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The Yorkshire & Humber community ageing research study

Submission date
26/02/2015

Recruitment status
No longer recruiting

Registration date
06/05/2015

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
People in the UK are living longer but, although some people remain very healthy in later life, others can develop health problems and eventually become frail. The purpose of our study is to investigate health in older age, and the reasons why some people remain fit and others experience poor health and frailty. 'Frailty' is a medical term used to describe a decline in a person's body. People with frailty often have weak muscles, walk slowly and get exhausted very easily. Some people are better able to cope with these changes, but we don't know why. We would like to work with a group of older people to understand how health problems and frailty might develop over time. We plan to recruit a 1000 people, some will be fit and others might have frailty. We hope that the information we collect will help us develop and test future treatments aimed at maintaining health and independence in older age.

Who can participate?
GPs will select patients over 75 based on a range of health conditions recorded in their notes. This is to help us find individuals who are fitter in older age, as well as those who might be in poor health or have frailty. Patients will be sent an invitation letter if they meet the criteria. And, if they agree, will be visited at home by a specialist elderly care researcher from Bradford Royal Infirmary. The researcher will explain the study and there will be an opportunity to ask questions.

What does the study involve?
Participants in the research will be asked some questions about their health, wellbeing and family circumstances. They will also be asked to undergo some simple physical assessments and measurements and to provide a sample of blood. All of the assessments will take place in an individual's home at a convenient time for them. The information participants provide will help us to understand the ageing process better. This will enable us to develop more appropriate treatments and services in the future. It will also be used as a comparison for data collected in future studies. Information provided may also be linked to information from other existing and future sources (data linkage). Blood samples will be stored in a 'bio-bank' for future use by ethically approved studies. All information about individuals collected during the research will be held in accordance with the Data Protection Act and Human Tissue Authority regulations

What are the potential benefits and risks of participating?
There are no direct benefits to participants. However, individuals may benefit from earlier detection of unmet needs through the assessments. Participants will also be helping to develop more appropriate health and social care services for all older people in the future. These assessments have been carried out on lots of older people before. However, participants may experience some discomfort or become tired. In this case we would stop the assessments at their request.

Where is the study run from?
This study is organised and run by the Academic Unit of Elderly Care and Rehabilitation at Bradford Teaching Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
January 2014 to December 2018

Who is funding the study?
The study is funded by the National Institute for Health Research – Yorkshire and Humber Collaboration for Leadership in Applied Health Research and Care

Who is the main contact?
If you have any questions or comments you can speak with the project manager Anne Heaven on 01274 382815.

Contact information

Type(s)
Public

Contact name
Dr Lesley Brown

Contact details
Academic Unit of Elderly Care & Rehabilitation
Temple Bank House
Bradford Royal Infirmary
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 383906
Lesley.brown@bthft.nhs.uk

Type(s)
Scientific

Contact name
Dr Andrew Clegg

Contact details
Academic Unit of Elderly Care and Rehabilitation
University of Leeds

Bradford Institute of Health Research
Temple Bank House
Bradford Royal Infirmary
Bradford
United Kingdom
BD9 6RJ
01274 38 3440
andrew.clegg@bthft.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ReDA 1735

Study information

Scientific Title
The Yorkshire & Humber Community Ageing Research (CARE) observational cohort Study

Acronym
CARE75+

Study objectives
Frailty is a state of vulnerability to poor resolution of homeostasis after a stressor event. It is the result of cumulative physiological decline in multiple organ systems and is associated with increased risk of a range of adverse outcomes, including admission to hospital, long-term care residence and mortality. A seemingly small insult experienced by an older person with frailty, for example a minor infection, new medication, or minor surgery, can result in a striking and disproportionate change in health status - i.e. from independent to dependent; lucid to delirious; mobile to immobile or falling. These are the common presentations of older people with frailty to secondary care, and identify those who are likely to take longer to recover from an acute illness and have future care needs.

The existing healthcare response to frailty is predominantly reactive and secondary care based. Frailty is a dynamic process that is incompletely understood but transition to a worse level of frailty is more common than improvement. Improved management of frailty requires an integrated approach spanning primary care, secondary care and social services that incorporates consideration of frailty transitions. Improved integrated pathways of care should include evidence based interventions where possible but, currently, there is only limited evidence available from clinical trials. One reason for this is that recruitment of older people with frailty to clinical trials has been disappointing. The cohort multiple randomised controlled trial (cmRCT) is an innovative trial design that has potential to enhance participation of frail older people in clinical trials and increase capacity to conduct high quality frailty research.

Here, the observational cohort (pilot) stage of the study is described, where we will establish a cohort (group) of around 1000 frail older people recruited from GP practices in the Yorkshire and Humber region. We will follow these people for up to four years and assess various health and social outcomes. Information gathered from the cohort observational stage will be used to identify eligible participants for the randomized controlled trial stage of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bradford/Leeds Research Ethics Committee, 10/10/2014, ref: 14/YH/1120

Study design
The cmRCT design has several key features: an observational cohort is established and used as a multiple trials facility; each RCT uses random selection of some (not all) patients; patient centred information and consent is applied. The process aims to replicate that in real world routine health care by taking informed consent only from those randomised to receive an intervention, as the on-going cohort study provides a natural control group.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Older people (>75 years) with and without frailty

Interventions
There are no interventions in this observational study.
Community dwelling older people (aged 75 years and over) will be eligible for the CARE study. We have developed and validated an electronic frailty index (eFI) that uses existing GP patient data to identify and severity grade frailty (mild, moderate, severe). For the pilot phase we will use the eFI to identify potential participants who are fit and those with mild, moderate and severe frailty. Following the pilot phase we will limit recruitment to those with mild, moderate and severe frailty.
We will conduct a number of assessments both physical and psychosocial. We will test hearing and visual acuity, grip strength and mobility. We will investigate formal and informal support networks and assess loneliness, depression, resilience and self-efficacy. We will also assess pain, activities of daily living and quality of life. We will record falls and hospital admissions and make an assessment of frailty using both deficit and phenotype models. We will also record height, weight and body mass index, co-morbidities and medications (prescribed and non-prescribed)

along with smoking, drinking and sleeping habits. Finally, we will collect approximately 30ml of blood. We will record full blood count results and store remaining aliquots in a bio-bank for future analysis.

Intervention Type
Not Specified

Primary outcome measure
The minimum dataset required for the CARE study has been established on the basis of expert consensus, with due consideration of the cmRCT design and the range of primary outcomes required for future trials. For primary outcomes, we have therefore included:
1. Basic activities of daily living (ADL) (Barthel index)
2. Instrumental ADL (Notting Extended Activities of Daily Living)
3. Frailty (measured using phenotype model & cumulative deficit model)
4. Health-related quality of life (EQ5D)
5. General health (SF36)
6. Pain (geriatric pain measure)
7. Depression (geriatric depression scale)
8. Loneliness (de Jong Gierveld loneliness scale)

All assessments will be undertaken at baseline (timepoint 1), 6 months (time point 2), 12 months (timepoint 3), 24 months (timepoint 4), 48 months (timepoint 5).

Secondary outcome measures
1. Health and social care resource use
2. Care home admission
3. Mortality
4. Cognition (Montreal Cognitive Assessment)
5. Hand grip strength assessment
6. Gait speed
7. Timed Up and Go test
8. Falls (self-report)

All assessments will be undertaken at baseline (timepoint 1), 6 months (time point 2), 12 months (timepoint 3), 24 months (timepoint 4), 48 months (timepoint 5).

Overall study start date
01/01/2014

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 03/05/2018:
1. Aged 75 years or older
2. Live in community
3. Identified as fit and or with mild, moderate and severe frailty (for pilot phase and main study)

Previous inclusion criteria:
1. Aged 75 years or older
2. Live in community
3. Identified as fit and or with mild, moderate and severe frailty (for pilot phase)
4. Mild, moderate and severe frailty (for main study)
The first 200 participants will be older people (>75 years) with and without frailty. The next 800 participants will be older people (>75 years) with frailty.

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
1000

Total final enrolment
353

Key exclusion criteria
1. Care home residents and people living at home who are bedbound
2. People with terminal cancer,
3. Those in receipt of the Amber Care Bundle (estimated life expectancy of three months or less)
4. People in receipt of palliative care services will also be excluded.

Note – if participants go into a care home/nursing home after they have undertaken their initial baseline assessment, they will not be excluded and can continue if they are still willing to do so.

Date of first enrolment
30/12/2014

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Westcliffe Medical Centre
Westcliffe Road

Shipley
West Yorkshire
Bradford
United Kingdom
BD18 3EE

Study participating centre
Tong Medical Practice
2 Procter St
Tong
Bradford
United Kingdom
BD4 9QA

Study participating centre
Saltaire Medical Practice
Richmond Road
Shipley
Bradford
United Kingdom
BD18 4RX

Study participating centre
Picton Medical Centre
Westbourne Green HCC
Manningham
Bradford
United Kingdom
BD8 8RA

Sponsor information

Organisation
Bradford Teaching Hospitals Foundation Trust

Sponsor details
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor type

Research organisation

Website
http://www.bradfordresearch.nhs.uk

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Both the process and results of the study will be disseminated using a variety of pathways including but limited to:
1. Publication in peer reviewed journals e.g. BioMed TrialsJournal, Age and Ageing
2. Website case studies e.g. NIHR CLAHRC
3. Publication in lay journals e.g. Age UK VOICE, practice newsletters
4. Posters and presentations at local, national and international conferences e.g. Health
5. Service Research Network Symposium 2015
6. Lay forums e.g Bradford Local Authority Older People's Focus Group

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/03/2019	23/03/2020	Yes	No
Results article	results	01/01/2019	25/02/2021	Yes	No
Other publications		30/08/2016	14/06/2023	Yes	No
Results article		22/11/2021	14/06/2023	Yes	No
Results article		15/12/2020	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Predictors of independence in older people: A longitudinal, population-based study using the CARE75+cohort	28/04/2025	10/06/2025	Yes	No