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Title	Implementation of the Frailty Care Bundle (FCB) to promote mobilisation, nutrition and cognitive engagement in older people in acute care settings: protocol for an implementation science study [version 1; peer review: 1 approved]
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Publication date	2022-01-11
Original Citation	Naughton, C., Cummins, H., de Foubert, M., Barry, F., McCullagh, R., Wills, T., Skelton, D. A., Dahly, D., Palmer, B., Murphy, A., McHugh, S., O'Mahony, D., Tedesco, S. and O'Sullivan, B. (2022) 'Implementation of the Frailty Care Bundle (FCB) to promote mobilisation, nutrition and cognitive engagement in older people in acute care settings: protocol for an implementation science study [version 1; peer review: 1 approved]', HRB Open Research 2022, 5:3, pp. 1-19. doi: 10.12688/hrbopenres.13473.1
Type of publication	Article (peer-reviewed)
Link to publisher's version	10.12688/hrbopenres.13473.1
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Item downloaded from	https://hdl.handle.net/10468/13532



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STUDY PROTOCOL

Implementation of the Frailty Care Bundle (FCB) to promote mobilisation, nutrition and cognitive engagement in older people in acute care settings: protocol for an implementation science study [version 1; peer review: 1 approved]

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v1 **First published:** 11 Jan 2022, **5**:3
https://doi.org/10.12688/hrbopenres.13473.1
Latest published: 11 Jan 2022, **5**:3
https://doi.org/10.12688/hrbopenres.13473.1

Abstract

Background: Older people are among the most vulnerable patients in acute care hospitals. The hospitalisation process can result in newly acquired functional or cognitive deficits termed hospital associated decline (HAD). Prioritising fundamental care including mobilisation, nutrition, and cognitive engagement can reduce HAD risk.
Aim: The Frailty Care Bundle (FCB) intervention aims to implement and evaluate evidence-based principles on early mobilisation, enhanced nutrition and increased cognitive engagement to prevent functional decline and HAD in older patients.
Methods: A hybrid implementation science study will use a pragmatic prospective cohort design with a pre-post mixed methods evaluation to test the effect of the FCB on patient, staff, and health service outcomes. The evaluation will include a description of the implementation process, intervention adaptations, and economic costs analysis. The protocol follows the Standards for Reporting Implementation Studies (StaRI).
The intervention design and implementation strategy will utilise the behaviour change theory COM-B (capability, motivation, opportunity)

Open Peer Review

Approval Status ✓

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version 1 11 Jan 2022	✓ view

1. **Roman Romero-Ortuno**, Trinity College Dublin, Dublin, Ireland

Any reports and responses or comments on the article can be found at the end of the article.

and the Promoting Action on Research Implementation in Health Services (i-PARIHS). A clinical facilitator will use a co-production approach with staff. All patients will receive care as normal, the intervention is delivered at ward level and focuses on nurses and health care assistants (HCA) normative clinical practices.
The intervention will be delivered in three hospitals on six wards including rehabilitation, acute trauma, medical and older adult wards.
Evaluation: The evaluation will recruit a volunteer sample of 180 patients aged 65 years or older (pre 90; post 90 patients). The primary outcomes are measures of functional status (modified Barthel Index (MBI)) and mobilisation measured as average daily step count using accelerometers. Process data will include ward activity mapping, staff surveys and interviews and an economic cost-impact analysis.
Conclusions: This is a complex intervention that involves ward and system level changes and has the potential to improve outcomes for older patients.

Keywords
Keywords: nurses, multidisciplinary, older people, nutrition, mobilisation, cognitive engagement, fundamental care, hospital associated decline, functional decline, implementation science, behaviour change theory

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Competing interests: No competing interests were disclosed.

Grant information: This research was funded by the Health Research Board (HRB) and South South West Hospital (APA-2019-009) under the Applied Partnership Award. The grant was assigned to Professor Corina Naughton.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Naughton C, Cummins H, de Foubert M *et al.* **Implementation of the Frailty Care Bundle (FCB) to promote mobilisation, nutrition and cognitive engagement in older people in acute care settings: protocol for an implementation science study [version 1; peer review: 1 approved]** HRB Open Research 2022, **5**:3 https://doi.org/10.12688/hrbopenres.13473.1

First published: 11 Jan 2022, **5**:3 https://doi.org/10.12688/hrbopenres.13473.1

Introduction

Older adults are among the highest users of acute care hospital and rehabilitation services (Boltz *et al.*, 2012 and Smyth *et al.*, 2017). The socio-demographic and health profile of older people admitted to acute care has changed over the past decades (Rechel *et al.*, 2013). Patients are older with higher levels of co-morbidity, physical and cognitive frailty, and polypharmacy (Buurman *et al.*, 2011; Walsh *et al.*, 2019). Due to these underlying vulnerabilities, this group are more susceptible to hospital harm and prolonged hospitalisation. Hospital associated decline (HAD) is the term used to describe a new functional or cognitive deficit that develops during hospitalisation that was not present at admission (Zisberg *et al.*, 2015). The main manifestations of HAD are reduction in mobility and function independence (washing, dressing, loss of continence) (Koch *et al.*, 2020; Tasheva *et al.*, 2020). In recent years there is a greater awareness of HAD, but many hospital systems struggle to implement effective and sustainable strategies as part of ward routinised care to mitigate HAD risk (de Foubert *et al.*, 2021).

In an older hospitalised population, the prevalence of HAD ranges from 33% to 40% and can persist for up to six months post discharge (Tasheva *et al.*, 2020; Zisberg *et al.*, 2011). The factors that contribute to HAD are a combination of disease focused models of care, a restrictive patient safety culture and routinised care that fails to consistently prioritise fundamental care above competing demands (Asmus-Szepesi *et al.*, 2015; WHO, 2015; Zisberg *et al.*, 2015). In particular, inadequate attention to early mobilisation, nutrition and cognitive engagement are associated with adverse patient outcomes including functional decline, sarcopenia, falls, delirium, pressure ulcers, delayed hospital discharge, readmissions and early transition to institutionalised care (Brown *et al.*, 2009; Covinsky *et al.*, 2011; Falvey *et al.*, 2015; Hoogerduijn *et al.*, 2012; Mudge *et al.*, 2016 and Zisberg *et al.*, 2015).

High quality older adult care is dependent on an effective multidisciplinary team approach, but the nursing team (nurses and health care assistants (HCAs)) are centrally responsible for delivering fundamental care. Nursing teams do not deliberately neglect fundamental care activities but competing priorities, inadequate staffing levels and skill-mix to meet the dependency and acuity of older patients, lack of workforce gerontological competencies, and hospital environments that are maladapted to the vulnerabilities of older people make hospitals a hazardous environment for this patient group (Aiken *et al.*, 2017; Recio-Saucedo *et al.*, 2018 and Szlejf *et al.*, 2012).

A systematic review of the literature identified 18 quasi-experimental studies of ward-based interventions, designed to promote behavioural change in prioritising fundamental care to improve patient outcomes (de Foubert *et al.*, 2021). The majority of studies focused on single care activities mainly mobilisation (n=10), followed by nutrition (n=6), with only four studies targeting two or more care activities that included cognition (de Foubert *et al.*, 2021). The Australian 'Eat, Walk, Engage' project suggested that it was possible to target all three areas simultaneously with synergistic benefits from addressing the major risk factors for HAD (Mudge *et al.*, 2015).

The Irish Health Service Executive (HSE) is acutely aware of hospital risk and have initiated recent campaigns such as 'Pressure Ulcer to Zero' and falls prevention as well as updated guidance on Nutrition in Acute Care Hospitals (HSE, 2018) and delirium. The initiatives are siloed and tend to focus on downstream risk for a single harm (e.g. documentation, single risk screening tools) rather than target the core, modifiable risk factors that manifests as pressure ulcers, falls, malnutrition or delirium. The protective behaviours to reduce HAD are early and consistent mobilisation, optimising nutrition intake (especially protein) and preserving cognitive function through cognitive orientation and stimulation (de Foubert *et al.*, 2021; Mudge *et al.*, 2015; Zisberg *et al.*, 2015).

The Frailty Care Bundle (FCB) is a new intervention in that it brings together the evidence-based principles on early mobilisation, enhanced nutrition and increased cognitive engagement into a single bundle of care to prevent hospital associated decline in older patients. It is a hybrid implementation science project with an equal focus on the intervention design, the process of implementation and evaluation of the effect on patient and service outcomes.

Aim

The Frailty Care Bundle (FCB) intervention aims to implement and evaluate evidence-based principles on early mobilisation, enhanced nutrition and increased cognitive engagement to prevent functional and hospital associated decline in older patients.

Objectives

- Objective1: Situational analysis
  Conduct a situational analysis on each study site to collect baseline information including ward routines, staff and patients' experiences, organisation nursing metrics (falls, pressure ulcers), and staffing levels.

- Objective 2: Intervention co-design and implementation
  Co-produce and implement the FCB principles in the target wards using a practice facilitation model and plan-do-study- act (PDSA) cycles to refine the intervention and implementation strategy.

- Objective 3: Evaluation
  Collect and analyze patient, process, service, and economic outcomes pre-post intervention, including patient follow-up at 1-month post-discharge.

- Objective 4: Knowledge translation and dissemination
  Work with clinical partners to build a sustainable model

Methods

Study design

The hybrid study will use a pragmatic prospective cohort design with a pre-post mixed methods evaluation. The Standards for Reporting Implementation Studies (StaRI) guides the description of the dual implementation process and testing of the intervention effect (Pinnock *et al.*, 2017). The evaluation will focus on the process of implementation (to what extent was the intervention taken-up and used by staff) and the outcomes

(what was the effect on patients and service outcomes). An economic analysis will entail a budget impact analysis to estimate the potential economic and financial impacts of adopting the intervention into clinical practice (Sullivan *et al.*, 2014).

The outcome and process measures are outlined below.

Study outcomes

Primary patient outcomes

- Patients' functional status (admission to discharge) will be measured using the modified Barthel Index (mBI) and patients' mobility measured as 'step count' using accelerometers

Secondary outcomes

- Patients' 4- meter walk test and hand grip strength
- Patients' self-reported physical function and activity 1-month following discharge compared to pre-admission baseline (2 weeks prior to admission)
- Patients' quality of life (QoL) measured using the EQ-5DL

Service outcomes

- Ward data on hospital stay, falls and pressure ulcers from nursing metrics
- Financial consequences of adoption FCB within a specific healthcare region.

Process outcomes

Several process outcomes will be monitored to better understand how the implementation plan was interpreted and operationalised by nursing staff and the MDT. We will examine contextual features of different wards and sites to identify how factors influenced uptake of the intervention.

- Nursing staff uptake of the FCB principles in daily practice will be identified through observation and staff self-report.
- Staff and patient attitude to mobilisation and nutrition during hospitalisation
- Environmental layout and workforce (nurse staffing levels and skill mix, allied health professional and catering staff work routines).

Setting

This study will take place in three Irish hospitals from the South / South West Hospital Group (SSWHG). Hospitals were purposefully selected to represent different hospital models and urban and rural location.

- Cork University Hospital (CUH) is a model 4, tertiary referral centre and academic teaching hospital with acute medical, surgical and orthopaedic trauma wards and emergency department (800 beds).
- South Infirmary Victoria University Hospital (SIVUH) is a model 2 hospital providing post-acute orthopaedic rehabilitation care and elective inpatient services (192 beds).
- Mallow General Hospital (MGH) is a model 2 district hospital serving a rural population providing mainly medical and day-case services (54 beds).

Organisations were selected to examine how organisational context and operational model impact on implementation. The Director of Nursing in each hospital agreed to participate in the study and hospitals signed data sharing agreements.

Six wards (two from each site) will be recruited. Wards will be purposefully sampled to represent a medical and surgical context and which have a high proportion of older patients (i.e. >50% bed occupancy by patients aged 65 years or older in the past 12 months).

Hospital 1: Orthopedic Rehabilitation - ward A (15 beds); ward B (18 beds)

Hospital 2: Acute Trauma wards – ward C (31 beds); ward D (31 beds)

Hospital 3: General Medical wards- ward E (22 beds); ward F (22 beds)

Ethics statement

Ethical approval to undertake the research was obtained from the Clinical Research Ethics Committee (CREC) of the Cork Teaching hospitals (ECM 4 10/09/2019). This research has minimal additional risk above standard clinical care. The intervention components are already well-established fundamentals of nursing care; the purpose of this study is to improve consistent implementation. It is not feasible or advisable to exclude patients from activities such as protected mealtime, mobilisation assessment or early mobilisation where it is deemed safe to do so. Thus a Wavier of Consent to participate was granted by CREC to deliver the intervention. i.e. patients and staff do not need to sign a consent form to be eligible for inclusion in the intervention component.

Patients will provide informed written consent to be included as part of the evaluation component and to allow collection of their personal medical data for follow-up. Staff will be deemed to consent to participate by completing and returning the staff surveys, while staff who participate in interviews will be asked to give written informed consent.

Intervention design & implementation

The intervention design and implementation strategy are informed by the behaviour change theory COM-B (capability, motivation, opportunity) and the Promoting Action on Research Implementation in Health Services (i-PARIHS) framework. We used the Implementation Guide and Toolkit for National Clinical Guidelines (NCEC 2018, p11) as a pragmatic resource

to operationalise implementation principles. Sustainability will be assessed using NHS Institute for Innovation and improvement sustainability model and guide (2010).

Intervention components

The FCB operationalises evidence-based principles (EBP) of fundamental care to prevent hospital associated decline through enabling ward staff to consistently prioritise and deliver the principles outlined in Table 1.

Proposed mechanism of the intervention

The underpinning concept is to enable nursing teams to prioritise patient early mobility (walking), nutrition intake (especially protein) and cognitive activity above competing demands on nursing time. The intervention aims to provide staff with strategies to keep fundamental care as a central component of daily nursing team communication and active decision making with a range of feasible and appropriate actions deliverable in real time (each shift) to address individual patient needs.

All patients will continue to receive care as normal, the FCB is complimentary to usual care and MDT management. The intervention is delivered at ward level (cluster) i.e. targeting nurses and HCAs, thus all patients on the ward will be included in the intervention during 2020–2021.

The causal assumptions of the intervention and theoretical framework guiding this evaluation are outlined in the logic model presented in Figure 1, The figure outlines the inputs, activities, outcomes as short-term, intermediate and long term. The policy impetus for the intervention were the updated HSE guideline (2018) Food, Nutrition, Hydration policy for Adult Patients in Acute Hospitals, The National Dementia Strategy (2014) and the Report of the Second Irish National Audit of Dementia care in acute Hospitals (Bracken-Scally *et al.*, 2020) as well as the social media campaign 'End PJ Paralysis'.

The project is delivered over three phases:

Phase 1: A detailed situational analysis will be undertaken on each hospital site (see evaluation) over a four-six week period. At baseline, ward data on mealtime routines and patient mobility will be collected using structured audit (appendix I). In addition, nursing staff will be asked to identify their ideas and priorities for change as part of the staff survey. Patient data will be collected on functional capability, average daily step count and attitudes to nutrition and mobilisation. Ward and system level barriers and enablers (resources, environmental lay-out, ward routines around communication and exchange of information) will be identified to inform the intervention.

Phase 2: Intervention design and implementation will take a two-tier approach focusing on system change through the establishment of a local implementation group (LIG); and ward level change whereby a clinical facilitator will work with the ward manager and staff over a four to six week period on each ward. Introducing change will use a plan-do-study-act (PDSA) cycles (Donnelly & Kirk, 2015) to work collaboratively with staff to:

a) establish a local implementation group

b) identify ward priorities for change

c) establish a time frame and sequence to implement the intervention components on each ward

c) identify specific actions and modes of implementation

d) adapt new and modify existing practice

e) sustain new ways of working

Phase 3: Sustainability (Post intervention evaluation)

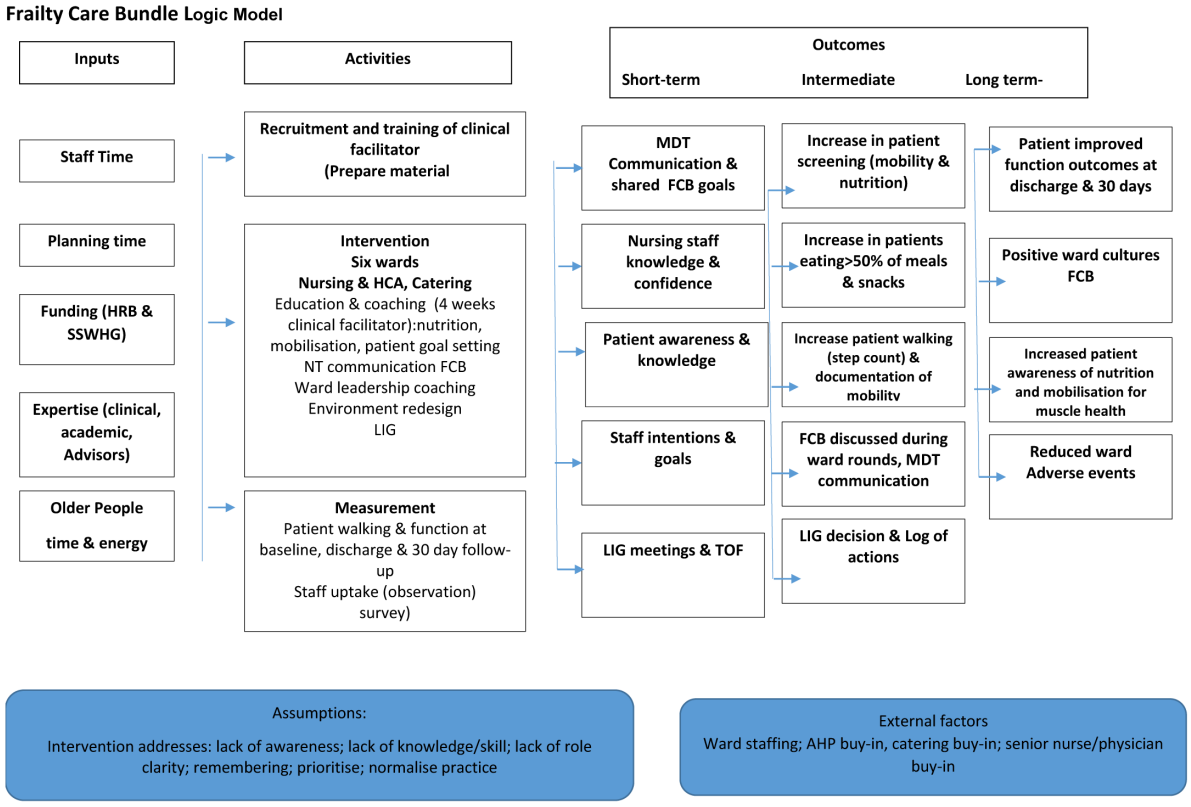
Three months following the end of the intervention period the ward level situational analysis and individual patient data collection will be undertaken to examine the uptake and sustainability of the intervention.

Intervention design and implementation

A clinical facilitation model will be used with a full-time clinical facilitator (MdF) employed to support implementation. The facilitator will work at both a ward and system level to effect change. Intervention components will be selected to address local barriers guided by the COM-B behaviour change theory. The

Table 1. Principles of Frailty Care Bundle (FCB).

Early mobilisation:	• Mobilisation assessment within 48 hrs of admission by nurses/physiotherapist • Individualised mobilisation goal (e.g. sit to stand activity, individualised walking target aligned to baseline function) • Provision of mobilisation assistance (as appropriate) and encouragement by nursing & multidisciplinary team (MDT)
Enhanced nutrition	• Increase supervision and assistance at mealtimes • Reduce disruption at mealtimes • Nutrition screening & weekly re-appraisal • Increase availability of high protein and calorie food (e.g. enhanced drinks round and protein snacks)
Cognitive engagement	• Increase cognitive engagement activities among patients (talking, games, reading, reminiscence) • Improvement in environment layout to promote orientation and patient mobilisation



Health Research Board (HRB), South South West Hospital group (SSWHG); Local Implementation Group (LIG), health care assistant (HCA), Terms of Reference (TOF), Frailty Care Bundle (FCB), Multidisciplinary team (MDT)

Figure 1. Logic model for Frailty Care Bundle.

theory proposes that behaviour change and adopting new practices is dependent on having the Capability (psychological knowledge and physical skills); Opportunity (physical and social) and Motivation (reflective and automatic) to change (Michie *et al.*, 2011). Table 2 provides an overview of potential intervention components aligned to the COM-B model.

The facilitator will gradually withdraw support as ward staff become more self-reliant and self-monitor to address ongoing barriers to implementation. The clinical facilitator will maintain a diary of implementation strategies and modifications and adaptations required for different wards and sites to achieve the project objectives.

A local implementation group (LIG) will be established on each site with representation from nursing and the wider multidisciplinary team (physiotherapy, nutrition, medical, nursing management, catering). The LIG will be chaired by an Assistant Director of Nursing (ADON) to enable the escalation of system level changes to hospital management to leverage resources and influence organisation culture. The research team will help support the LIG and assist it to develop and modify local policies and procedures to incorporate FCB principles, e.g. ward policy on protected mealtimes.

Patient and public involvement (PPI)

The FCB involves older people within the community through the Cork Age Alliance. We held a workshop with six members (prior to COVID-19) of the Cork Age Alliance to frame the project principles and identify change ideas from the older person's perspective. We will recruit 3-4 patients during the baseline data collection to act as a patient advisory panel. The role of the panel is to advise on the development of patient resources (information leaflet, mobility goal setting).

Evaluation

A mixed methods pre-post evaluation will be used. Baseline data (Time 1) will be collected prior to the intervention and at three-months post implementation on each of the participating wards. Data collection will include: individual

Table 2. Outlining role of facilitator and use of COM-B to select intervention components.

COM-B	Intervention function	Intervention components
Capability: psychological (knowledge, memory, attention, decision processes)	Education	• Education: raise awareness, deliver ward-based small group education sessions on safe mobilisation, enhanced nutrition and cognitive engagement strategies in collaboration with ward AHPs • Beliefs about capability and consequences • Maintain a log of number of staff attending teaching /coaching sessions and action plans, aim for >90% of ward staff to attend session • Prompting & reminding by clinical facilitator • One-to-one bed side teaching as required
Capability physical (skills, abilities or proficiencies acquired through practice)	Training	• Nurse assessment of mobility, Use of mobility aids and equipment, calculation of MUST nutrition screening tool
Opportunity: Social (social influences such as social pressure, norms, conformity, social comparison)	Persuasion	• Provide individual and team-based coaching on change implementation • Rapid cycle audit and feedback (verbal & visual feedback), • Patient stories and case studies
	Modelling	• Support staff to identify natural occurring opportunities to integrate FCB principles within routine ward activity (e.g. mobilising patient to the toilet)
	Enablement	• Ward huddles to improve nursing team communication on FCB • Establish nursing staff norms (e.g. daily mobility check, assisted meal-times, recording daily level of mobility) • Patient daily mobility goal & monitoring • Standardised toolkit of resources to include staff education presentation, mobility assessments tools and management algorithms will be developed in collaboration with ward staff and AHPs
Opportunity: Physical (environment context and resources)	Environment restructuring	• Posters, notices, visual reminders • Reducing clutter on corridors • Floor/wall stickers with distance markers (5 metres) • Access to mobility equipment
Motivation: reflective (beliefs about capabilities and consequences, roles, identity, intentions, goals, optimism)	Persuasion	• Provide feedback on ward data and observation at pre-existing communication channels (staff handover, ward meetings), • Action plans to address barriers and strategies to overcome them
	Enablement	• Provide staff with on-going opportunities to feed into changes • Visible support from senior nursing
Automatic motivation (emotions, reinforcement)	Incentivisation	• Rewards e.g. prizes for best change ideas, celebrate progress • Positive feedback (audit & feedback) • Disseminate progress outside of ward (e.g. presentations hospital quality improvement day/conference)
External context		
Motivation	Environmental/ social planning	Local implementation Group: representation from AHPs, medical, nursing, catering
Chaired by ADON		
Opportunity	Service provision	Negotiate & assist in modifying professional and organisational resources: • raise awareness at a system level, • modify nursing documentation to incorporate new elements • negotiate organisation resources (availability of protein snacks, enhanced drinks round, mobilisation equipment) • resource for environment redesign • identify system level barriers and escalate to Hospital management (e.g. inadequate nursing and AHP staffing levels)

patient, staff, mapping of ward activity, routine ward data on adverse events and economic costs.

1. Patient recruitment

While all patients will be included in the intervention and ward audits (mealtimes and mobility), a volunteer sub-group of patients will be recruited to participate in the pre-post evaluation (patient level).

Inclusion criteria:

- Age 65 years or older
- Medically stable and able to sit out of bed within 72 hours of admission
- Patients are eligible to be mobilised by nursing staff based on physiotherapy or nursing assessment
- Mobile prior to admission (able to walk across a medium size room (e.g. siting room, 3-4 meters, +/-walking aid) in the two weeks prior to admission
- Can provide written informed consent (no significant cognitive impairment or delirium as measured by 4-AT or recorded in medical notes)

Exclusion criteria

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

Sample size

Based on ward bed occupancy (currently>95%) and weekly patient flow (discharge rates), it is anticipated it will be feasible to collect data on an average of 15 patients per ward pre-post the intervention. This will provide an overall population sample of 180 patients. At this sample size (90 pre and 90 post), a between-patient effect size should be detected reflecting a 40% improvement in average daily step count (using log-linear models) with 80% power (the variance estimate underpinning this calculation is from our previous research on in-hospital walking in this population (McCullagh *et al.*, 2020). Further, adjustment for baseline predictors of walking (e.g. age, physical performance) will reduce the variance of the estimator, allowing for the detection of even smaller effect sizes (and greater power to detect the 40% improvement noted above).

Data collection

Eligible patients will be identified in consultation with ward nurses and the patients' medical/surgical teams. A log will be maintained of all eligible patients screened, patients recruited or declined, discharged, withdrew and lost to follow-up.

Data will be collected by the research team (MdF, HC, FB) on patients' recruited to the study (T1) and patient discharge (T2) using structured questionnaires in face-to-face interviews and medical chart reviews (appendix 1). Patient participants will be contacted at one-month follow-up (T3) using telephone interviews.

All questionnaires, interview schedules and data collection instruments for audit are available in an open access repository (Naughton *et al.*, 2021).

Descriptive data

Patient demographic and health profile data will be collected including age and gender and validated instruments will be used to collect medical profile (Table 3).

Charlson co-morbidity index (CCI) (Charlson *et al.*, 1994) will be calculated based on the presence (yes, no) of 19 chronic disease categories. There are several modifications of the CCI but summation of chronic disease burden remains strongly predictive of hospital outcomes and mortality (Austin *et al.*, 2015).

The clinical frailty scale (CFS) developed by Rockwood *et al.* (2005) is a judgement-based frailty tool that evaluates specific domains including comorbidity, function, and cognition to generate a frailty score ranging from 1 (very fit) to 9 (terminally ill). It is a widely used clinical tool and is an accurate predictor of hospital outcomes and mortality (Church *et al.*, 2020).

Sarcopenia will be measured using SACR -F (Cruz-Jentoft *et al.*, 2010), it is a five-item instrument used as a screening tool with good construct validity and good internal consistency reliability and factorial, criterion, and construct validity (Malmstrom & Morley, 2013).

Additional single items to indicate functional capability (energy, pain, sleeping, falls) will be used based on Tilda longitudinal study of ageing.

Table 3 provides an overview of the patient level data to be collected.

Primary outcome measures

The main patient outcome measures will be functional outcome measured using the modified Barthel Index (basic activities of daily living) (Shah *et al.*, 1989). In a hospitalised population baseline mBI looks at functional ability two weeks prior to admission. In this study we will also look at current mBI which is likely to be disrupted due to a temporary health crisis e.g. hip fracture. The mBI is widely used clinically and in research as a valid measure of functional capability in older people and across a wide range of conditions. It demonstrated good inter-rater reliability and predictive outcomes (Hopman-Rock *et al.*, 2019).

Patient process outcomes will include a measure of inpatient mobility recorded as average step count over a four-day period. Due to slow gait speed, the Step Watch Activity Monitor (SAM) attached via a Velcro strap to the patient's ankle was selected as the most reliable measure (McCullagh *et al.*, 2017; Resnick *et al.*, 2001). The SAM can be worn continuously

Table 3. Patient level data.

Category	Tool	Source	Time 1 Within 72 hrs of admission + clinically stable	Time 2 On Patient discharge	Time 3 One month post discharge
Patient characteristics		Medical Record (MR)	X		
Diagnosis		MR	X		
Co-morbidities	Charlson co-morbidities index	MR & Personal Interview (PI)	X		
Pharmacy	Number of prescribed medication	MR	X		
Nutrition Screening	MUST tool BMI	MR	X	X	
	Perceived weight changes	PI			X
	Simplified nutritional appetite questionnaire	PI	X	X	X
Delirium and Cognitive Screening	4-AT	MR & PI	X		
Functional Activity	mBI (2 weeks prior to admission)	PI	X	X	X
	Lawton Scale (2 weeks prior to admission)	PI	X		X
Sarcopenia	SACR-F	MR & PI	X		
Frailty	Hand grip strength	Assessed by researchers	X	X	
	Gait Speed Test (4m)	Assessed by researchers	X	X	
	Clinical frailty Scale (CFS)	Self-report & assessed by researchers	X	X	X
QoL	EQ-5D- 5L	PI	X		X
Falls	Self-report	PI	X	X	X
Physical activity while hospitalised (walking)	Step watch accelerometer	Worn for 4 days on recruitment to study or until hospital discharge			
Physical Activity at home	Yale questionnaire (2 weeks prior to admission)	Self-report	X		X
Patient attitude to nutrition & walking in hospital	Attitudes Towards Mobility during Hospitalization and Attitudes to nutrition	PI	X	X	X
Patient hospital experience	Bespoke questions	PI	X	X	X
Adverse events (infections, illness, falls)		MR & PI		X	X

MR=medical record, PI=patient interview

and is waterproof to allow patients to shower. The SAM is programmed to each individual specified to the patient's height, gait pattern and gait cycle.

Secondary outcomes

Functional capability

A range of secondary outcomes will be measured including the Lawton scale for instrumental activities of living (managing transport, finances, medication) (Graf, 2008), the four-metre walk test (Peters *et al.*, 2013) and hand grip strength measured using analogue, hydraulic hand dynamometer. The instruments are widely used in frailty research and show good internal reliability and predictive outcomes (Bobos *et al.*, 2020; Carmona-Torres *et al.*, 2019; Kon *et al.*, 2014).

Patient attitude to mobility will be measured using 3-items from the measure of older adult patients' attitudes towards mobility during hospitalization (ATM-H) (Levin *et al.*, 2017).

At one-month follow-up, the Yale physical assessment scale will be used to compare pre-admission activity with one-month post discharge activity level (Dipietro *et al.*, 1993) and has established reliability (De Abajo *et al.*, 2001).

Nutrition

Measures of nutrition will include patient body mass index (BMI), malnutrition universal screening tool (MUST) score (BAPEN 2020) and simplified nutritional appetite questionnaire (SNAQ) (Kruizenga *et al.*, 2005). The SNAQ was included as it uses self-report and is suitable for use in the one-month telephone follow-up. Both tools are widely used and validated (Dent *et al.*, 2019). Bespoke questions (4-items) will be used to assess attitudes to nutrition.

Quality of life

Quality of life will be measured at T1 and T3 using the EQ-5D-5L. The EQ-5D-5L consists of the 5D descriptive system and the EQ visual analogue scale (EQ VAS) (EuroQol Group 2009). The five dimensions are: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: 1=no problems, slight problems, moderate problems, severe problems and 5=extreme problems. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement. In a systematic review, Feng *et al.* (2021, p 647) concluded the 'EQ-5D-5L exhibits excellent psychometric properties across a broad range of populations, conditions and settings'.

Ward staff

All ward staff members (nurses and HCA) will be asked to complete a survey at baseline and three months' post intervention in relation to attitudes to mobilisation and nutrition, care left undone and quality of ward environment. Surveys will be distributed by ward managers and returned by staff to a sealed survey collection box on the ward. Return of the survey will indicate respondents' consent to participate in the study.

We will aim to achieve a consensus sample whereby all eligible staff will have the opportunity to complete the survey. It is estimated up to 100 staff will be eligible to participate. Table 4 provides an overview of the staff data to be collected, data instruments and schedule.

Table 4. Ward Staff Survey.

Category	Tool	Pre Intervention	Three months post intervention
Staff demographic: Age Gender Staff grade Duration as registered staff Duration on current ward			
Attitude to Mobilisation	Barriers to Early Mobilisation (Hoyer *et al.*, 2015).	X	X
Attitude to nutrition	Bespoke questions modeled on the items from Hoyer *et al.* (2015)	X	X
Care environment (nurses only)	Practice Environment Scale of the Nursing Work Index (Aiken & Patrician, 2000; Lake, 2007).	X	X
Readiness to change	Organisation readiness to implement change (Shea *et al.*, 2014)	X	

Interviews. In addition, key ward staff members (ward managers) and AHPs, (physiotherapy dieticians) will be identified for interview to provide insight into ward barriers and facilitators and the implementation processes. Participants will be asked to sign consent forms.

Ward activity mapping

A situational analysis of each ward will involve non-participant observation of ward activity (observer not involved in patient care) using structured audit tools for mealtimes and patient mobilisation and qualitative observation on ward environment and nursing team communication. Each ward will have 1-2 days of detailed observation (08:00 – 17:00) pre and post the intervention.

Mealtime observation. Mealtime observation aims to estimate how much of each meal (breakfast, lunch, and supper) a patient eats (Young *et al.*, 2016). This is based on visual inspection of the food tray and is coded as: none, 25%, 50%, 75% or 100%. Associated factors such as meal type (general or texture modified), assistance required, and delay in receiving assistance and mealtime interruptions will be recorded (Supplemental file). Observers will also note ward context (busyness of environment, how staff were occupied during meal times, nutrition communication) (Naughton *et al.*, 2021).

Mobilisation observation. Observation of patient activity will be recorded every 30 minutes from 08:00 to 17:00. Only patients eligible for mobilisation (can sit out of bed) will be included. Patients on bed-rest or palliative pathway are excluded. Each room or patient bay will be observed for two minutes at a time, noting patient location (hall, bedroom, bathroom), patient position (walking, sitting in a chair, sitting in bed, or lying-in bed) and activity (exercise, resting, sleeping, eating, TV, radio, reading, talking). The mean proportion of time in each location, position and activity is calculated across all patients observed (Mudge *et al.*, 2016).

Observation will also include the quality of the environment (clutter on corridors, signage, lighting), busyness and noise on ward, interaction between patients and staff.

No patient or staff identifying information will be collected during this activity. Results from the observations will be returned to staff as part of audit and feedback.

Workforce. Ward staffing levels and skill mix will be monitored over one week as part of the environmental mapping. As there is no electronic record of staffing, we will record the number of nurses (excluding CNMII), HCAs and student nurses at 10 am and the number of patients (Table 5) to calculate nurse to patient ratios and total staff to patient ratios (Griffiths *et al.*, 2020).

Ward organisation. Monthly ward data on pressure ulcer and falls will be monitored over the course of the project (see Table 5). Data is routinely collected as part of nursing metrics.

Patient safety monitoring

Falls are the most likely unintended consequence of the intervention due to increased mobilisation and will be actively monitored (see above). Each falls incident is subject to critical incident review, the potential role of the FCB will be considered, any incident that implicates the FCB will be reported to CREC and the hospital patient safety officer. Any patient complaint will be managed through the hospital patient safety and advise service.

As part of patient follow-up, we will ask patients about their overall hospital experience. It is possible that both positive and negative experiences will be recorded. Where patients make a complaint, they will be advised of the hospital patient complaints procedure.

Table 5. Daily ward staffing statistics.

Week Beginning:	Mon 10 am	Tues 10 am	Wed 10 am	Thur 10 am	Fri 10 am	Sat 10 am	Sun 10 am
Ward:							
Number of patients							
Number of patients Requiring a special (request submitted)							
How many patients have a dementia/ delirium							
Ward manager							
Number of registered nurses (exclude ward manager I							
Number of ward HCAs							
Number of specials (not part of ward compliment)							
Number of 4th year student nurses							
Number of 1-3 yr student nurses							

Process evaluation

A concurrent process evaluation will run in tandem with the intervention implementation and evaluation.Using the MRC process evaluation framework, the study will focus on the measures and research questions outlined in Table 6. The process evaluation will examine how the intervention was received by ward staff and to what extent staff could make sense of the changes and incorporate them into their clinical practice.

Economic analysis

A budget impact analysis using a micro-costing analysis will be employed to estimate the resource implications of implementing the intervention. This will examine how much it will cost (affordability) and describe the incremental (change) in costs and resources of implementation. Primary data will be collected on wards to identify and measure resources for the intervention and current practice which will then be valued (nursing time spent in training and delivering the intervention, mobilisation coach, education material). Potential cost off-sets will be identified (reduction in length of stay, incidents of adverse patient outcomes).

Data management

A detailed data management plan (DMP) will be developed by HC and BP. Data will be managed in line with General Data Protection Regulations (GDPR 2018). Patient data will be entered and stored in Castor EDC., a cloud-based, encrypted and password protected data management platform for clinical trials. Data entry will be undertaken by HC and MdF directly into castor, data checking rules will be built into the database and 20% of data entry will be independently checked by CN.

Staff survey, ward audit and ward falls and pressure ulcer data will be entered into SPSS v25 data analysis software and stored in UCC password protected google drive, the same mechanism for data entry and checking will apply.

Staff interview data will be recorded and transcribed verbatim and entered into NIVO software package for analysis.

Statistical methods

All quantitative analyses will be conducted by the Principal Statistician [DD]. Prior to any analyses, research data will be made FAIR, and undergo quality checking, and any potential errors will be verified against source documents.

The specifics of the statistical modelling will vary, but will feature mixed-effects generalized linear models with adjustment for key patient and (time-varying), ward/hospital-level predictors of outcomes. The project will recruit two distinct patient populations the first is a surgical orthopaedic (acute and rehabilitation) and the second medical population.

The model estimated effect of the intervention on outcomes will be reported alongside 95% confidence intervals.

Table 6. Process evaluation framework.

Dimension	measure	Research question	Data source
Implementation process	process	How was the intervention developed and delivered? What inputs, resources and structures were put in place?	Team activity logs, interviews/focus groups
	fidelity	To what extent did intervention delivery align or diverge with protocol, international evidence base? What adaptations were made to fit with different context ?	interviews/focus groups
	Dose	What was the duration, coverage of the intervention	Clinical facilitator log
	Reach	The extent that the intervention components are visible	Record of staff education Point prevalence audits
Mechanisms	Participants response to and interaction with intervention	How did staff feel /think about intervention, what difference it made to day-to-day practice? What proportion of staff reported change in attitude/practice	Qualitative interviews Staff survey
	Mediators	What aspects of intervention influenced implementation (people, operations, relations)	Interviews/focus groups
	Unexpected pathways and consequences	Was there something about the intervention that was unexpected and might have influenced its implementation?	Interviews/focus groups
Context	Barriers & facilitators	What factors external to the intervention influenced its implementation and in which way? (individual, environment, ward operations/routines, inter-professional relations, border health system)	Interviews/focus groups

A detailed Statistical Analysis Plan (SAP) will be finalised and registered on the Open Science Framework, alongside the analysis script, written in R, using R Studio.

The SAP will outline the research hypotheses tested, methods for dealing with missing data, data transformation for non-linear data, statistical tests and associated R codes.

Qualitative data will be analysed using Braun & Clarke (2006) thematic analysis framework, guided by the research questions outlined in Table 5.

Modifications of study due to COVID-19

Over the past 24 months the pandemic has significantly disrupted the delivery of the intervention and data collection.

Timeline. The FCB project commenced in March 2020, however, three weeks later due to the COVID-19 pandemic the project was suspended. Over the following 24 months the project was suspended on two further occasions due to national infection control measures. There was also periodic disruption at local ward level as they managed COVID-19 or other infectious disease outbreaks. All the clinical sites involved in the project experienced outbreaks of COVID-19.

The main change to the protocol has been the length of time required to deliver the intervention and to modify the delivery in the context of a nursing workforce that is experiencing unprecedented strain. The original intension was for the clinical facilitator to work intensively with each ward for four to six weeks, then gradually withdraw support over four weeks. This time-frame was unrealistic and the clinical facilitator works with participating wards over a longer period.

- More time is required to provide education to staff as social distancing measures requires that attendance is limited to 1-2 people per session or sessions are rescheduled due to staff shortages.

- The clinical facilitator works more flexibly and at a pace that recognises the high levels of physical and psychological fatigue among front-line staff as they face on-going challenges in delivering patient care as the pandemic continues.

- The average time the clinical facilitator spends with each ward is four to five months

- As senior leadership is pre-occupied with managing COVID-19, it has been very difficult to establish a LIG to action system changes on some sites.

Patient recruitment

- The number of patients aged 65 years and older and who met all the eligibility criteria especially cognition and in hospital for more than 3-4 days was below expected. In order to reach our target sample we made a pragmatic decision to reduce the recruitment age to 60 years to increase the pool of potentially eligible patients. This was a modification to the protocol.

Intervention components

- Intervention components were altered due to the COVID-19 pandemic. It was envisioned that patients' families and friends relative's would be a key component in assisting patients with mobilisation, nutrition, and cognitive engagement. Due to visitor restrictions this was no longer possible.

- Mobilisation on corridors was restricted during COVID-19 outbreaks

- Alterations to the patient information leaflet was required to reflect this.

- Patient cognitive engagement resources and activities are required to be single patient use packs. The use of patient group activities sessions can no longer be facilitated.

- Health care assistants, a key part of the workforce involved in direct patient care, have to spend a significant part of their time undertaking ward and medical equipment cleaning duties thus time to focus on mobilisation, nutrition and cognitive activity is compromised

Research Staff

- Extension of staff contracts and further funding for same was required due to increased time required to deliver the FCB project

- A risk register was required by the governing university body to continue to allow research staff be present in the clinical site during Covid-19 pandemic.

- An activity log detailing time spent in the clinical site of all researchers was required daily by the governing university body

- Research staff must limit the amount of time spent on the clinical site and only be present if deemed necessary for the purpose of the FCB project. This continues to impact the overall presence and visibility of the FCB project and continues to adversely affect timelines to deliver the intervention.

Dissemination plan

We have undertaken concurrent dissemination during the course of the project. One of the main mechanism for dissemination is our twitter account @FrailtyCareBund

We have shared resources developed as part of the project directly through email e.g. a patient leaflet highlighting the benefits of nutrition, mobilisation and cognitive engagement for older people during hospital.

We were part of an 'Health Ageing' series featured in the Irish Examiner.

Publications

de Foubert, M., Cummins, H., McCullagh, R., Brueton, V. and Naughton, C., 2021. Systematic review of interventions

targeting fundamental care to reduce hospital-associated decline in older patients. *Journal of Advanced Nursing*

Corina Naughton, Helen Cummins, Marguerite de Foubert. A systematic review and meta-analysis of interventions targeting ward culture (nursing teams) to reduce hospital associated decline in hospitalised older patients. PROSPERO 2020 CRD42020177969

Conferences presentations

- Irish Society for Clinical Nutrition and Metabolism 2021, oral presentation
- Irish Hip Fracture Meeting 2021, oral presentation
- European Geriatric Medicine Society 2021 Congress, poster presentation
- "What Matters" Innovation towards Age Friendly Systems UCC SONM, oral presentation
- "Stepping Forward with Confidence" Irish Frailty Network Conference 2021, oral presentation
- Irish Gerontology Society, 2021, oral presentation

Study status

The status of the project on 12/11/2021 are outlined in Table 7.

Discussion

The FCB intervention protocol uses a theory driven approach to address some of the concerns in care for older people in acute care hospitals, namely, how to consistently prioritise fundamental care related to mobility, nutrition and cognition above competing demands on nursing time (Palmer, 2018;

Table 7. Study phase.

Phase:	Site		
	1	2	3
Exploring & Preparing			
Form LIG	✓		
Baseline data collection + ward mapping	✓	✓	✓ (ongoing)
Recruit patients	✓	✓ (ongoing)	✓ (ongoing)
Disseminate Staff questionnaires	✓	✓ (ongoing)	✓ (ongoing)
Planning & Resourcing			
Disseminate baseline audit data	✓	✓	✓ (ongoing)
Display audit data	✓		
Formulate & agree education content with AHP's	✓	✓	✓
Ongoing LIG meetings	✓	✓	
Environment redesign	✓		
Resources (assessment tools, posters, patient leaflets)	✓	✓	✓
Implementing & Operationalising			
Begin staff education	✓	✓	✓ (ongoing)
Implement intervention once 80% staff educated	✓	✓	
Facilitator present on ward	✓	✓ (ongoing)	✓ (ongoing)
PDSA cycles	✓	✓ (ongoing)	✓ (ongoing)
Ongoing LIG meetings	✓	Did not establish	
Full Implementation & Sustainability			
Facilitator withdrawal	✓	✓	
Education resources available at ward level	✓		
Ongoing education of new staff	✓		
Post implementation 3-month follow up audit	✓	✓	
Post implementation patient recruitment	✓	✓ (two wards)	

Zisberg *et al.*, 2015). The project proposes a multilevel approach focusing on system enablers as well as behaviour change of the nursing and wider multidisciplinary team. A detailed baseline situational analysis with stakeholders will inform the intervention components and implementation plan. The evaluation uses a pre-post design and the primary outcomes are patient functional capability and in-hospital mobilisation measured as step-count using accelerometers.

This is one of only a few studies studies that aims to improve the three major components of HAD simultaneously (de Foubert *et al.*, 2021). Older people are among the most vulnerable patient groups in acute care and experience longer hospital stays and more adverse events than other age groups (Connolly *et al.*, 2021; Long *et al.*, 2013). In older patients there are multiple reasons for longer hospital stays including that recovery from acute health crisis takes longer and discharge can be more complicated due to social factors, the need for community support or transfer to rehabilitation or long-term care. The time spent in acute care is more than the management of an acute condition, it represents a valuable opportunity to accelerate recovery through implementation of rehabilitation principles (Stucki *et al.,* 2005). Expert input from AHPs is essential for higher risk and more complex patients, but individual patient time with an AHP is limited to short episodic periods and management plans (Boltz *et al.*, 2012; Zisberg *et al.*, 2015). It is nursing team interventions that determines patients' activation over the course of the day and seven days a week.

A detailed understanding of how the nursing team can remember, prioritise and motivate patients to walk more, eat more, and engage more in cognitive activities is essential to reduce HAD and related adverse events. At the core of how activities become a priority is the quality of inter and intra-team communication, that is how nurses communicate with the wider interdisciplinary team around patient safety and recovery goals and how nurses communicate with each other to set priorities during their day (Ryan *et al.*, 2019; Wong *et al.*, 2020).

Delivering the project has become significantly more difficulty during the COVID-19 pandemic, but it is even more essential due to older adult decondition following prolonged restricted physical activity and the debilitating effects of COVID-19 infection itself (de Biase *et al.*, 2020; Spruit *et al.*, 2020). The protocol has be to adopt to the new reality of COVID-19 infection control precautions, high levels of fatigue among front-line staff, staff shortages and episodic interruptions. None the less, staff have demonstrated enormous resilience and have retained enthusiasm and energy to engage with and test change ideas to achieve the project objective of improving care for older people.

Conclusion

The importance of the FCB has taken on new significance in the face of the COVID-19 pandemic. Understanding how to support the capacity of nursing and the wider multi-disciplinary team to deliver mobilisation, optimise nutrition and cognitive activity is vital in the current climate. Equally important is measuring the effect on patient functional outcomes in order to build the business case for resources and sustainability.

Data availability

Underlying data

No data are associated with this article.

Extended data

Figshare: Frailty Care Bundle Data Collection, https://doi.org/10.6084/m9.figshare.16692553. (Naughton *et al.*, 2021)

This project contains the following extended data:

- All Data collection materials.docx (All questionnaires, interview schedules and data collection instruments for audit)

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ✔

Version 1

Reviewer Report 12 January 2022

https://doi.org/10.21956/hrbopenres.14685.r31201

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This is a well-written protocol of a complex intervention underpinned by behaviour change theories that will implement and evaluate evidence-based principles on early mobilisation, enhanced nutrition and increased cognitive engagement to prevent functional decline and hospital-associated decline in older patients ("Frailty Care Bundle" programme).

The protocol aims are very clear; strengths of the approach are the multicentric design, the use of situational analysis and the co-production with patients, with a view to conducting an evaluation with a high translational aim. Of particular relevance is the consideration of overall functional status as the primary outcome. In addition, a good selection of outcome measures has been selected as a secondary outcome. An economic analysis is planned.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Geriatric Medicine, Ageing, Frailty

I confirm that I have read this submission and believe that I have an appropriate level of

expertise to confirm that it is of an acceptable scientific standard.