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Staying Active with Multimorbidity In Acute hospital settings (StAMInA) trial: protocol for a feasibility randomised controlled trial of allied health assistant mobility rehabilitation for patients with multimorbidity

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ABSTRACT

Introduction Key to improving outcomes for patients with multimorbidity is increasing mobility through prescription of a physical activity programme, but this can be difficult to achieve in acute hospital settings. One approach that would assist physiotherapists to increase levels of physical activity is delegation of rehabilitation to allied health assistants. We aim to conduct a randomised controlled trial to determine the feasibility of an allied health assistant providing daily inpatient mobility rehabilitation for patients with multimorbidity.

Methods and analysis Using a parallel group randomised controlled design, participants will be allocated to allied health assistant mobility rehabilitation or physiotherapist mobility rehabilitation. Adult inpatients (n=60) in an acute hospital with a diagnosis of multimorbidity who walked independently preadmission will be included. The experimental group will receive routine mobility rehabilitation, including daily mobilisation, from an allied health assistant under the supervision of a physiotherapist. The comparison group will receive routine rehabilitation from a physiotherapist. Feasibility will be determined using the following areas of focus in Bowen's feasibility framework: Acceptability (patient satisfaction); demand (proportion of patients who participate); implementation (time allied health assistant/physiotherapist spends with participant, occasions of service); and practicality (cost, adverse events). Staff involved in the implementation of allied health assistant rehabilitation will be interviewed to explore their perspectives on feasibility. Secondary outcomes include: Physical activity (daily time spent walking); daily mobilisation (Y/N); discharge destination; hospital readmission; falls; functional activity (Modified Iowa Level of Assistance Scale); and length of stay. Descriptive statistics will be used to describe feasibility. Secondary outcomes will be compared between groups using Poisson or negative binomial regression, Cox proportional hazards regression, survival analysis, linear regression or logistic regression.

Ethics and dissemination Ethics approval was obtained from Peninsula Health (HREC/97 431/PH-2023). Findings will be disseminated in peer-reviewed journals and conference presentations.

Trial registration number Australian and New Zealand Clinical Trial Registry ACTRN12623000584639p.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial will investigate the feasibility of allied health assistant mobility rehabilitation for patients with multimorbidity in the acute hospital environment using the Bowen framework; the impact of allied health mobility rehabilitation for patients with multimorbidity on patient (eg, physical activity), staff (eg, acceptability of allied health assistant rehabilitation of multimorbidity) and organisational outcomes (eg, length of stay, cost) will be investigated.

⇒ As this is a feasibility study, we cannot determine whether allied health assistant mobility rehabilitation, under the supervision of a physiotherapist, leads to superior or non-inferior patient outcomes compared with physiotherapist care; as such, findings related to patient outcomes are estimates of effect and must be interpreted with caution.

⇒ Neither participants nor staff will be blind to group allocation which may affect participants' responses to the intervention received and may lead to differential use of supplemental care by staff members; also, participants will be randomised individually which introduces a minor risk of contamination bias that will be monitored in this feasibility trial.

⇒ Delegation of mobility rehabilitation to allied health assistants may compromise quality and safety of care, which will be monitored in this feasibility trial.

⇒ To ensure the quality of data extracted from electronic medical records we will extract data via a curated data platform and/or use a data collection template, categorise data items, and provide training to the data extractor.

INTRODUCTION

Multimorbidity, defined as the 'coexistence of two or more chronic conditions in the same individual',[1] is a major challenge to the healthcare system with 60% of hospital inpatients having multimorbidity.[2] People with multimorbidity are 49% more likely to be hospitalised and have a 49% longer length of hospital stay than those without multimorbidity.[3] Multimorbidity is particularly prevalent in older adults, for whom hospitalisation is significantly associated with increased likelihood of developing new or worsening disability.[4 5] Most older adults do not recover to their preadmission function level within 1 year of discharge, and are at risk of placement in residential aged care and death.[5 6] As the worldwide population ages and incidence of multimorbidity grows, there is a need to develop innovative models of care to improve the quality of care and outcomes for patients with multimorbidity.[7 8]

Key to improving outcomes for patients with multimorbidity is rehabilitating mobility through exercise.[9] Exercise can be defined as the prescription of a physical activity programme that involves the patient undertaking voluntary muscle contraction and/or body movement with the aim of relieving symptoms, or reducing activity limitation or improving, retaining or slowing deterioration in health.[10] For the purposes of this study, we define mobility rehabilitation as patient education and exercise prescribed to increase the activity and participation in mobility, such as specific impairment-based exercises of the lower limbs, practice of transfers and walking as part of a physical activity programme. Mobility rehabilitation can be difficult to achieve in acute hospital settings, where there is high demand for beds and a focus on discharge planning to maintain patient flow through the health service.[11–13] However, it could be argued that mobility rehabilitation during acute hospitalisation should be prioritised given that higher physical activity levels are associated with a shorter length of stay and discharge home.[14 15] The challenge is how to provide rehabilitation in a health system stretched for resources.[16]

Employing more physiotherapists to provide mobility rehabilitation in an acute hospital setting may not be tenable due to costs and workforce shortages of health professionals.[17] An alternative approach is to delegate the provision of mobility rehabilitation to allied health assistants under the supervision of a physiotherapist. Allied health assistants are support staff who complete clinical and non-clinical tasks under the supervision and delegation of an allied health professional.[18] Clinical tasks include any direct therapeutic interventions provided to patients such as exercise therapy and education, while non-clinical tasks may include administration duties (eg, completing paperwork for equipment hire), maintenance of equipment and cleaning the clinical environment.[19 20] Because allied health assistants cannot perform clinical tasks that involve diagnosing or assessing patient health conditions,[19 20] allied health professionals must perform a comprehensive assessment of the patient and prescribe appropriate therapy prior to delegating the allied health assistant to perform any clinical tasks.

There has been significant investment in the assistant workforce to support allied health professionals working in Australia, Canada, Finland, New Zealand, Norway, the UK and the USA.[18 21–23] Across all countries there has been an emphasis on enhancing assistants' roles in the provision of patient care. Currently, allied health assistants spend only 24% of their working day providing patient care in acute hospital settings, and allied health professionals spend 17% of their time performing tasks that could be performed by allied health assistants.[19 24] This suggests the allied health assistant workforce is underused and has capacity to provide more patient care. Using this workforce to rehabilitate mobility of patients with multimorbidity may be a cost-effective alternative to employing additional physiotherapists to provide mobility rehabilitation in acute hospitals.

While allied health assistant care of people with acute hip fracture has been recently trialled,[25] people with multimorbidity can present to hospital with a wider variety of acute medical conditions, such as cardiac, renal, gastrointestinal and respiratory disease. Compared with surgical care, the management of these conditions may not be informed by a clinical guideline or pathway and therefore, there is greater variation in how they are clinically managed. As such, inpatients with these conditions may be more complex for allied health assistants to rehabilitate. However, if allied health assistants can safely rehabilitate this population, they may have capacity to provide a greater frequency of mobility rehabilitation than physiotherapists; because their role in clinical assessment is limited, allied health assistants might have more time to provide rehabilitation than physiotherapists.[19] This may lead to better outcomes for people with multimorbidity, such as shorter length of hospital stay and improvement in function.[26]

For allied health assistant rehabilitation to be cost-effective, this care needs to replace physiotherapy rehabilitation rather than supplement it. However, research to date has only investigated the addition of allied health assistant rehabilitation to physiotherapy rehabilitation in acute hospital settings.[18] It is unknown if (1) it is feasible for allied health assistants to provide mobility rehabilitation for patients with multimorbidity in acute hospital under the supervision of a physiotherapist or (2) if allied health assistants can substitute the role of physiotherapy mobility rehabilitation. Therefore, prior to conducting a full-scale non-inferiority randomised controlled trial (RCT) comparing the effect of allied health assistant and physiotherapist care on mobility outcomes in people with multimorbidity, the primary aim of this feasibility RCT is to determine the feasibility of allied health assistant mobility rehabilitation of patients with multimorbidity in the acute hospital environment. Feasibility will be determined using the Bowen *et al* framework and will assess: Acceptability, demand, implementation and practicality.[27] The secondary aims are to estimate the effect of

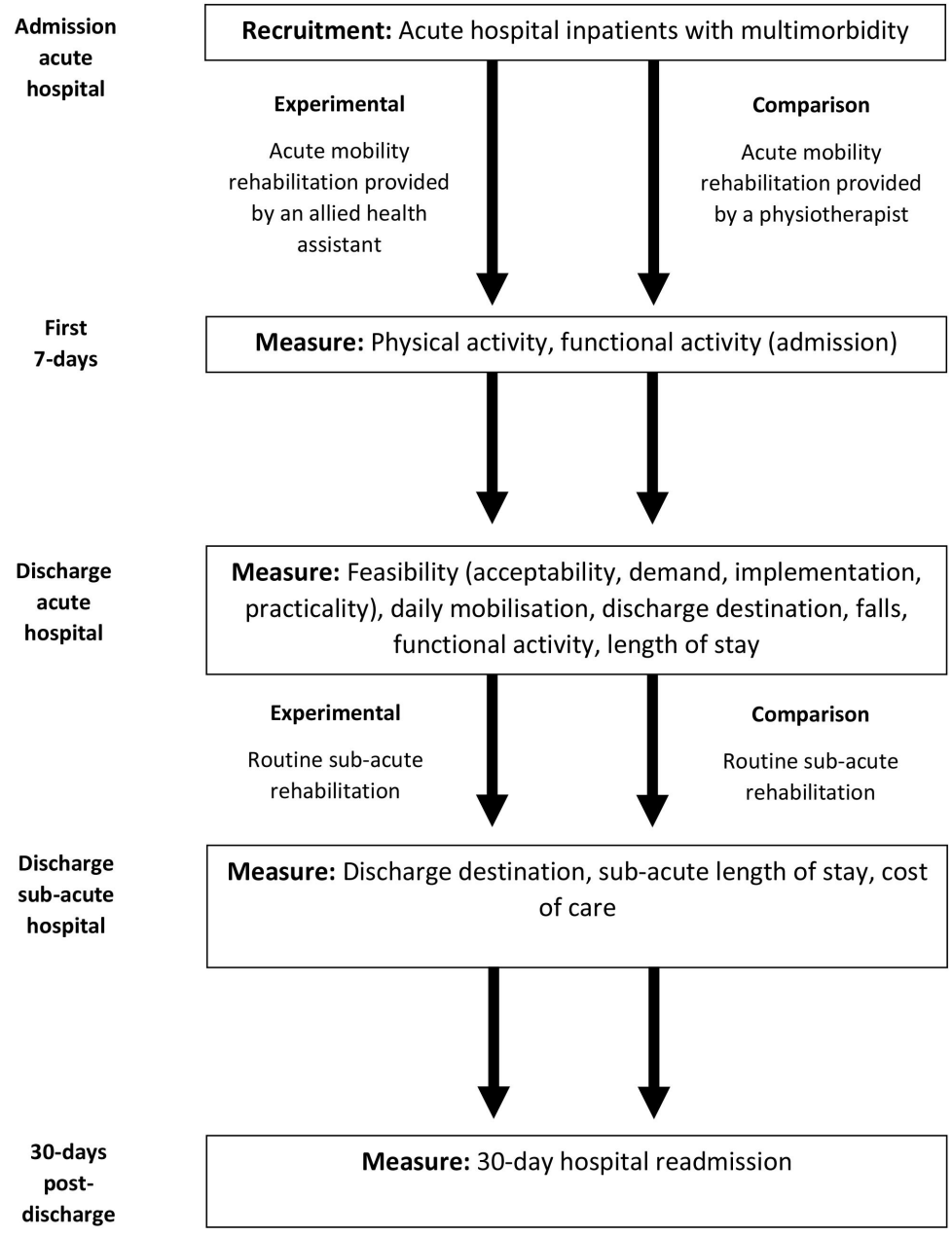

Figure 1 Participant timeline.

allied health assistant mobility rehabilitation of patients with multimorbidity on (1) patient outcomes (physical activity, daily mobilisation, discharge destination, hospital readmission, falls, functional activity) and (2) organisational outcomes (length of stay).

METHODS AND ANALYSIS

Trial design

A feasibility RCT will be conducted in a general medical ward at a publicly-funded acute hospital in Melbourne, Australia. Allied health assistant mobility rehabilitation (experimental group) will be compared with usual physiotherapy mobility rehabilitation of patients with multimorbidity (comparison group). Please refer to figure 1 for an overview of the participant timeline.

Staff involved in the implementation of allied health assistant rehabilitation of patients with multimorbidity will be interviewed to establish their perspectives on feasibility.

Study setting

The trial will be conducted on a general medical ward at a 450-bed publicly-funded tertiary hospital that provides acute healthcare services to approximately 300 000 people on the Mornington Peninsula in Victoria, Australia.[28] Patients admitted to the ward typically present for non-surgical management of respiratory conditions (eg, chronic obstructive pulmonary disease, asthma), kidney disease (eg, renal failure), gastrointestinal disease, cardiac disease (eg, cardiac failure), urinary tract infection and delirium. The median length of stay in the ward

is 4 days (IQR 2–8) and 90% of patients are discharged within 12 days.

Randomisation and allocation procedure

Participants will be randomised to either allied health assistant or usual physiotherapy mobility rehabilitation. Participants will be assigned remotely, using a simple randomisation design, by consulting an allocation sequence established at the beginning of recruitment. This sequence will be created using a computer random number generator prepared by a member of the research team who is not involved in recruitment, patient rehabilitation or assessment. Allocation will be determined by email contact with the research team member after the participant has been determined eligible for participation and has provided written informed consent to take part in the study. The allocation sequence will remain concealed throughout enrolment and assignment. Participants, physiotherapists and allied health assistants cannot be blind to the treatment allocation due to the nature of the intervention.

Participants

Patient participants eligibility criteria

Eligible participants must meet the following criteria:

- Inpatient at the general medical ward.
- Coexistence of two or more chronic conditions,[1] as documented on their medical record; chronic conditions may include, but are not limited to, cardiovascular disease, diabetes, arthritis, osteoporosis, back pain, respiratory disease, arthritis, kidney disease, liver disease, cancer, obesity and mental health conditions.[29]
- Referred to physiotherapy; and on initial assessment physiotherapist prescribed mobility rehabilitation.
- Walked independently prior to admission with or without the use of a walking aid.
- Willingness and ability to participate in mobility rehabilitation, as determined by initial physiotherapy assessment.
- Aged 18 years or older.
- Able to communicate in conversational English.

Exclusion criteria are:

- Not referred to physiotherapy; and not prescribed mobility rehabilitation.
- Not suitable for mobilisation or mobility rehabilitation.
- Requiring specialist physiotherapy skills to mobilise.
- Non-ambulant or requires assistance of another person to walk prior to admission.
- Undergone major surgery and those admitted with acute stroke.

Patients are typically prescribed mobility rehabilitation if they are below their preadmission level of mobility and/or at risk of decline. Patients who are functioning at their premorbid level and independently mobilising in the ward would not be prescribed mobility rehabilitation. If the patient is not appropriate for mobilisation they will not be eligible for participation in the study. Mobilisation will be contraindicated if the patient experiences any of the following complications: severe pain; nausea or vomiting with or without antiemetic; vitally unstable (eg, hypotension, febrile, abnormal heart rate or rhythm); disorientated, heavily sedated or difficult to rouse.[25]

Participants initially assessed as not appropriate for mobilisation, by either the treating physiotherapist or physician, can be included in the study if their medical stability improves on any day during their admission. Patients with multimorbidity who were non-ambulant prior to admission cannot be expected to ambulate. Patients requiring specialist physiotherapy skills to mobilise, such as patients on mechanical ventilation (eg, Bilevel Positive Airway Pressure) or those with high O_2 requirements (ie, >40%) who require specialist cardiorespiratory physiotherapy skills, will be excluded because allied health assistants do not possess the skills or qualifications required to provide this specialist care.

Eligible patients will include those who are admitted to the general medical ward with multimorbidity, which includes patients presenting with a variety of medical conditions. However, those who have undergone major surgery (ie, an operation on an organ within the cranium, chest, abdomen or pelvic cavity, or any orthopaedic operation requiring general anaesthetic) and those with acute stroke will be excluded because their care is (1) dictated by guidelines that do not apply to all patients with multimorbidity and (2) requires a specialised skill set to deliver mobility rehabilitation.[30 31]

Staff participants eligibility criteria

Staff participants for this trial are allied health assistants, physiotherapists and their manager responsible for mobility rehabilitation in the general medical ward.

Recruitment

All patients admitted to the ward will be screened for eligibility. Patients appropriate for mobility rehabilitation after their first physiotherapy assessment will be approached on the ward by a member of the research team. Patients expressing interest will be provided a participant information and consent form (online supplemental file 1).

Prior to gaining written, informed consent the patient's cognition will be screened by a member of the research team using the Short Portable Mental Status Questionnaire.[32] Patients scoring 8 or higher will provide their own consent to participate in the study. For patients scoring 7 or lower (indicative of cognitive impairment) a member of the research team will consult with the treating medical team to conduct a formal assessment of the patient's cognitive capacity. If the patient is deemed to have cognitive capacity to provide consent, the patient will provide their own consent. If the patient is deemed to not have capacity to provide consent, consent will be obtained from their medical treatment decision-maker (ie, the person responsible for making medical treatment decisions on behalf of the patient) using a specific participant information and consent form (online supplemental file

Table 1 Description of intervention and comparison group interventions according to the template for intervention description and replication (TIDieR)

	Experimental group	Comparison group
Brief name	Allied health assistant mobility rehabilitation of patients with multimorbidity.	Physiotherapist mobility rehabilitation of patients with multimorbidity.
Why	Improve/maintain mobility and physical activity during acute hospitalisation.	Improve/maintain mobility and physical activity during acute hospitalisation.
What materials	Management guided by evidence-based recommendations.* Education (approximately 5 hours) provided to allied health assistant from a physiotherapist (see online supplemental file 5).	Management guided by evidence-based recommendations.*
What procedures	Mobilisation (eg, transferring out of bed, walking)±progression of gait aid, standing/seated exercises and education.	Mobilisation (eg, transferring out of bed, walking)±progression of gait aid, standing/seated exercises and education.
Who provided	Allied health assistant (initial assessment by physiotherapist).	Physiotherapist.
How provided	Face-to-face.	Face-to-face.
Where (setting)	Acute hospital, general medical ward.	Acute hospital, general medical ward.
When/how much (dose)	Daily during acute hospital admission.	Daily during acute hospital admission.
Tailoring	Sessions tailored to the needs and progress of the individual.	Sessions tailored to the needs and progress of the individual.
Fidelity checking measures	Allied health assistant time spent managing patients with multimorbidity. Number of occasions of service provided to the patient by an allied health assistant.	Physiotherapist time spent managing patients with multimorbidity. Number of occasions of service provided to the patient by a physiotherapist.

*Bricca *et al*.[9]

2). For patients whose cognitive impairment may improve during the course of their hospital admission, a member of the research team will confirm willingness to continue with participation in the trial and will obtain written informed consent from the participant when they regain capacity to provide consent (online supplemental file 3).

Eligible staff participants will be invited via email to participate in semi-structured interviews. Staff expressing interest will be contacted by a member of the research team who will explain the trial and gain written informed consent prior to the interview (online supplemental file 4).

Intervention

The experimental group will receive routine mobility rehabilitation delivered by a senior allied health assistant under the supervision of a registered physiotherapist (table 1). Allied health assistants will have a certificate IV allied health assistant qualification (ie, highest-level allied health assistant qualification in Australia) and at least 6 months prior experience working in a hospital. These requisites will ensure that (1) the provision of mobility rehabilitation is within the allied health assistants' scope of practice and (2) they can identify patient circumstances that require further physiotherapist input.[33] Three allied health assistants have a certificate IV qualification and will be trained to provide mobility rehabilitation to participants in this trial.

Routine acute mobility rehabilitation of patients with multimorbidity may include the safe supervision of any form of skills-based and/or functional strengthening exercise, including but not limited to: mobilisation (eg, walking); progression of gait aid; standing or seated lower limb exercises; and education (eg, correct use of gait aid, falls risk strategies, correct performance of exercises).[10] The allied health assistant may provide mobility rehabilitation to patients requiring assistance of two persons to mobilise, with help of another allied health assistant, a nurse, or a physiotherapist.

The allied health assistant will provide mobility rehabilitation after the first physiotherapy assessment. From this assessment the physiotherapist will prescribe the rehabilitation programme and provide a handover to the allied health assistant.[33] All therapy will be tailored to the individual needs of patients and provided face-to-face on the general medical ward. The aim is to provide rehabilitation at least daily during the acute hospital admission. After each treatment, the allied health assistant will inform the physiotherapist of the details of the session and the participant's progress.[33] The physiotherapist will use this feedback to adjust the rehabilitation programme and determine the discharge plan. The allied health

assistant can refer the patient back to the physiotherapist if the participant's condition deteriorates or if their mobility is not progressing as expected. Prior to discharge the physiotherapist will complete a discharge assessment.

The allied health assistant will receive clinical supervision from a physiotherapist. This supervision will include monthly meetings to discuss professional and clinical skill development and may also involve direct supervision/observation of the allied health assistant's management of patients with multimorbidity.[34 35] The allied health assistant will also be educated on acute physiotherapy management of people with multimorbidity prior to the commencement of the trial. The education will be provided by a physiotherapist, with at least 5 years of work experience in general medicine, and include a total of 5 hours of tutorials and clinical exposure learning activities (online supplemental file 5).

Allied health assistant mobility rehabilitation of patients with multimorbidity will be compared with usual practice where a physiotherapist manages the acute mobility rehabilitation (table 1). Allied health assistants may assist the physiotherapist to mobilise a participant who requires the assistance of two people but will not be delegated the role of providing routine mobility rehabilitation for participants randomised to the comparison group. All interventions, including both allied health assistant and physiotherapy mobility rehabilitation, will be provided 5 days per week from Monday to Friday as there is no weekend physiotherapy service on the general medical ward.

Outcomes

Outcomes for this trial will be at the patient, staff and organisational level (table 2). Patient and organisational data will be routinely collected (ie, documented in patient medical records, and hospital costing data systems) with the exception of physical activity, functional activity and patient satisfaction survey, which will be administered by an assessor blind to group allocation. Routinely collected data, with the exception of daily mobilisation, will be collected via the National Centre for Healthy Ageing, Healthy Ageing Data Platform, which curates high-quality data from the health network electronic medical record and costing data system.[36] Routinely collected data on daily mobilisation will be collated by a researcher who is also blind to group allocation; to ensure the quality of this data, we will use a data collection template, categorise data items relating to daily mobilisation (eg, mobilised yes/no, mobilised by assistant/physiotherapist/nurse) and provide training to the data extractor.[37]

Staff involved in the implementation of mobility rehabilitation will be interviewed by a member of the research team, either face-to-face or via video-conferencing (eg, Zoom). Individual semi-structured in-depth interviews will be approximately 30 min duration (table 3). Four areas of focus in the Bowen framework were used to inform development of the interview guide: Acceptability, demand, implementation and practicality.[27] Interviews will be audiotaped and transcribed verbatim. Each participant will be sent a copy of their transcript for correction, clarification, and further comment, to maximise accuracy of the data (a process termed 'member checking').[38]

Primary outcome measure

The primary outcome of feasibility will be determined using the following areas: Acceptability, demand, implementation and practicality.[27] All patient participant outcomes relating to feasibility will be measured at discharge from acute hospital. Staff interviews will be conducted at the conclusion of their involvement in the trial.

Acceptability

Acceptability of allied health assistant mobility rehabilitation will be evaluated by:

- Individual semi-structured interviews with staff members to evaluate satisfaction with allied health assistant mobility rehabilitation, perceived positive and negative effects, intent to continue to use allied health assistant rehabilitation.
- Patient satisfaction with physiotherapy care will be measured using a modified 11-item version of a questionnaire for hospital inpatients receiving physiotherapy care.[25 39] The patient rates their agreement with each item on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree) (table 4).

Demand

Demand for allied health assistant mobility rehabilitation will be evaluated by:

- Individual semi-structured interviews with staff members to establish perceived demand for allied health assistant mobility rehabilitation.
- Proportion of eligible patients who participate.

Implementation

Implementation will evaluate whether allied health assistant mobility rehabilitation is successfully delivered to intended participants by:

- Individual semi-structured interviews with staff members to establish factors affecting implementation ease or difficulty.
- Time allied health assistant/physiotherapist spent with patient participants, with time categorised as direct contact activities (eg, therapy) or indirect (eg, notes).
- Number of physiotherapy/allied health assistant treatment sessions provided to each patient participant.

Practicality

Practicality of allied health assistant mobility rehabilitation will be evaluated by:

- Individual semi-structured interviews with staff members to explore their perception of the positive and negative effects of allied health assistant mobility rehabilitation on patients.

Table 2 Outcome measures

Outcome measure	Description	Administration	Baseline	Daily in acute hospital	Discharge acute	Discharge subacute	30-day follow-up	Trial conclusion
Primary								
Acceptability								
Patient satisfaction	11-item questionnaire, satisfaction with inpatient physiotherapy care	Questionnaire, self-report			✓			
Staff interview	Interview to establish staff satisfaction and intent to use allied health assistant mobility rehabilitation	Interview						✓
Demand								
Proportion of patients who participate	Proportion of eligible patients who participate	Audit			✓			
Staff interview	Interview to establish staff demand for allied health assistant mobility rehabilitation	Interview						✓
Implementation								
Time physiotherapist spends with participant	Time physiotherapist spends performing direct and indirect patient activities	Medical record via data platform			✓			
Time assistant spends with participant	Time assistant spends performing direct and indirect patient activities	Medical record via data platform			✓			
Physiotherapist occasions of service	Occasions of service provided by physiotherapist	Medical record via data platform			✓			
Assistant occasions of service	Occasions of service provided by assistant	Medical record via data platform			✓			
Staff interview	Interview to establish factors affecting implementation ease or difficulty	Interview						✓
Practicality								
Cost of acute physiotherapy service	Cost of acute physiotherapy rehabilitation	Medical record via data platform, pay rates			✓			
Cost of acute patient care	Cost of acute inpatient care	Hospital costing data			✓			
Adverse events	Any incident of patient harm	Medical record via data platform			✓			
Staff interview	Interview to establish staff perception of the positive and negative effects of allied health assistant mobility rehabilitation on patients	Interview						✓

Continued

Table 2 Continued

Outcome measure	Description	Administration	Baseline	Daily in acute hospital	Discharge acute	Discharge subacute	30-day follow-up	Trial conclusion
Secondary								
Patient outcomes								
Physical activity	Daily average time (in minutes) spent walking, lying and sitting; and daily average number of steps	Activity monitor (activPal)		✓				
Compliance with daily mobilisation guidelines	Proportion of days participant mobilises	Medical record audit			✓			
Reason for not mobilising	Documented reason for participant not mobilising	Medical record audit			✓			
Discharge destination	Destination that participant is discharged to	Medical record via data platform			✓	✓		
Hospital readmission	30-day hospital readmission at participating health network	Medical record via data platform					✓	
Recurrent and injurious falls	Falls during acute inpatient admission	Medical record via data platform			✓			
Functional activity - assistance	Modified Iowa Level of Assistance Scale	Clinical assessment	✓		✓			
Organisational outcomes								
Length of stay	Number of days spent in hospital	Medical record via data platform			✓	✓		
Cost of subacute physiotherapy service	Cost of subacute physiotherapy rehabilitation	Medical record via data platform, pay rates				✓		
Cost of subacute patient care	Cost of subacute patient care	Hospital costing data				✓		

Table 3 Semi-structured interview guide

Topic	Sample question	Bowen *et al*[22] area of focus
Introduction	What is your role/position in the physiotherapy department?	Not applicable
	What is your previous experience in managing patients with multimorbidity?	Not applicable
Role of allied health assistant in rehabilitation of patients with multimorbidity and project outcomes	Describe the role that the allied health assistant has in providing rehabilitation to patients with multimorbidity in this study?	Practicality
	Describe the outcomes for (1) patients and (2) staff?	Practicality
	What were the benefits of allied health assistant rehabilitation?	Practicality
	What were the burdens of allied health assistant rehabilitation?	Practicality
	Describe any safety issues with allied health assistant rehabilitation for patients with multimorbidity? How/Why was this the case?	Practicality
Implementation of allied health assistant rehabilitation	Describe your experience with implementing allied health assistant rehabilitation?	Implementation
	What were the barriers/challenges of implementation?	Implementation
	What were the facilitators of implementation?	Implementation
	How could implementation be improved?	Implementation
Future role of allied health assistant rehabilitation	Would you like to continue to use allied health assistant rehabilitation for patients with multimorbidity? Why?	Acceptability/demand
	Describe the sustainability of allied health assistant rehabilitation?	Acceptability/demand
	Do you think any changes should be made to the allied health assistant rehabilitation model of care?	Acceptability/demand
	Tell me about whether allied health assistant rehabilitation can be used in other health settings or with other patient populations?	Acceptability/demand
	How does allied health assistant rehabilitation fit with organisation goals and culture?	Acceptability
	What are the positive/negative effects on the organisation?	Acceptability

- Cost of acute physiotherapy service, based on time spent treating patients and pay rates for allied health assistants and physiotherapists.[40 41]
- Cost of acute patient care will be calculated using hospital costing data.
- Adverse events will include any incident of patient harm. Patient harm events will be categorised as 'not related to the study', 'probably not related to the study', 'unlikely but possibly related' or 'probably related to the study' by an independent, medical academic. Harm events will also be classified as 'serious' or 'non-serious' (see https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm).

Secondary outcome measures

The secondary outcomes for this trial will provide an estimate of the effect of allied health assistant mobility rehabilitation on patient and organisational outcomes.

Patient outcomes

Physical activity will be measured using a tri-axial accelerometer-based activity monitor (activPAL) to objectively measure walking (daily time in minutes spent walking) completed on the ward by people with multimorbidity. The activPAL is a valid and reliable measure of physical activity in older adults.[42] The activity monitor will be attached to the participant's thigh by a member of the research team and will remain in place for the first 7 days after the commencement of rehabilitation, or until the time of discharge from acute hospital if that occurs earlier. To allow for continuous 24-hour monitoring the blinded assessor will tape the activity monitor inside a zip-lock bag affixed to the skin with a waterproof medical dressing. The activity monitor will also provide data for secondary analysis of the number of daily steps. Sedentary behaviour will be expressed as daily time spent sitting or lying.

The *number of days that the patient mobilises* during their acute hospital stay will be audited at discharge from acute hospital. For the purpose of this trial, mobilisation will be measured on an ordinal scale: (1) Step transfer out of bed; (2) standing or walking less than 5 m; and (3) walking away from the bedside for a distance of at least 5 m.[25] The healthcare worker(s) who mobilise the patient will be recorded. *Documented reasons for patients not mobilising*, including the days on which mobilisation is medically contraindicated, will also be recorded.

Discharge destination will be selected from the following destinations: (1) home; (2) relative/friend's home; (3) residential care; (4) inpatient transition care programme; (5) sub-acute rehabilitation/geriatric evaluation and management.

Table 4 Modified patient satisfaction questionnaire

Item no.	Item
1	My therapists were good about explaining the reason for my physiotherapy
2	The therapists were thorough in treating and examining me
3	I had easy access to the therapists I needed regarding feedback on my physiotherapy
4	My therapists treated me in a very friendly and courteous manner
5	Those who provided my physiotherapy care always took their time when they treated me
6	The therapists always acknowledged what I told them
7	I had no doubts about the ability of the therapists who treated me
8	The therapists who treated me had a genuine interest in me as a person
9	The therapists who treated me gave me respect
10	During my physiotherapy care I was allowed to say everything that I thought was important
11	I was very satisfied with the physiotherapy care I received

NB: The patient rates their agreement with each statement on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree).

Thirty-day hospital readmission will include any unplanned readmission within 30-days of discharge from the health service (ie, readmission from private residence). Planned admissions will be excluded.[43 44]

Recurrent and injurious falls during acute hospital stay will be recorded, where a fall is defined as 'unintentionally coming to rest on the ground, floor, or other lower level'.[45] Falls will be classified to reflect the degree of harm; falls that result in either the permanent or temporary loss of function will be classified as an 'injurious fall', while falls that result in no loss of function will be classified as a 'non-injurious' fall.

Functional activity at baseline and discharge from acute hospital will be measured using the Modified Iowa Level of Assistance Scale (mILOA). The mILOA consists of six items and measures the assistance required to achieve functional tasks, including moving from lying to sitting on the edge of the bed; moving from sitting to standing; walking; and negotiating one step. It also measures walking distance and the use of an assistive device. For each item of the mILOA, a score from 0 to 6 is given for the amount of assistance required. The mILOA total score is the sum of all six items (range 0–36), with a higher score representing more assistance. The mILOA has excellent inter-rater reliability and known-groups validity and is responsive to functional change in acute hospital inpatients.[46] Further, the mILOA has been shown to correlate significantly with the Elderly Mobility Scale.[47]

Patient demographic data, including age, gender, living arrangements, medical comorbidities, surgical approach and premorbid mobility will also be routinely collected. Survival risk associated with medical comorbidities will be summarised using the Charlson Comorbidity Index.[48]

Organisational outcomes

Patient length of stay will be measured as the number of days from (1) patient admission to discharge from acute hospital (acute hospital length of stay) or (2) patient admission to discharge from subacute hospital (subacute length of stay). The length of stay will therefore, be inclusive of the patient's time spent in both acute and subacute hospital, where applicable.

Cost of subacute physiotherapy service will be calculated using the time spent treating and managing participants and pay rates for allied health assistants and physiotherapists.[40 41] *Cost of subacute patient care* will be calculated using hospital costing data. Costs related to subacute care have been categorised as a secondary outcome because the allocated intervention will be ceased at time of discharge from acute hospital and is not expected to have a direct effect on costs related to subacute care.

Data analysis

Data monitoring and auditing

As this is a small, investigator-initiated feasibility trial, there is no external data monitoring committee. Audits are routinely completed by the approving ethics committee, on an annual basis.

Sample size estimation

We aim to recruit 60 patient participants, a sample size comparable to other feasibility trials, which should enable the primary aim of feasibility to be addressed.[25 49 50] We also plan to interview 6–10 staff participants, as recommended for thematic analysis of small qualitative projects.[51]

Data analysis plan

We will determine the feasibility of the model of care using a realist approach which considers both quantitative and qualitative data.[52] Allied health assistant mobility rehabilitation will be considered feasible if[25]:

1. Patients and staff find the intervention to be acceptable.
2. Staff report demand for allied health assistant mobility rehabilitation.
3. At least 50% of eligible patients participate in the trial (exceeding the 25th percentile for recruitment rates of published RCTs[53]) OR a recruitment rate of at least seven participants per month is achieved.
4. Allied health assistant rehabilitation can be implemented in acute care with high fidelity.
5. Allied health assistant mobility rehabilitation is safe for patients with multimorbidity.
6. The cost of allied health assistant mobility rehabilitation is comparable to, or less than, the cost of usual care of physiotherapy mobility rehabilitation.

Descriptive statistics will describe the characteristics of the sample by group (means (SD), percentages

and frequencies) as well as patient satisfaction, the time physiotherapist/allied health assistant spent with patient, cost of physiotherapy service/patient care and adverse events.[54] Analyses will be completed according to intention-to-treat principles. Cost analysis will be from a health service perspective with a time horizon inclusive of the acute hospital admission.

Physical activity will be measured via patients' daily average time (in minutes) spent walking. A difference in daily average walking time between groups will be investigated via Poisson or negative binomial regression. Missing data will be managed via multiple imputation, and this feasibility study will help to clarify the extent to which missing data for this outcome presents a problem in analysis. Analyses will be repeated for daily average number of steps and daily average time (in minutes) spent sedentary in lying and sitting.

Daily mobilisation will be analysed via a time-to-event framework, and mobilisation rate ratios will be calculated using Cox proportional hazards regression to directly compare mobilisation rates in the experimental and comparison groups. As patients can have multiple mobilisations, recurrent event data will be analysed via the Williams and Peterson Gap time survival model, with robust SEs to account for correlation within patients.[55] In survival analyses, discharge will be considered a censoring event. This equates to an assumption that data regarding mobilisation on days following discharge are missing at random (given timing of discharge). The appropriateness of this assumption will be checked in sensitivity analyses. No interim analyses will be conducted.

Length of stay will be analysed using survival analysis (time-to-discharge). If any randomised patient dies during the trial, death will be modelled as a competing risk. Sensitivity analysis will be conducted stratifying for complex admissions, where a complex admission is defined as any admission where a participant is readmitted to an acute hospital from a subacute hospital. Functional activity (mILOA) will be analysed using linear regression controlling for baseline scores.[56]

Dichotomous outcomes will be analysed using logistic regression. These include discharge destination (home vs residential care), 30-day readmission (30-day readmission vs no readmission) and faller (fall vs no falls).

This trial will be reported according to the Consolidated Standards of Reporting Trials 2010 checklist for randomised pilot and feasibility trials, including losses and exclusions after randomisation, missing data and the number of patients who crossed over (ie, were referred back to the physiotherapist) including the reasons why.[57]

Qualitative analysis of transcripts will be undertaken by two investigators independently, using qualitative data management software.[58] The de-identified transcripts will be read by each investigator and codes devised to represent the data. Codes will be reviewed and emerging themes will be developed inductively through a process of collapsing codes together and defining categories.[59] Emergent themes will then be mapped onto areas of focus in Bowen's framework.[27] Consensus between the investigators on the emerging themes and categories will be achieved through discussion.

DISCUSSION

If the feasibility of allied health assistant mobility rehabilitation (ie, the intervention) is supported in terms of acceptability, practicality, implementation and therapist demand, then patient demand (recruitment rate), the amount of missing data and estimates of effect will be used to inform planning for a larger full-scale RCT.[60] Outcomes with minimal missing data, potentially worthwhile treatment effects, and/or clinically important measures will be considered for inclusion in the main trial. Estimated effects will be considered 'potentially worthwhile' if clinically important differences are contained within the 95% CI.[61 62] The proposed primary outcome (ie, mILOA) and trial design (ie, non-inferiority RCT) will inform the required sample size for a larger trial, with the recruitment rate from our feasibility trial informing practical decisions for reaching the target sample size, such as the number of wards participating and the length of time the larger trial will run.

Patient and public involvement statement

Patients and the public have not been involved in the design of this study. Patients will be involved in determining the acceptability of allied health assistant care through completion of a satisfaction questionnaire.

ETHICS AND DISSEMINATION

Ethical approval was granted by Peninsula Health ethics committee before the trial commenced (HREC/97431/PH-2023). Participants will provide their own written consent to participate OR where participants do not have capacity to provide their own consent, consent will be obtained from their medical treatment decision-maker on behalf of the participant. Findings will be disseminated in peer-reviewed journals and conference presentations.

Trial status

Enrolment for the trial began in August 2023 and is still in progress. Data collection will continue until April 2024.

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REFERENCES

1 World Health Organization. Multimorbidity: technical series on safer primary care. 2016. Available: https://apps.who.int/iris/bitstream/handle/10665/252275/9789241511650-eng.pdf
2 Ho IS-S, Azcoaga-Lorenzo A, Akbari A, *et al*. Variation in the estimated prevalence of Multimorbidity: a systematic review and Metanalysis of 193 International studies. *BMJ Open* 2022;12:e057017.
3 Palladino R, Tayu Lee J, Ashworth M, *et al*. Associations between Multimorbidity, Healthcare utilisation and health status: evidence from 16 European countries. *Age Ageing* 2016;45:431–5.
4 Tazzeo C, Zucchelli A, Vetrano DL, *et al*. Risk factors for Multimorbidity in adulthood: A systematic review. *Ageing Res Rev* 2023;91:S1568-1637(23)00198-8.
5 Gill TM, Allore HG, Gahbauer EA, *et al*. Change in disability after hospitalization or restricted activity in older persons. *JAMA* 2010;304:1919–28.
6 Boyd CM, Landefeld CS, Counsell SR, *et al*. Recovery of activities of daily living in older adults after hospitalization for acute medical illness. *J Am Geriatr Soc* 2008;56:2171–9.
7 Martínez-Velilla N, Casas-Herrero A, Zambom-Ferraresi F, *et al*. Effect of exercise intervention on functional decline in very elderly patients during acute hospitalization: A randomized clinical trial. *JAMA Intern Med* 2019;179:28–36.
8 The Lancet. The lancet (editorial). making more of Multimorbidity: an emerging priority. *Lancet* 2018;391:391.
9 Bricca A, Harris LK, Jäger M, *et al*. Benefits and harms of exercise therapy in people with Multimorbidity: A systematic review and meta-analysis of randomised controlled trials. *Ageing Research Reviews* 2020;63:101166.
10 Taylor NF, Dodd KJ, Shields N, *et al*. Therapeutic exercise in Physiotherapy practice is beneficial: a summary of systematic reviews 2002-2005. *Aust J Physiother* 2007;53:7–16.
11 Holdar U, Wallin L, Heiwe S. Why do we do as we do? factors influencing clinical reasoning and decision-making among Physiotherapists in an acute setting. *Physiother Res Int* 2013;18:220–9.
12 Thomas S, Mackintosh S, Halbert J. Determining current physical therapist management of hip fracture in an acute care hospital and physical therapists' rationale for this management. *Phys Ther* 2011;91:1490–502.
13 Walkeden S, Walker KM. Perceptions of Physiotherapists about their role in promotion at an acute hospital: a qualitative study. *Physiotherapy* 2015;101:226–31.
14 McCullagh R, Dillon C, Dahly D, *et al*. Walking in hospital is associated with a shorter length of stay in older medical Inpatients. *Physiol Meas* 2016;37:1872–84.
15 Tasheva P, Vollenweider P, Kraege V, *et al*. Association between physical activity levels in the hospital and hospital-acquired functional decline in elderly patients. *JAMA Netw Open* 2020;3:e1920185.
16 Flaherty E, Bartels SJ. Addressing the community-based geriatric Healthcare workforce shortage by Leveraging the potential of Interprofessional teams. *J Am Geriatr Soc* 2019;67:S400–8.
17 Duckett S, Breadon P. Unlocking skills in hospitals: better jobs, more care. 2014. Available: http://grattan.edu.au/wp-content/uploads/2014/05/810-unlocking-skills-in-hospitals.pdf
18 Snowdon DA, Storr B, Davis A, *et al*. The effect of delegation of therapy to Allied health assistants on patient and Organisational outcomes: a systematic review and meta-analysis. *BMC Health Serv Res* 2020;20:491.
19 Somerville L, Davis A, Elliott AL, *et al*. Building Allied health workforce capacity: a strategic approach to workforce innovation. *Aust Health Rev* 2015;39:264–70.
20 Lizarondo L, Kumar S, Hyde L, *et al*. Allied health assistants and what they do: A systematic review of the literature. *J Multidiscip Healthc* 2010;3:143–53.
21 Brice-Leddy L, Park D, Bateman W, *et al*. Enabling access to rehabilitation in acute care exploring Physiotherapists' and occupational therapists' perspectives on patient care when assistants become the primary therapy provider. *Physiother Can* 2020;72:169–76.
22 Eliassen M, Henriksen N, Moe S. The practice of support personnel, supervised by Physiotherapists, in Norwegian Reablement services. *Physiother Res Int* 2019;24:e1754.
23 Sørvoll M, Obstfelder A, Normann B, *et al*. How Physiotherapists supervise to enhance practical skills in dedicated aides of toddlers with cerebral palsy: A qualitative observational study. *Physiotherapy Theory and Practice* 2019;35:427–36.
24 Snowdon DA, King OA, Dennett A, *et al*. Delegation of patient related tasks to Allied health assistants: a time motion study. *BMC Health Serv Res* 2022;22:1280.
25 Snowdon DA, Vincent P, Callisaya ML, *et al*. Feasibility of Allied health assistant management of people with acute hip fracture: protocol for a feasibility randomised controlled trial. *BMJ Open* 2021;11:e054298.
26 Peiris CL, Shields N, Brusco NK, *et al*. Additional physical therapy services reduce length of stay and improve health outcomes in people with acute and subacute conditions: an updated systematic review and meta-analysis. *Arch Phys Med Rehabil* 2018;99:2299–312.
27 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
28 Australian Bureau of Statistics. *Census Quickstats: Mornington Peninsula (S)*. Geelong (VIC): Australian Bureau of Statistics, 2021. Available: https://www.abs.gov.au/census/find-census-data/quickstats/2021/214
29 Australian Government. *Chronic conditions and multimorbidity*. Canberra (ACT): Australian Institute of Health and Welfare, 2022. Available: https://www.aihw.gov.au/reports/australias-health/chronic-conditions-and-multimorbidity
30 Stroke Foundation. *Clinical Guidelines for Stroke Management*. Melbourne Australia, 2022.
31 Australian and New Zealand Hip Fracture Registry (ANZHFR) Steering Group. Australian and New Zealand Guideline for Hip Fracture Care: Improving Outcomes in Hip Fracture Management of Adults, Available: https://anzhfr.org/wp-content/uploads/2016/07/ANZ-Guideline-for-Hip-Fracture-Care.pdf
32 Pfeiffer E. A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. *J Am Geriatr Soc* 1975;23:433–41.
33 Department of Health. Supervision and delegation framework for allied health assistants, Available: https://content.health.vic.gov.au/sites/default/files/migrated/files/collections/policies-and-guidelines/

s/supervision-and-delegation-framework-for-allied-health-assistants.pdf
34 Snowdon DA, Leggat SG, Harding KE, *et al*. Direct supervision of Physiotherapists improves compliance with clinical practice guidelines for patients with hip fracture: a controlled before-and-after study. *Disabil Rehabil* 2020;42:3825–32.
35 Snowdon DA, Cooke S, Lawler K, *et al*. Physiotherapists prefer clinical supervision to focus on professional skill development: a qualitative study. *Physiother Can* 2020;72:249–57. 10.3138/ptc-2019-0004 Available: https://www.researchgate.net/publication/338379618_Physiotherapists_Prefer_Clinical_Supervision_to_Focus_on_Professional_Skill_Development_A_Qualitative_Study
36 Andrew NE, Beare R, Ravipati T, *et al*. Developing a linked electronic health record derived data platform to support research into healthy ageing. *Int J Popul Data Sci* 2023;8:2129.
37 Gregory KE, Radovinsky L. Research strategies that result in optimal data collection from the patient medical record. *Appl Nurs Res* 2012;25:108–16.
38 Krefting L. Rigor in qualitative research: the assessment of trustworthiness. *Am J Occup Ther* 1991;45:214–22. 10.5014/ajot.45.3.214 Available: https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-14-108
39 Ampiah PK, Ahenkorah J, Karikari M. Patients' satisfaction with inpatient Orthopaedic Physiotherapy services at a tertiary hospital in Ghana. *J Patient Exp* 2019;6:238–46.
40 Victorian Government. Allied health professionals (Victorian public health sector) (single interest employers) enterprise agreement 2021-2026. 2021.
41 Victorian Government. Health and Allied services, managers and administrative workers (Victorian public health sector) (single interest employers) enterprise agreement 2021-2025. 2021.
42 Wu Y, Petterson JL, Bray NW, *et al*. Validity of the activPAL monitor to measure stepping intensity: A systematic review. *Gait & Posture* 2022;97:165–73.
43 Fisher SR, Kuo Y-F, Sharma G, *et al*. Mobility after hospital discharge as a marker for 30-day readmission. *J Gerontol A Biol Sci Med Sci* 2013;68:805–10.
44 Kim SJ, Lee JH, Han B, *et al*. Effects of hospital-based physical therapy on hospital discharge outcomes among hospitalized older adults with community-acquired pneumonia and declining physical function. *Aging Dis* 2015;6:174–9.
45 Buchner DM, Hornbrook MC, Kutner NG, *et al*. Development of the common data base for the FICSIT trials. *J American Geriatrics Society* 1993;41:297–308. 10.1111/j.1532-5415.1993.tb06708.x Available: https://agsjournals.onlinelibrary.wiley.com/toc/15325415/41/3
46 Kimmel LA, Elliott JE, Sayer JM, *et al*. Assessing the Reliability and validity of a physical therapy functional measurement tool—the modified Iowa level of assistance scale—in acute hospital Inpatients. *Phys Ther* 2016;96:176–82.
47 Soh S-E, Stuart L, Raymond M, *et al*. The validity, reliability, and responsiveness of the modified Iowa level of assistance scale in hospitalized older adults in subacute care. *Disabil Rehabil* 2018;40:2931–7.
48 Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying Prognostic Comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.
49 Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011;45:626–9.
50 Salisbury LG, Merriweather JL, Walsh TS. The development and feasibility of a ward-based Physiotherapy and nutritional rehabilitation package for people experiencing critical illness. *Clin Rehabil* 2010;24:489–500.
51 Braun V, Clarke V. *Successful Qualitative Research: A Practical Guide for Beginners*. Newcastle upon Tyne, UK: SAGE, 2013.
52 Fletcher A, Jamal F, Moore G, *et al*. Realist complex intervention science: applying realist principles across all phases of the medical research Council framework for developing and evaluating complex interventions. *Evaluation (Lond)* 2016;22:286–303.
53 Jacques RM, Ahmed R, Harper J, *et al*. Recruitment, consent and retention of participants in randomised controlled trials: a review of trials published in the National Institute for health research (NIHR) journals library (1997-2020). *BMJ Open* 2022;12:e059230.
54 Lee EC, Whitehead AL, Jacques RM, *et al*. The statistical interpretation of pilot trials: should significance thresholds be reconsidered *BMC Med Res Methodol* 2014;14:41.
55 Kelly PJ, Lim LLY. Survival analysis for recurrent event data: an application to childhood infectious diseases. *Stat Med* 2000;19:13–33.
56 Vickers AJ, Altman DG. Analysing controlled trials with baseline and follow up measurements. *BMJ* 2001;323:1123–4.
57 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
58 QSR International Pty Ltd. Nvivo qualitative data analysis software (version 10). 2012.
59 Saldana J. *The coding manual for qualitative researchers, 3rd edn*. Thousand Oaks (CA): Sage, 2016.
60 Arain M, Campbell MJ, Cooper CL, *et al*. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol* 2010;10:67.
61 Cooper I, Brukner P, Devlin BL, *et al*. An anti-inflammatory diet intervention for knee osteoarthritis: a feasibility study. *BMC Musculoskelet Disord* 2022;23:47.
62 McGlothlin AE, Lewis RJ. Minimal clinically important difference: defining what really matters to patients. *JAMA* 2014;312:1342–3.