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Does personalised care planning improve the quality of life of older people with frailty and is it cost-effective?

Submission date 18/08/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/08/2020	**Overall study status** Completed	
Last Edited 20/03/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Frailty is a condition that affects one in ten people over the age of 65 and can mean they are at higher risk of falls, disability, hospital and care home admission and poorer quality of life. As the population ages, frailty also impacts on health and social care services. Care for older adults should be proactive and person-centred rather than focused on different diseases and personalised care planning or PCP is one way to deliver person-centred care. Researchers have developed a PCP intervention called PROSPER that aims to improve the quality of life of older adults with frailty and also reduce the burden on health and social care systems.

Who can participate?
People aged 65 or older and identified as having some signs of frailty by their GP records

What does the study involve?
A researcher will visit participants in their own home to describe the trial and answer any questions. If people are happy to take part the researchers will ask them to fill in some questionnaires about their quality of life. Participants will then be randomly divided into two groups – intervention and usual care. Participants in the intervention group will be contacted by a Personal Independence Coordinator from Age UK who will work with them for 12 weeks to help improve their wellbeing and self-management skills. Participants in the usual care group will carry on as normal. Everyone will be asked to complete the questionnaires again at 6 and 12 months after they started the study.

What are the possible benefits and risks of participating?
Participants in the intervention group may experience improved physical and mental health.

Where is the study run from?
The study is run by researchers from the Academic Unit of Ageing & Stroke Research at the Bradford Institute for Health Research and the Clinical Trials Research Unit at the University of Leeds

When is the study starting and how long is it expected to run for?
September 2019 to October 2025

Who is funding the study?
National Institute for Health Research Programme Grant for Applied Research (UK)

Who is the main contact?
The study team can be contacted via PROSPER@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Integrated Research Application System (IRAS)
270305

Central Portfolio Management System (CPMS)
43820

Study information

Scientific Title
PROSPER: A definitive, multi-site, individually randomised controlled trial of PeRsOnaliSed care Planning for oldER people with frailty

Acronym
PROSPER Definitive v1.0

Study objectives
Personalised care planning (PCP) improves the quality of life of older people with frailty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/05/2020, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8083; bradfordleeds.rec@hra.nhs.uk), REC ref: 20/YH/0108

Primary study design
Interventional

Study design
Interventional randomized controlled trial with embedded qualitative evaluation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Older people with frailty

Interventions
The study is a multi-centre, individually randomised trial with clustering in the intervention arm. The researchers will aim to recruit 1337 older people with frailty from general practices across five localities in England over a period of 15 months. Potential participants will be identified by practice staff from primary care records according to pre-defined inclusion and exclusion criteria using bespoke electronic searches. Practice staff will send a letter of invitation for trial participation along with a participant information sheet to all eligible participants identified through the search. Participants will be requested to indicate their willingness to be involved in the study via a reply form returned via post to the research teams or via telephone. The local research team will visit willing participants at their own home to seek written informed consent and collection of baseline data.

Following consent and baseline data collection, an automated system will be used to randomly allocated to participants to either the usual care or PROSPER intervention. The PROSPER intervention is a 12-week tailored intervention delivered within a participant's home by a trained Age UK delivery team around an individual's personal priorities and predicaments within a socially-orientated model of care. Age UK workers will deliver the intervention to several participants and therefore the study has a partially nested hierarchical design resulting in clustering within the intervention arm.

As part of the study, the researchers will define usual care as "the wide range of care that is provided in a community whether it is adequate or not, without a normative judgement", and will be available to all study participants including those in the intervention arm. To increase external validity and relevance of the study findings the researchers plan to use an unrestricted usual care approach, whereby the protocol does not restrict access to usual care. Use of services will be recorded at baseline and at follow-up assessments in both intervention and control arms.

To help further understand the implementation of the intervention and usual care, researchers will also be observing the 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.

Follow-up data will be collected from all participants at 6 and 12 months following randomisation. This data will be self-reported, with participants either completing postal questionnaires, telephone assessments, or completing questionnaires with researcher support, dependent upon the participant's abilities. Researchers will also collect additional data regarding the participant's safety (e.g. hospital admissions), and health and social care resource use (i.e. primary/secondary care) from the participant's electronic health records. Researchers collecting follow-up data will be unaware of the participant's allocation (blind) and will be asked to document if they become aware of the participant's allocation during the study.

Intervention Type
Other

Primary outcome(s)
Health-related quality of life measured using the Physical Component Summary (PCS) and Mental Component Summary (MCS) of the Short-Form 12 item Health Questionnaire (SF12) at 12 months post-randomisation

Key secondary outcome(s)
1. Basic and instrumental activities of daily living, measured using the Nottingham Extended Activities of Daily Living Scale (NEADL) at 12 months post-randomisation
2. Admissions to care homes and overall health and social care resource use, measured by participant-reported and routine data derived resource use at 12 months post-randomisation
3. Cost-effectiveness measured using decision analytical cost-effectiveness model at 12 months post-randomisation
4. Generalisability of PCP across the wider NHS measured using a mixed-methods process evaluation at 3 months post-randomisation:
4.1. Assessment of intervention fidelity by examining training & skill acquisition, intervention delivery, content of care sessions, receipt and enactment using observations, qualitative interviews and quantitative data
4.2. Process of implementation within the service context explored using a combination of qualitative observations, semi-structured interviews and documentary analysis

Completion date
08/10/2025

Eligibility

Key inclusion criteria
1. eFI score of 0.21 or above
2. Aged 65 years or over
3. Willing and able to give informed consent (or personal consultee if lack capacity)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
1337

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

Date of first enrolment
01/01/2021

Date of final enrolment
27/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: Yorkshire and Humber
-
-
England
S10 2SB

Study participating centre
NIHR CRN: North West Coast
-
-
England
L7 8XP

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
Current IPD sharing statement as of 16/08/2022:
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.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from CTRU-DataAccess@leeds.ac.uk. Data will be shared according to a controlled-access approach. Data will only be shared for participants who have given consent to the use of their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/01/2025	04/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		08/10/2022	10/10/2022	Yes	No