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The effectiveness of a new intervention for older people living with frailty

Submission date	Recruitment status	[_] Prospectively registered
29/07/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2023	Other	

Plain English summary of protocol

Background and study aims
The number of older people is increasing and this is leading to a rise in the number of people living with multiple illnesses at the same time. Some symptoms and concerns are particularly neglected in this population, such as breathlessness (which frequently leads to admission to hospital), unintentional weight loss (which increases frailty), pain medicines use and possible adverse effects. A new service has been developed in Hull to redesign care of older frail people, through a new Integrated Care Centre and within care homes. This is because current care pathways are not always the optimal way to deliver care to older people with multiple illnesses. However, this new service needs evaluation to find out if it improves the well-being and health status of older people or not. This study will assess the effectiveness of this new service.

Who can participate?
People aged 65 years and above identified to be at risk of severe frailty

What does the study involve?
The researchers will compare the health status and quality of life of people receiving the new service with a matched group not receiving the service. They will assess if health status and quality of life are better in those with the new service or not.

What are the possible benefits and risks of participating?
It is unlikely that there will be any direct personal benefit in taking part. However, the information provided will help decide if overall health and well-being have been improved by using this new service and give the researchers ways to improve this service in the future. There is no significant risk in taking part, other than the time the study will take.

Where is the study run from?
University of Hull (UK)

When is the study starting and how long is it expected to run for?
October 2018 to December 2022

Who is funding the study?
University of Hull (UK)

Who is the main contact?
Prof. Fliss Murtagh, fliss.murtagh@hyms.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
250981

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 250981

Study information

Scientific Title
A non-randomised controlled study to assess the effectiveness of a new proactive multidisciplinary care intervention for older people living with frailty

Study objectives
A new, anticipatory, multidisciplinary care service is effective at improving the wellbeing and quality of life (QoL) of older people living with severe frailty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048 088; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 18/YH/0470

Study design
Community-based non-randomized controlled study

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
The new, anticipatory, multidisciplinary care service includes interventions by a multidisciplinary team of geriatricians, nurse practitioners, general practitioners with an extended role in frailty care, pharmacists, occupational therapists, physiotherapists, social workers, clinical support workers, carers' support, and volunteers.

The intervention provided by this new service consists of individually-tailored assessments during a single appointment, taking approximately 3-5 hours. Assessments are based on the individual's comprehensive geriatric assessment and individualised care needs. All participants receive personalised care planning, physical health review, assessment of psychological wellbeing/mental health, medication review, social needs review, and functional/therapy review. Participants are also encouraged to discuss the ReSPECT (Recommended Summary Plan for Emergency Care and Treatment) form, a tool completed by professionals to promote advance care planning and individualised recommendations for a person's future clinical treatment.

Intervention Type
Other

Primary outcome(s)
Wellbeing measured by the Integrated Palliative care Outcome Scale (IPOS) at baseline, 2-4 weeks, and 10-14 weeks

Key secondary outcome(s))
Quality of life measured by EQ-5D-5L at baseline, 2-4 weeks, and 10-14 weeks

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Aged 65 years and above
2. Identified to be at risk of severe frailty (electronic Frailty Index [eFI score ≥0.36])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
253

Key exclusion criteria
1. Aged less than 65 years
2. Electronic Frailty Index <0.36
3. Unable to consent

Date of first enrolment
01/04/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Jean Bishop Integrated Care Centre
63-69 David Lister Drive
Hull
United Kingdom
HU9 2BL

Sponsor information

Organisation
University of Hull

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
University/education

Funder Name
University of Hull

Alternative Name(s)
HU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
It is not expected that participant-level data would be made public due to confidentiality. However, The University of Hull will keep identifiable information about participants for 10 years after the study has finished.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Primary results	05/01/2023	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 3	08/01/2019	29/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes