older people with frailty and some overlap with Age UK model framework during the study recruitment period.

Carer:
1. Lacks capacity to provide informed consent

Date of first enrolment
21/01/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Leeds
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0216-20003

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention,

usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/04/2020	15/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	cost analysis	08/05/2021	11/05/2021	Yes	No
Other publications	process evaluation	16/09/2022	09/11/2022	Yes	No