

# A frailty care bundle to improve mobilisation (walking), nutrition and distraction activities for older people during an acute hospital stay

<b>Submission date</b> 26/09/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/09/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Older people admitted to acute care hospitals are more likely to experience a decline in physical function (ability to walk) due to inactivity (sitting in a bed or chair) and or sub-optimal food and fluid intake - this is termed hospital-associated decline. The patient may also experience brain fuzziness and poor concentration due to a lack of cognitive (mind) stimulation and orientation. Patients who experience trauma such as a hip fracture are at very high risk of decline. The study aimed to reduce the risk of a decline in physical and cognitive function by increasing patients' opportunity to walk more, eat food rich in protein and engage in distraction activities to stimulate the mind.

### Who can participate?

The study will be undertaken in four acute trauma and rehabilitation wards and four medical wards. All patients aged 65 years old and over in the participating acute trauma wards will be eligible to receive the intervention. A subset of patients who could provide written consent will be recruited for the evaluation. All nursing staff working in the participating wards will be included in the study.

### What does the study involve?

The evaluation used a pre (baseline)- post-intervention design. The main outcome of interest was the patient's physical function.

Nursing staff received education on strategies to prioritise patient mobilisation, nutrition and cognitive engagement above competing demands on nursing times. This included a) setting an individual patient mobility (walking) goal, assisting patients during meal times, providing extra snacks for patients, providing distraction resources, providing a patient information leaflet, audit and feedback on patient mobilisation and nutrition intake.

### What are the possible benefits and risks of participating?

There is more nursing attention on fundamental care including encouraging and assisting patients to walk and eat. Patients have access to distraction resources (colouring books, puzzles, and crosswords). Participants will be more likely to maintain or regain their physical function and

are better able to maintain independence once they return home. There was minimal additional risk above routine hospital care associated with participating in the study intervention for patients or staff. The study aimed to improve evidence-based standards in care on mobilisation, nutrition and cognitive engagement for older people. While staff participation in the intervention (education, use of goal setting, and supporting patient cognition) was encouraged as part of normalized principles of good fundamental care, staff ultimately could decide not to engage. There was a risk of research-associated fatigue in answering questions or completing surveys. Participation in all evaluation activities was voluntary. Staff and patients could withdraw at any time without providing a reason.

Where is the study run from?

The School of Nursing and Midwifery University College Cork (Ireland)

When is the study starting and how long is it expected to run for?

January 2019 to July 2022 (the trial was extended by 1 year due to COVID-19 pandemic disruption)

Who is funding the study?

Health Research Board (HRB) (Ireland)

Who is the main contact?

Professor Corina Naughton

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## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Corina Naughton

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

Implementation of the Frailty Care Bundle (FCB) to promote mobilisation, nutrition and cognitive engagement in older people in acute care settings

**Acronym**

FCB

**Study objectives**

Implementation of the Frailty Care Bundle will reduce the risk of functional decline by increasing older patients' mobilisation, nutrition intake and cognitive engagement in acute care settings

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 12/11/2019, Clinical Research Ethics Committee of the Cork Teaching Hospitals (University College Cork, Lancaster Hall, 6 Little Hanover Street, Cork, Ireland; +353-21-4901901; crec@ucc.ie), ref: ECM3 12/11/2019

**Study design**

Multicentre interventional pre-post study design

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Prevention of functional decline in older patients during hospitalisation

**Interventions**

The Frailty Care Bundle (FCB) is a multi-component behaviour change intervention aimed at nursing and the wider multidisciplinary team. All hospital wards in the study received the intervention, there were no control wards. The intervention involved a clinical facilitator working with ward staff to deliver staff education, set patient mobility goals, introduce a patient mobility board to aid nursing and physiotherapy communication on mobility, promote assisted mealtimes, provide extra snacks, and provide distraction resources.

All patients on the ward were eligible to receive the intervention delivered by ward staff, and a subset of patients who provided informed written consent were recruited for the evaluation.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Patient physical function measured using the modified Bartel Index at baseline (pre-hospital admission), enrollment to study, hospital discharge and 6-8 weeks following hospital discharge

### **Key secondary outcome(s)**

1. Patients' average daily step count was measured using an accelerometer The Step Watch Activity Monitor (SAM), over 3-4 days on enrollment and into the study during hospitalisation
2. Gait speed-measured using a 4-metre walking test at enrollment to study and hospital discharge
2. Hand-grip strength measured using Jamar Dynamometer at enrollment to study and hospital discharge
3. Appetite measured using the simple nutrition assessment questionnaire (SNAQ) at enrollment to study, hospital discharge and 6-8 weeks follow-up
4. Quality of life measured using EQ-5D Visual Analogue Scale (EuroQol Group 2009) at enrollment to study and 6-8 weeks follow-up

Staff outcome measures in a pre-post staff survey

5. Attitude to mobilisation measured using Barriers to Mobilisation (Hoyer et al 2015)
6. Attitudes to nutrition measured using a bespoke instrument pre-post intervention
7. Intervention acceptability, perceived improvement in mobilisation, nutrition, and cognitive activity measured using a bespoke instrument post-intervention staff survey

### **Completion date**

31/07/2022

## **Eligibility**

### **Key inclusion criteria**

1. Aged 65 years old and over (age limit was reduced to 60 years to increase the pool of patients for recruitment)
2. Medically stable and able to sit out of bed
3. Eligible to be mobilised by nursing staff based on physiotherapy or nursing assessment
4. Mobile prior to admission (able to walk across a medium-size room (e.g. 3-4 meters, +/-walking aid) in the two weeks prior to admission)
5. Able to provide written informed consent (no significant cognitive impairment or delirium as measured by 4-AT or recorded in medical notes)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Lower age limit**

60 years

### **Sex**

All

## **Total final enrolment**

120

## **Key exclusion criteria**

1. Unable to mobilise with assistance prior to admission
2. Can only be mobilised by a physiotherapist
3. Patients on end-of-life or palliative pathway
4. Patients who cannot provide informed consent to participate

## **Date of first enrolment**

20/11/2019

## **Date of final enrolment**

30/01/2022

## **Locations**

### **Countries of recruitment**

Ireland

### **Study participating centre**

#### **Cork University Hospital**

Wilton

Cork

Ireland

T12 EC8P

### **Study participating centre**

#### **South Infirmary-Victoria University Hospital**

Hibernian Road

Cork

Ireland

T12 V0HD

### **Study participating centre**

#### **Mallow General Hospital**

Kilnockin

Mallow

Co Cork

Ireland

P51 N288

## **Sponsor information**

## Organisation

Health Research Board

## ROR

<https://ror.org/003hb2249>

## Organisation

South/SouthWest Hospital Group

# Funder(s)

## Funder type

Government

## Funder Name

Health Research Board

## Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Ireland

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/03/2024	11/03/2024	Yes	No

<a href="#">Protocol article</a>		11/01/2022	27/09/2022	Yes	No
<a href="#">Other publications</a>	Economic cost analysis	01/09/2024	04/09/2024	Yes	No
<a href="#">Participant information sheet</a>	version 1.3	12/10/2019	03/10/2022	No	Yes
<a href="#">Participant information sheet</a>	version 1.3	12/10/2019	03/10/2022	No	Yes