

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

<b>Submission date</b> 29/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/01/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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

**Study website**

<https://www.hyms.ac.uk/research/research-centres-and-groups/wolfson/pace>

## Contact information

**Type(s)**

Principal Investigator

**Contact name**

Prof Fliss Murtagh

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

250981

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Community

**Study type(s)**

Quality of life

**Participant information sheet**

See trial outputs table

**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 measure**

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

**Secondary outcome measures**

Quality of life measured by EQ-5D-5L at baseline, 2-4 weeks, and 10-14 weeks

**Overall study start date**

01/10/2018

**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  $\geq 0.36$ ])

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

The clinical minimally important difference in the primary outcome (IPOS total score) is 4.8, with the mean (SD) for the baseline IPOS of 27.4 (9.3) (IPOS validation study; personal communication, Ramsenthaler, 2018). To achieve 90% power at 5% significance level, 80 patients in each group are therefore required. Allowing for 50% attrition at the 2-4 week follow-up, the sample size is inflated to 160 per group.

**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**

England

United Kingdom

**Study participating centre**

**Jean Bishop Integrated Care Centre**

63-69 David Lister Drive

Hull

United Kingdom

HU9 2BL

**Sponsor information****Organisation**

University of Hull

**Sponsor details**

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United Kingdom

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**Sponsor type**

University/education

**Website**

<http://www2.hull.ac.uk/>

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/01/2023

**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?
<a href="#">Participant information sheet</a>	version 3	08/01/2019	29/07/2022	No	Yes
<a href="#">Results article</a>	Primary results	05/01/2023	09/01/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No