ISRCTN15145850 https://doi.org/10.1186/ISRCTN15145850

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

Submission date
26/09/2022

Recruitment status
No longer recruiting

Registration date
03/10/2022

Overall study status
Completed

Last Edited
04/09/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 sup-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
corina.naughton@ucc.ie

Contact information

Type(s)
Principal investigator

Contact name
Prof Corina Naughton

ORCID ID
https://orcid.org/0000-0001-8360-064X

Contact details
School of Nursing and Midwifery
College of Medicine and Health
Brookfield Health Sciences Complex
Cork
Ireland
T12 AK54
+353 214901551
corina.naughton@ucc.ie

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
Kilknockin
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?
Results article		01/03/2024	11/03/2024	Yes	No
Protocol article		11/01/2022	27/09/2022	Yes	No
Other publications	Economic cost analysis	01/09/2024	04/09/2024	Yes	No
Participant information sheet	version 1.3	12/10/2019	03/10/2022	No	Yes
Participant information sheet	version 1.3	12/10/2019	03/10/2022	No	Yes