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Complete List of Authors:	Naseri, Chiara; Curtin University, Faculty of Health Science, School of Physiotherapy and Exercise Science McPhail, Steven; Queensland University of Technology, School of Public Health and Social Work, Faculty of Health; Metro South Hospital and Health Service, Centre for Functioning and Health Research Netto, Julie; Curtin University, Faculty of Health Science, School of Occupational Therapy and Social Work Haines, Terrence; Monash University, Faculty of Medicine, Nursing & Health Science Morris, Meg; La Trobe University, Healthscope & La Trobe Centre for Sport & Exercise Medicine Research Etherton-Beer, Christopher; University of Western Australia, School of Medicine and Pharmacology; University of Western Australia, WA Centre for Health & Ageing Flicker, Leon; University of Western Australia, WA Centre for Health & Ageing Lee, Den-Ching ; Monash University, Faculty of Medicine, Nursing and Health Science Francis-Coad, Jacqueline; The University of Notre Dame Australia, School of Physiotherapy, Institute for Health Research Hill, Anne-Marie; Curtin University, School of Physiotherapy and Exercise Science
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AUTHORS:

Chiara Naseri [1] B.Sc (Physiotherapy)

Steven McPhail [2,3] PhD

Julie Netto [4] PhD

Terrence Haines [5] PhD

Meg E Morris [6] PhD

Christopher Etherton-Beer [7] PhD

Leon Flicker [8] PhD

Den-Ching A Lee [5] PhD

Jacqueline Francis-Coad [9] PhD

Anne-Marie Hill [1] PhD

This study was conducted at Curtin University, Faculty of Health Science, School of Physiotherapy and Exercise Science.

Author institutional affiliations:

1. School of Physiotherapy and Exercise Sciences, Faculty of Health Science, Curtin University, Perth, Western Australia

2. School of Public Health and Social Work, Faculty of Health, Queensland University of Technology

3. Centre for Functioning and Health Research, Metro South Health, Brisbane, Queensland

4. School of Occupational Therapy and Social Work, Faculty of Health Science, Curtin University, Perth, Western Australia

5. Faculty of Medicine, Nursing and Health Science, Monash University, Melbourne, Victoria

6. Healthscope & La Trobe Centre for Sport & Exercise Medicine Research, La Trobe University, Victoria, Australia

7. Department of Geriatric Medicine, School of Medicine and Pharmacology, Royal Perth Hospital Unit, University of Western Australia, Perth, Western Australia

8. Western Australian Centre for Health & Ageing, Centre for Medical Research, University of Western Australia, Perth, Western Australia

9. School of Physiotherapy, Institute for Health Research, The University of Notre Dame Australia, Fremantle, Western Australia

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Corresponding author from whom reprints can be obtained:

Chiara Naseri

School of Physiotherapy and Exercise Science

Faculty of Health Science, Curtin University

GPO Box U1987

Perth, Western Australia 6845

chiara.naseri@postgrad.curtin.edu.au

Tel: +61 8 9266 4104 Mobile: +61409 570 448

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ABSTRACT

Introduction Older adults recently discharged from hospital have greater incidence of adverse events, functional decline, falls and subsequent re-admission. Providing education to hospitalised patients on how to prevent falls at home could reduce post-discharge falls. There has been limited research investigating how older adults respond to tailored falls prevention education provided at hospital discharge. The aim of the study is to evaluate how providing tailored falls prevention education to older patients at the point of, and immediately after hospital discharge in addition to usual care, affects engagement in falls prevention strategies in the six months post-discharge period, including their capability and motivation to engage in falls prevention strategies.

Methods and analyses This prospective observational cohort study is nested within a randomised controlled trial, using an embedded mixed-method design. Participants (n=390) are over the age of 60, scoring greater than 7/10 on the Abbreviated Mental Test Score. Participants discharged from hospital rehabilitation wards in Perth, Western Australia, will followed up for six months post-discharge. Primary outcome measures are engagement in falls prevention strategies, including exercise, home modifications and receiving assistance with activities of daily living. Secondary outcomes will measure capability, motivation and opportunity to engage in falls prevention strategies, based on the constructs of the COM-B behaviour system. Quantitative data for the primary and secondary outcomes are collected at baseline, then at six months post-discharge using structured phone interviews. Qualitative data for the secondary outcomes are collected from a purposive sample of the cohort, using a semi-structured in-depth phone interviews. Quantitative data will be analysed using regression modelling and qualitative data will be analysed using interpretive phenomenological analysis.

Ethics and dissemination Results will be presented in peer-reviewed journals and at conferences worldwide. This study is approved by hospital and university Human Research Ethics Committees.

Trial Registration: This study is nested within the larger "Back to My Best" clinical trial (ANZCTR - ACTRN12615000784516)

Strengths and limitations of this study

- This process evaluation will be nested within a larger RCT representing a broad cohort of older adults recruited from three public metropolitan rehabilitation hospitals in Australia.
- While the main trial aims to reduce falls following hospital discharge by increasing older adults' engagement in falls prevention strategies, this study will assess their response to the tailored falls prevention education intervention during their post-discharge recovery.
- It will determine if providing tailored falls prevention education can facilitate capability, opportunity, and motivation for older adults to engage in falls prevention strategies at home after hospital discharge.
- The prospective design, robust data collection and the convergent embedded mixed method design uses triangulation to describe the effects of the education on engagement in falls prevention strategies, to outline barriers to engagement and provide a more holistic understanding of the factors that mediate the effectiveness of the intervention.
- A possible limitation is that the participants have been drawn from a high-risk population that may still be affected by their illness

BACKGROUND

Globally, falls and falls-related injuries have been identified as a major public health problem associated with population ageing, causing physical injuries including hip fracture, head injury and negatively impacting quality of life among older people. [1-4] In 2015, direct medical costs for fatal falls in the US have more than tripled since the year 2000, [5] and in Australia the age-standardised falls-related hospitalisations for older adults has continued to increase by 2.3% per year. [6] Direct costs do not account for the long-term effects of these injuries such as permanent disability, dependence on others and reduced participation in life. [7-9]

Falls are known to be increased among older adults who have been discharged from hospital, [10-13] and it is also known that hospitalisation of older adults, including those who are admitted for acute care and rehabilitation, is associated with decline in function and mobility. [13-16] At least 40% of older adults fall at least once in the six-months period following hospital discharge, with more than half of falls resulting in an injury. [17, 18] This is substantially higher than the annual rate of falls (30%) and injurious falls (10%) reported in the general community. [19]

There is evidence for the effectiveness of exercise and physical activity in reducing falls among older community dwelling adults including those with comorbidities. [20-22] There is also evidence that interventions, including home safety modifications and vitamin d supplementation are effective in reducing falls. [23, 24] However this evidence does not specifically apply to the older population who have been recently hospitalised. A wide variety of interventions have been evaluated for their efficacy in improving transitions from hospital to home, but these were not focused specifically on falls prevention, and systematic reviews of

these trials have suggested they produce limited positive outcomes and do not significantly reduce adverse events including falls. [25-29]

Older people have been found to have low levels of awareness of the risk of falls, despite their increased falls risk during the post-discharge period. [30, 31 Previous research has also shown that older adults have reduced knowledge about how best to prevent falls after they return home from hospital. [32, 33] A recent study showed that older people understood and effectively engaged in their discharge plan, yet experienced unanticipated problems, such as difficulty taking medications, uncontrolled pain, poor dietary intake and fragmented social supports, indicating that more support may be required. [34] A pilot randomised controlled trial (RCT) demonstrated that tailored education was received positively by older adults and resulted in increased engagement in falls prevention strategies after discharge, [35] and a recent systematic review found that falls prevention programs that contained a patient education component were effective in reducing rate of falls after hospital discharge. [36] However, there has been no RCTs to date to show that using patient education alone can reduce falls after discharge.

An RCT in which this study is nested, [37] (n=390) is the first trial being undertaken to evaluate whether providing tailored falls prevention education, that includes individual health professional consultations in hospital and after discharge in addition to usual care, reduces falls rates in older adults after discharge from hospital.

Tailored health education aims to change individuals' health behaviours. [38, 39] When this education is used as an intervention, it presents a challenge for identifying effective components, and therefore reporting of findings, and subsequent replication. [40, 41] The

behaviour of interest in this study is engagement in falls prevention strategies, with the intention of reducing falls after hospital discharge. [37] The intervention has been developed using the framework of the Capability Opportunity Motivation Behaviour (COM-B) model of health behaviour change. [42] Capability includes an individual's psychological and physical capacity to engage in falls prevention strategies behaviour. Opportunity, both social and physical, includes those factors that lie outside the individual that make the behaviour possible, such as being able to access home assistance or modifications. [42] Motivation includes all processes that inspire and direct behaviour, such as believing that it would be good to exercise. [42] The use of a theoretical framework to design and measure tailored health education facilitates understanding of a possible causal relationship between the intervention and the desired behaviour, and enables identification of active intervention components designed to change behaviour. [41] The aim of the main trial is to reduce falls by increasing engagement in falls prevention strategies, therefore it is important to understand if the education has the intended effect on this intermediate outcome of engagement in falls prevention strategies, to understand the effect of the intervention on falls rates. [37] It is yet to be determined if providing tailored falls prevention education can facilitate capability, opportunity, and motivation for older adults to engage in falls prevention strategies at home after hospital discharge. (Figure 1)

STUDY AIMS

The primary aim is to evaluate the impact of tailored falls prevention education provided at hospital discharge in addition to usual care, on older adults 'engagement in falls prevention strategies in the six months after hospital discharge. This will be compared to those who receive usual care alone. The secondary aims are a) to evaluate older adults' capability, and motivation, to engage falls prevention strategies for those participants who received tailored

falls prevention education in addition to usual care, compared to those that received a social intervention in addition to usual care; and b) to identify the opportunity (social and physical environment) surrounding the participant that made the behaviour possible, by exploring the barriers and facilitators identified by older adults to engage in falls prevention strategies in the six months following hospital discharge

METHOD

Design

The study design comprises a process evaluation which is nested within a RCT currently being conducted in Perth, Australia [37]. The process evaluation uses a convergent embedded mixed method design; [43, 44] as both quantitative and qualitative data will be collected, analysed, then merged to enrich the interpretation of the results through methodological triangulation. Measuring engagement is a complex concept. [45, 46] By using triangulation to describe the effects of the education on engagement in falls prevention strategies through both quantitative and qualitative data sources, this aims to provide a more holistic understanding of the phenomena. [47, 48]

Ethical considerations

The study is nested within the larger "Back to My Best" clinical trial (ANZCTR - ACTRN12615000784516). [37] Ethics approvals have been obtained from Human Research Ethics Committee of North Metropolitan Health Service and South Metropolitan Health Service with reciprocal approval from The University of Notre Dame Australia and Curtin University. Participant information forms are provided at the time of consent at baseline in

hospital as a part of the RCT and all participants will provide written informed consent to participate in the study.

Setting and Participants

The setting and participants have been described in full previously. [37] Briefly, participants (n=390) who have been recruited in hospital as a part of the main RCT, [37] provide written informed consent and are then randomly assigned (concealed) to either the intervention group or the control group prior to discharge from aged care rehabilitation and stroke units at three WA hospitals. These wards admit patients with a variety of diagnoses, such as osteoarthritis, recent stroke, Parkinson's disease, dementia, recent orthopaedic or general surgery, or recovering from a general medical condition.

Inclusion and Exclusion Criteria

Inclusion criteria for the RCT have been described previously [37]. All participants will contribute data for this process evaluation. Briefly, participants must be 60 years of age or older, and have cognitive function rated >7/10 in Abbreviated Mental Test Score (AMTS) [49]

Outcome Measures

Quantitative

Primary outcome: engagement in falls prevention strategies in the six months after discharge. Falls prevention strategies measured are those suggested to the participant as a part of the tailored education intervention, which is based on current evidence for falls prevention, provided prior to discharge. Each participant has been encouraged to engage in a falls

prevention plan which has been tailored by the delivering therapists. This intervention has been described in full elsewhere. [37] Strategies are defined as:

i. Receiving assistance (both formal and informal assistance) with activities of daily living (ADL). Activities of daily living are defined according to the Katz index of Independence in Activities of Daily Living, [50] and include toileting, showering, and eating.

ii. Receiving assistance with instrumental activities of daily living (IADL). Instrumental ADL are defined using the Lawton index, [51] and include home cleaning, shopping, transport.

These two outcomes will be measured using yes/no responses and also frequency (days per week and hours of total assistance per week) and type of assistance (whether paid formal services from home care provider or informal family or friends' assistance to the participant).

iii. Engagement in exercises, including all type and frequency (hours per week and number of times per week) and where completed such as at home, in a healthcare centre, with or without provider assistance.

iv. Home modifications, such as installation of equipment or rails, or alteration of home layout, including whether assessment was provided by an occupational therapist and the level of assistance obtained to make these modifications.

These primary outcomes will be measured in hospital (baseline) by recruiters for the main RCT (who are blinded to group allocation), then measured at six-months following hospital discharge through a structured phone survey by a trained research assistant who is also blinded to group allocation. These surveys have been modified from previous surveys used in falls prevention trials, including the pilot trial which evaluated these outcomes. [18, 33, 35, 52, 53]

The secondary quantitative outcome measures are:

i. Participants perceived levels of capability (knowledge and awareness) about falls prevention after discharge, such as awareness of risk of falls, awareness of injury and benefits of engaging falls prevention strategies; measured through a structured phone survey using Likert scales, [54] at baseline and at six-month follow up.

ii. Motivation, such as beliefs in benefits of engaging strategies, confidence to engage strategies; develops and enacts plan to engage strategies.

These secondary outcomes will be measured alongside the primary outcomes, using the methods described above. Survey items for secondary outcomes will be measured using five-point Likert scales, [54] (strongly agree to strongly disagree). Items are based on the domains of the COM-B, [42] and modified from previous surveys which have evaluated capability, motivation and confidence regarding falls prevention. [18, 33, 35, 52, 53]

iii. Motivation to engage in exercise will be additionally measured using the Self-Efficacy for Exercise scale (SEE). [55]

The Self-Efficacy for Exercise scale (SEE), [55] a 9-item scale that rates older peoples' response to a statement about barriers to exercise (scores range from 0=not very confident to 10=very confident; with a total possible score of 90). [56]

Qualitative

The secondary qualitative outcomes relate to opportunity (described as being both social and physical in the COM-B framework), [42] and include both barriers and enablers that participants encounter when seeking to engage in falls prevention strategies. These secondary outcomes will be measured by completing semi-structured in-depth phone interviews at the conclusion of the observation period. Questions will be guided by participant responses gained from earlier structured phone interviews, using open-ended questions designed to encourage

the participants to reflect on their previous responses. Questions will be framed around barriers and enablers to engaging in falls prevention strategies, graduated return to independence and engaging in exercise. This may be physical opportunity provided by their environment including access and social supports, or cultural milieu including stigmas or fears that dictate older adult decision-making. [42]

Demographic data will be gathered in hospital at baseline by recruiters during a face to face interview as a part of the RCT. These data will include age, gender, diagnosis, length of stay in hospital, history of falls prior to hospitalisation and during hospital stay, presence of visual impairment, presence of hearing impairment, number and type of medications, signs of depression (measured using Geriatric Depression Scale), [57] and use of walking aids.

Other data is also collected at baseline during the face to face interview then again at six-months after discharge using a structured phone survey. These variables are living situation (home alone, with partner, other situation), level of indoor and outdoor mobility, including any use of walking aids, functional mobility measured using Katz and Lawton's Scales [50, 51], and health related quality of life measured using the Assessment of Quality of Life tool (AQoL) [58].

Additionally, as part of the main trial, data are collected regarding the intervention provision by the educators. These data include the number of education sessions provided to each intervention group participant, the duration, and whether an action plan was completed. These data will also be used during sensitivity analyses, to assist to explain participants knowledge, motivation, and engagement in falls prevention strategies after discharge.

Data collection and procedure

Baseline surveys for primary and secondary outcomes are conducted by a trained research assistant who is blinded to group allocation, then participants are randomly allocated to intervention or control group. The RCT protocol, including randomisation, blinding, and the intervention procedure has been described in detail elsewhere. [37] Briefly, participants receive tailored falls prevention education by trained physiotherapist educators during a one-to one interaction in hospital, between 2 and 4 sessions for approximately 45 minutes, incorporating a video and workbook. The education assists the participant to prepare a tailored plan to initiate after hospital discharge. The participants are then followed up by phone after discharge by the educators once a month for three months, to further assist them to enact their plan, and address any barriers that may have arisen since discharge.

At six-months following hospital discharge, the structured qualitative phone survey will be conducted to collect quantitative follow up data, after which the participant will be invited to participate in a semi-structured in-depth phone interview to collect qualitative data that measures the secondary outcome which explores opportunity (barriers and enablers) to engagement in falls prevention strategies.

Purposive sampling for qualitative data collection will occur after the 6-month period and following completion of primary and secondary quantitative data collection. The sample selected will represent the cohort, with consideration of age, diagnosis, gender, falls history, and whether intervention or control group. Purposive sampling will be finalised and justified by referring to data and theoretical saturation and confirmed through consensus of a second researcher reviewing the transcribed narrative data.[47, 59] A phone interview was selected to collect data, rather than a focus group, or face to face interview, as the participants have

previously received monthly phone monitoring of falls data from the RCT, so the researcher has established a genuine rapport and reciprocity with the participants.[60] To ensure quality data collection that is sufficient to answer the study aim, the semi-structured survey has been piloted to ensure the questions are easily understood and screened for blind spots, bias, and potentially sensitive questions. [47] Each interview will be recorded and transcribed verbatim. [60, 61]. Additional interviews will be completed as necessary until data saturation has occurred. [47, 59, 61] The researcher will keep a journal to record observations and reflections regarding data collection and procedure. [60]

Statistical Analysis

Quantitative data

Quantitative data will be analysed using Stata (Stata Statistical Software: College Station, TX: StataCorp LP) [62] and intention to treat analysis will be undertaken when examining potential influence of group allocation on process outcomes based on the trial randomisation. [63]. Primary and secondary outcomes will be summarized using descriptive statistics. The primary analysis will compare engagement with each strategy between the control and intervention groups for six months post-discharge from hospital, using regression models that will control for baseline measures of engagement and be conducted with adjustment for potential covariates consistent with the prior pilot study for this trial. [37] Similarly, secondary analyses will compare the aforementioned secondary outcomes to examine potential between group differences using regression models that will control for baseline and be conducted with adjustment for potential covariates consistent with the prior pilot study for this trial. [37] Sensitivity analyses will also be conducted to examine whether the trial findings are robust to planned analysis choices (e.g., intention-to-treat versus as treated analyses, or adjusted versus unadjusted regression models). The significance level for analyses will be set at 0.05, and the

sample size was determined by primary trial effect analysis (rather than this nested study examining process outcomes), which has previously been described. [37]

Qualitative data

Qualitative data from researcher field notes, phone interview transcriptions and participant open-ended answers to structured questions in the quantitative survey will be used, with the intent to triangulate the different data sources and gain a multi-layered understanding of the findings. [45, 47, 59] Interpretive phenomenological analysis (IPA) will be used to describe and interpret participants' behaviours regarding engagement in falls prevention strategies. [64] Briefly, following IPA guidelines' the two researchers will independently produce detailed interpretive coding of how and why the participants experienced barriers or enablers to engaging falls prevention strategies since hospital discharge. These coded data will then be examined by the two researchers together to identify emergent themes then re-examined to ascertain if it described the data collected and if all coded data were captured within these identified emergent themes. [64] Member-checking will occur by the first researcher returning to a sample of participants to ask them how accurately their realities have been represented in the final interpretations. [61] To add rigor, a third researcher who is not involved in data collection, will then be invited to scrutinize the data and to arbitrate any differences between coding and themes, and review final interpretations. [48, 61] Purposive sampling for qualitative data collection will be finalised and justified by consensus between all three researchers referring to the findings to confirm saturation of themes. [64]

Finally, quantitative and qualitative data will be synthesised to enrich the interpretation of the findings with the aim of adding validity to the study. [45, 48, 61, 64]. An overview of the

procedure for primary and secondary quantitative and qualitative data collection and statistical analysis is presented in Figure 2.

DISCUSSION

Older people are known to have increased rates of falls and functional decline following hospital discharge, [10-13]. Falls related injuries among these older adults are associated with readmission and substantial economic health care costs. [7-9] This study will seek to understand whether providing tailored education facilitates older adults' engagement in falls prevention strategies following hospital discharge. Recent studies investigating readmissions have found that patients are unprepared to manage their physical limitations during their immediate recovery after hospital discharge. [34, 65, 66] These investigations have shifted from a hospital-centric model to a patient-centred approach to understand the lived experience of older adults as they transition from hospital to home. [67, 68] This is important because other systematic reviews of discharge planning have identified that while readmissions may be reduced with such interventions, the impact on health outcomes for the patients is uncertain. [69]

This process evaluation will assess older adults' response to the tailored falls prevention education programme, and investigate how the intervention was received and interpreted by the older participant during their post-discharge recovery. [70-73] When delivering interventions that seek to facilitate health behaviour change, it is also important to understand the process by which behaviour changes and the mediating factors. [41] This provides evidence to develop a sound basis for defining effective intervention components. [68] The application of the framework of the COM-B model to the findings, [42] will assist to characterise how the intervention altered motivation, capability or opportunity. Additionally, secondary analysis of

barriers or enablers to engagement will be mapped onto the COM-B model and subsequently identify more precise determinants of engagement.

This study has strengths and limitations that warrant consideration. A strength is that the participants are a broad cohort recruited from a representative sample of three public metropolitan rehabilitation hospitals in Australia. The delivery of a falls prevention education intervention just prior to discharge with follow-up sessions by telephone during one month after hospital discharge has previously shown promising effects on older adult engagement in falls prevention strategies in a pilot trial. [35] Other strengths include the prospective design, robust data collection and the convergent embedded mixed method design, which combines the advantages of both quantitative and qualitative data. [61]

A possible limitation is that the participants have been drawn from a high-risk population that may still be affected by their illness. To minimise bias, the primary and secondary data will not be collected until six months post-discharge. We are also relying on self-reported data at six months, and this will be cross-checked with baseline data including from medical files and researcher notes. Participants are only contacted by phone and not interviewed face to face, however we have found in our earlier trials [18, 35] that this allows more complete responses as older people especially if unwell are not always able to attend a clinic setting.

Conclusion

We will clarify whether providing tailored falls prevention education can positively change health behaviour. We will also explore older adults' knowledge of falls prevention strategies and motivation to engage falls prevention strategies following hospital discharge. Findings will enable generation of robust recommendations for clinicians and researchers about the role of

tailored falls prevention education at the point of hospital discharge. Ultimately, we aim to understand if providing older adults with tailored education enables them to change their health behaviour in the post discharge period and if this engagement in relevant strategies reduces falls after hospital discharge.

DECLARATIONS

Consent for publication

Not applicable

Competing interests

None to declare

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Authors contributions

AMH, CN, SM and TH conceptualised the current study design and resultant research protocol with ongoing expertise and support from JN, CE-B, MEM and JF-C. AMH and CN lead trial management including data collection and management and site procedure, in consultation with TH, MEM, CE-B and LF. AMH, CN and SM lead statistical analyses with support from TH, JN, D-CAL and JF-C. CN led the drafting of all sections of the manuscript in consultation with AMH, SM, JN, CE-B, MEM, LF and D-CAL. All authors critically revised the

manuscript for important intellectual content and read and approved of the final version of the manuscript.

FIGURE LEGEND

Figure 1. COM-B system applied to falls prevention behaviour post-discharge

Figure 2. Study Procedure

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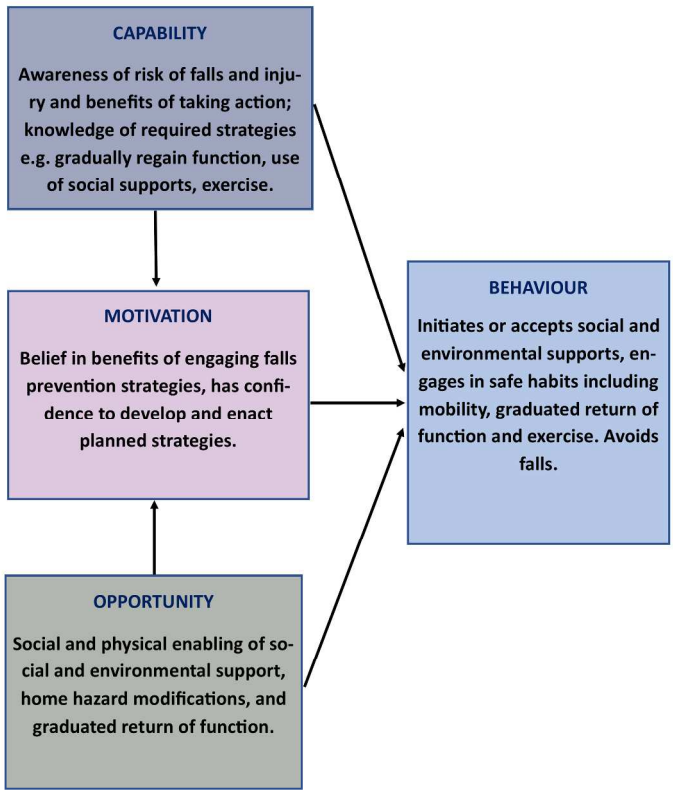
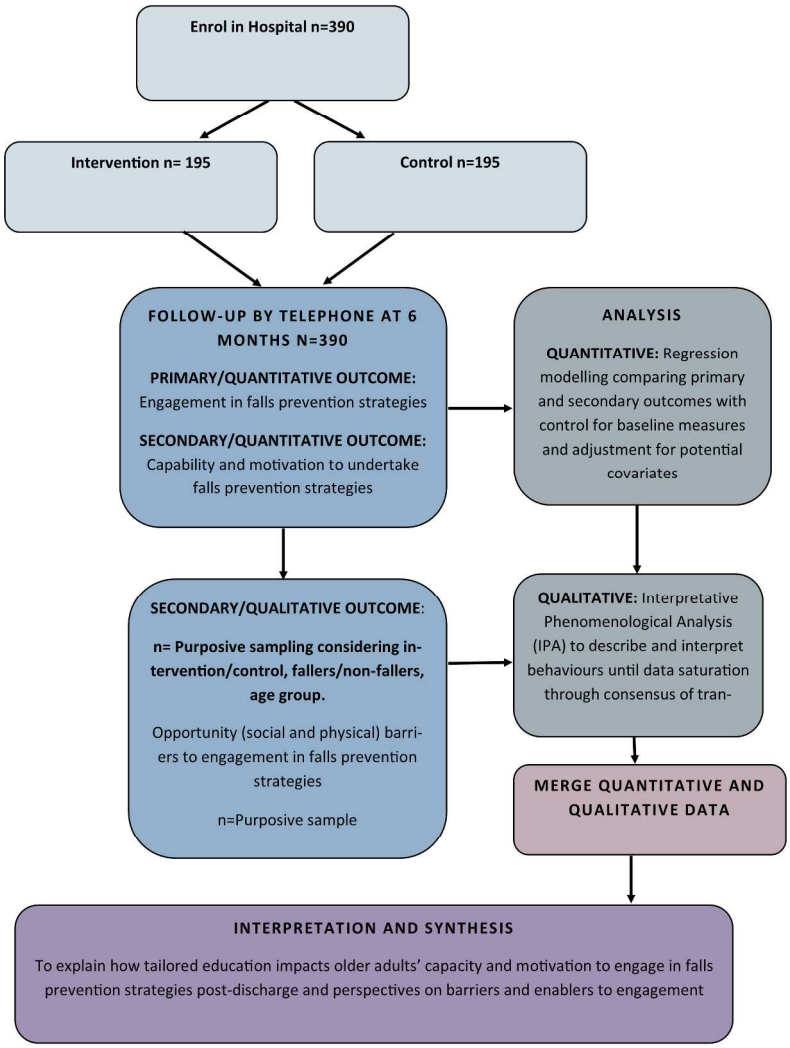
Figure 1. COM-B system applied to falls prevention behaviour post-discharge



209x297mm (300 x 300 DPI)

Figure 2. Study Procedure



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Impact of tailored falls prevention education for older adults at hospital discharge on engagement in falls prevention strategies post discharge: protocol for a process evaluation.

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RUNNING HEAD: Fall prevention for older adults after hospital

TITLE: Impact of tailored falls prevention education for older adults at hospital discharge on engagement in falls prevention strategies post discharge: protocol for a process evaluation.

AUTHORS:

Chiara Naseri [1] B.Sc (Physiotherapy)

Steven McPhail [2,3] PhD

Julie Netto [4] PhD

Terrence Haines [5] PhD

Meg E Morris [6] PhD

Christopher Etherton-Beer [7] PhD

Leon Flicker [8] PhD

Den-Ching A Lee [5] PhD

Jacqueline Francis-Coad [9] PhD

Anne-Marie Hill [1] PhD

This study was conducted at Curtin University, Faculty of Health Science, School of Physiotherapy and Exercise Science.

Author institutional affiliations:

1. School of Physiotherapy and Exercise Sciences, Faculty of Health Science, Curtin University, Perth, Western Australia

2. School of Public Health and Social Work, Faculty of Health, Queensland University of Technology

3. Centre for Functioning and Health Research, Metro South Health, Brisbane, Queensland

4. School of Occupational Therapy and Social Work, Faculty of Health Science, Curtin University, Perth, Western Australia

5. Faculty of Medicine, Nursing and Health Science, Monash University, Melbourne, Victoria

6. Healthscope & La Trobe Centre for Sport & Exercise Medicine Research, La Trobe University, Victoria, Australia

7. Department of Geriatric Medicine, School of Medicine and Pharmacology, Royal Perth Hospital Unit, University of Western Australia, Perth, Western Australia

8. Western Australian Centre for Health & Ageing, Centre for Medical Research, University of Western Australia, Perth, Western Australia

9. School of Physiotherapy, Institute for Health Research, The University of Notre Dame Australia, Fremantle, Western Australia

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Corresponding author from whom reprints can be obtained:

Chiara Naseri

School of Physiotherapy and Exercise Science

Faculty of Health Science, Curtin University

GPO Box U1987

Perth, Western Australia 6845

chiara.naseri@postgrad.curtin.edu.au

Tel: +61 8 9266 4104

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ABSTRACT

Introduction Older adults recently discharged from hospital have greater incidence of adverse events, functional decline, falls and subsequent re-admission. Providing education to hospitalised patients on how to prevent falls at home could reduce post-discharge falls. There has been limited research investigating how older adults respond to tailored falls prevention education provided at hospital discharge. The aim of this study is to evaluate how providing tailored falls prevention education to older patients at the point of, and immediately after hospital discharge in addition to usual care, affects engagement in falls prevention strategies in the six months' post-discharge period, including their capability and motivation to engage in falls prevention strategies.

Methods and analyses This prospective observational cohort study is a process evaluation of a randomised controlled trial, using an embedded mixed-method design. Participants (n=390) who have been enrolled in the trial are over the age of 60, scoring greater than 7/10 on the Abbreviated Mental Test Score. Participants are being discharged from hospital rehabilitation wards in Perth, Western Australia, and followed up for six months post-discharge. Primary outcome measures for the process evaluation are engagement in falls prevention strategies, including exercise, home modifications and receiving assistance with activities of daily living. Secondary outcomes will measure capability, motivation and opportunity to engage in falls prevention strategies, based on the constructs of the COM-B behaviour system. Quantitative data are collected at baseline, then at six months post-discharge using structured phone interviews. Qualitative data are collected from a purposive sample of the cohort, using a semi-structured in-depth phone interviews. Quantitative data will be analysed using regression modelling and qualitative data will be analysed using interpretive phenomenological analysis.

Ethics and dissemination Results will be presented in peer-reviewed journals and at conferences worldwide. This study is approved by hospital and university Human Research Ethics Committees.

Trial Registration: This is a process evaluation for the "Back to My Best" clinical trial, which is registered through the Australian New Zealand Clinical Trials Registry (ACTRN12615000784516)

Strengths and limitations of this study

- This is a process evaluation of a RCT representing a broad cohort of older adults recruited from three public metropolitan rehabilitation hospitals in Australia.
- The education intervention delivered in the RCT is being evaluated for its effect on falls rates following hospital discharge. This process evaluation will assess participants' response to the education, which aims to increase older adults' engagement in falls prevention strategies after they are discharged from hospital.
- It will determine if providing falls prevention education can facilitate capability, opportunity, and motivation for older adults to engage in falls prevention strategies at home after hospital discharge.
- The prospective design, robust data collection and the convergent embedded mixed method design uses triangulation to describe the effects of the education on engagement in falls prevention strategies, to outline barriers to engagement and provide a more holistic understanding of the factors that mediate the effectiveness of the education.
- A possible limitation is that the participants have been drawn from a high-risk population that may still be affected by their illness

INTRODUCTION

Globally, falls and falls-related injuries have been identified as a major public health problem associated with population ageing, causing physical injuries including hip fracture, head injury and negatively impacting quality of life among older people. [1-3] In 2015, direct medical costs for fatal falls in the US have more than tripled since the year 2000, [4] and in Australia the age-standardised falls-related hospitalisations for older adults has continued to increase by 2.3% per year. [5] Direct costs do not account for the long-term effects of these injuries such as permanent disability, dependence on others and reduced participation in life. [6,7]

Falls are known to be increased among older adults who have been discharged from hospital, [8, 9] and it is also known that hospitalisation of older adults, including those who are admitted for acute care and rehabilitation, is associated with decline in function and mobility. [10,11] At least 40% of older adults fall at least once in the six-months period following hospital discharge, with more than half of falls resulting in an injury. [12, 13] This is substantially higher than the annual rate of falls (30%) and injurious falls (10%) reported in the general community. [14]

There is evidence for the effectiveness of exercise and physical activity, [15, 16] along with home safety modifications and vitamin d supplementation, [17, 18] in reducing falls among older community dwelling adults including those with comorbidities. However, this evidence does not specifically apply to the older post-discharge population. A wide variety of interventions have been evaluated for their efficacy in improving transitions from hospital to home, but these have not focused specifically on falls prevention, and reviews suggest they produce limited positive outcomes and do not significantly reduce adverse events including falls. [19-21]

Older people have been found to have low levels of awareness of their falls risks and the benefits of falls prevention strategies, despite their increased falls risk during the post-discharge period. [22-24] A recent study showed that older people understood and effectively engaged in their discharge plan, yet experienced unanticipated problems, such as difficulty taking medications, uncontrolled pain, poor dietary intake and fragmented social supports, indicating that more support may be required. [25] A pilot randomised controlled trial (RCT) demonstrated that tailored education was received positively by older adults and resulted in increased engagement in falls prevention strategies after discharge, [26] and a recent systematic review found that falls prevention programs that contained a patient education component were effective in reducing rate of falls after hospital discharge. [27] However, there has been no RCTs to date to show that using patient education alone can reduce falls after discharge. An RCT, [28] is the first trial being undertaken to evaluate whether providing tailored falls prevention education, that includes individual health professional consultations in hospital and after discharge in addition to usual care, reduces falls rates in older adults after discharge from hospital. The protocol for the RCT has been published previously. [28]

The education intervention has been developed using the framework of the Capability Opportunity Motivation Behaviour (COM-B) model of health behaviour change. [29] The aim of the education is to increase engagement in falls prevention strategies, therefore it is important to understand the intended effect on this intermediate outcome of engagement in falls prevention strategies. It is yet to be determined if providing tailored falls prevention education can facilitate capability, opportunity, and motivation for older adults to engage in falls prevention strategies at home after hospital discharge. (Figure 1)

STUDY AIMS

The primary aim is to evaluate the impact of tailored falls prevention education provided at hospital discharge in addition to usual care, on older adults' engagement in falls prevention strategies in the six months after hospital discharge. This will be compared to those who receive usual care alone. The secondary aims are a) to evaluate older adults' capability, and motivation, to engage falls prevention strategies for those participants who received tailored falls prevention education in addition to usual care, compared to those that received a social/control intervention in addition to usual care; and b) to identify the opportunity (social and physical environment) surrounding the participant that made the behaviour possible, by exploring the barriers and facilitators identified by older adults to engage in falls prevention strategies in the six months following hospital discharge

METHOD

Design

The study design comprises a process evaluation of an RCT currently being conducted in Perth, Australia [28]. The protocol for the RCT has been previously published. [28] This process evaluation uses a convergent embedded mixed method design; [30] as both quantitative and qualitative data will be collected, analysed, then merged to enrich the interpretation of the results through methodological triangulation. Measuring engagement is a complex concept. [31] By using triangulation to describe the effects of the education on engagement in falls prevention strategies through both quantitative and qualitative data sources, this aims to provide a more holistic understanding of the phenomena. [32, 33]

Ethical considerations

Ethics approvals have been obtained from Human Research Ethics Committee of North Metropolitan Health Service and South Metropolitan Health Service with reciprocal approval from The University of Notre Dame Australia and Curtin University. Participant information forms are provided at the time of consent at baseline in hospital as a part of the RCT and all participants will provide written informed consent to participate in the study. The "Back to My Best" clinical trial is registered through Australian New Zealand Clinical Trials Registry (ACTRN12615000784516).

Patient involvement

Patients were not directly involved in the design of this process evaluation. Participants are informed at enrolment that they can elect to receive a plain language summary of results when the process evaluation is completed, each participant is reminded of this during the final phone call contact with researchers. Participants will be acknowledged and thanked for their contributions during the publication and distribution of results.

Setting and Participants

The setting and participants for the RCT have been described in full previously. [28] Briefly, participants (n=390) are recruited in hospital, [28] provide written informed consent and are then randomly assigned (concealed) to either the intervention group or the control group prior to discharge from aged care rehabilitation and stroke units at three Western Australian hospitals. These wards admit patients with a variety of diagnoses, such as osteoarthritis, recent stroke, Parkinson's disease, dementia, recent orthopaedic or general surgery, or recovering from a general medical condition.

Inclusion and Exclusion Criteria

Inclusion criteria for the RCT have been described previously [28]. All participants will contribute data for this process evaluation. Briefly, participants must be 60 years of age or older, and have cognitive function rated >7/10 in Abbreviated Mental Test Score (AMTS) [34]

Education Intervention

The education intervention, which has been described in full previously, [28] is based on a pedagogically sound program found to be effective in improving knowledge, confidence and motivation for older patients to engage in falls prevention strategies after hospital discharge. [26] The program is planned to take between 2 and 4 sessions to deliver in an estimated total time of 45 minutes. The education is delivered by physiotherapists and includes providing written and video materials followed by individualised discussion. The education content is based on the principles of health behaviour change, with messages that include falls prevention strategies tailored for each participant, such as instructions on how to engage in exercise according to their capability, to modify home hazards, to use their walking aid, to return to normal function, and how to seek assistance if required for home tasks or personal care. [28]

The control group receive a social intervention, between 1 and 3 sessions (estimated total time of 45 minutes) with a trained health professional who discusses aspects of positive ageing using a scripted programme, without any falls prevention information.

The intervention is delivered in addition to usual inpatient care, including discharge planning, falls education, home-visits and equipment provision, and addition of social supports. [28]

Outcome Measures

Quantitative

Primary outcome: engagement in falls prevention strategies in the six months after discharge. Falls prevention strategies measured are those suggested to the participant as a part of the tailored education intervention, which is based on current evidence for falls prevention, provided prior to discharge. Each participant has been encouraged to engage in a falls prevention plan which has been tailored by the delivering therapists. This intervention has been described in full elsewhere. [28] Strategies are defined as:

i. Receiving assistance (both formal and informal assistance) with activities of daily living (ADL). Activities of daily living are defined according to the Katz index of Independence in Activities of Daily Living, [35] and include toileting, showering, and eating.

ii. Receiving assistance with instrumental activities of daily living (IADL). Instrumental ADL are defined using the Lawton index, [36] and include home cleaning, shopping, transport.

These two outcomes will be measured using yes/no responses and frequency (days per week and hours of total assistance per week) and type of assistance (whether paid formal services from home care provider or informal family or friends' assistance to the participant).

iii. Engagement in exercises, including all type (such as a strength and balance exercise program, group exercise, swimming, golf, tai chi, walking, dancing), whether a balance component is included, and frequency (hours per week and number of times per week) and where completed such as at home, in a healthcare centre, with or without health provider assistance.

iv. Home modifications, such as installation of equipment or rails, or alteration of home layout, including whether assessment was provided by an occupational therapist and the level of assistance obtained to make these modifications.

These primary outcomes will be measured in hospital (baseline) by recruiters for the RCT (who are blinded to group allocation), then measured at six-months following hospital discharge through a structured phone survey by a trained research assistant who is also blinded to group allocation. These surveys have been modified from previous surveys used in falls prevention trials, including the pilot trial which evaluated these outcomes. [13, 26, 37]

The secondary quantitative outcome measures are:

i. Participants perceived levels of capability (knowledge and awareness) about falls prevention after discharge, such as awareness of risk of falls, awareness of injury and benefits of engaging falls prevention strategies; measured through a structured phone survey using Likert scales, [38] at baseline and at six-month follow up.

ii. Motivation, such as beliefs in benefits of engaging strategies, confidence to engage strategies; develops and enacts plan to engage strategies.

These secondary outcomes will be measured alongside the primary outcomes, using the methods described above. Survey items for secondary outcomes will be measured using five-point Likert scales, [38] (strongly agree to strongly disagree). Items are based on the domains of the COM-B, [29] and modified from previous surveys which have evaluated capability, motivation and confidence regarding falls prevention. [13, 26, 37]

iii. Motivation to engage in exercise will be additionally measured using the Self-Efficacy for Exercise scale (SEE). [39]

The Self-Efficacy for Exercise scale (SEE), [39] a 9-item scale that rates older peoples' response to a statement about barriers to exercise (scores range from 0=not very confident to 10=very confident; with a total possible score of 90).

Qualitative

The secondary qualitative outcomes relate to opportunity (described as being both social and physical in the COM-B framework), [29] and include both barriers and enablers that participants encounter when seeking to engage in falls prevention strategies. These secondary outcomes will be measured by completing semi-structured in-depth phone interviews at the conclusion of the observation period. Questions will be guided by participant responses gained from earlier structured phone interviews, using open-ended questions designed to encourage the participants to reflect on their previous responses. Questions will be framed around barriers and enablers to engaging in falls prevention strategies, graduated return to independence and engaging in exercise. This may be physical opportunity provided by their environment including access and social supports, or cultural milieu including stigmas or fears that dictate older adult decision-making. [29]

Demographic data will be gathered in hospital at baseline by recruiters during a face to face interview. These data will include age, gender, diagnosis, length of stay in hospital, history of falls prior to hospitalisation and during hospital stay, presence of visual impairment, presence of hearing impairment, number and type of medications, signs of depression (measured using Geriatric Depression Scale), [40] and use of walking aids.

Other data is also collected at baseline during the face to face interview then again at six-months after discharge using a structured phone survey. These variables are living situation

(home alone, with partner, other situation), level of indoor and outdoor mobility, including any use of walking aids, functional mobility measured using Katz and Lawton's Scales [5, 36], and health related quality of life measured using the Assessment of Quality of Life tool (AQoL) [41].

Additionally, as part of the education intervention, data are collected regarding the delivery of the program by the educators. These data include the number of education sessions provided to each intervention group participant, the duration, and whether an action plan was completed. These data will also be used during sensitivity analyses, to assist to explain participants' knowledge, motivation, and engagement in falls prevention strategies after discharge.

Data collection and procedure

Baseline surveys for primary and secondary outcomes are conducted by a trained research assistant who is blinded to group allocation, then participants are randomly allocated to intervention or control group. The RCT protocol, including randomisation, blinding, and the intervention procedure has been described in detail elsewhere. [28] Briefly, participants receive tailored falls prevention education by trained physiotherapist educators during a one-to one interaction in hospital. The education assists the participant to prepare a tailored plan to initiate after hospital discharge. The participants are then followed up by phone after discharge by the educators once a month for three months, to further assist them to enact their plan, and address any barriers that may have arisen since discharge.

At six-months following hospital discharge, the structured phone survey will be conducted to collect quantitative follow up data, after which the participant will be invited to participate in a semi-structured in-depth phone interview to collect qualitative data that measures the

secondary outcome which explores opportunity (barriers and enablers) to engagement in falls prevention strategies.

Purposive sampling for qualitative data collection will occur after the six-month period and following completion of primary and secondary quantitative data collection. The sample selected will represent the cohort, with consideration of age, diagnosis, gender, falls history, and whether intervention or control group. Purposive sampling will be finalised and justified by referring to data and theoretical saturation and confirmed through consensus of a second researcher reviewing the transcribed narrative data.[42] A phone interview was selected to collect data, rather than a focus group, or face to face interview, as the participants have previously received monthly phone monitoring of falls data from the RCT, so the researcher has established a genuine rapport and reciprocity with the participants.[43] To ensure quality data collection that is sufficient to answer the study aim, the semi-structured survey has been piloted to ensure the questions are easily understood and screened for blind spots, bias, and potentially sensitive questions. [33] Each interview will be recorded and transcribed verbatim. Additional interviews will be completed as necessary until data saturation has occurred. The researcher will keep a journal to record observations and reflections regarding data collection and procedure. [43]

Statistical Analysis

Quantitative data

Quantitative data will be analysed using Stata (Stata Statistical Software: College Station, TX: StataCorp LP) [44] and intention to treat analysis will be undertaken when examining potential influence of group allocation on process outcomes based on the trial randomisation. [45]. Primary and secondary outcomes will be summarized using descriptive statistics. The primary

analysis will compare engagement with each strategy between the control and intervention groups for six months post-discharge from hospital, using regression models that will control for baseline measures of engagement and be conducted with adjustment for potential covariates consistent with the prior pilot study for this trial. [26] Similarly, secondary analyses will compare the secondary outcomes to examine potential between group differences using regression models that will control for baseline and be conducted with adjustment for potential covariates consistent with the prior pilot study for this trial. [26] Sensitivity analyses will also be conducted to examine whether the trial findings are robust to planned analysis choices (e.g., intention-to-treat versus as treated analyses, or adjusted versus unadjusted regression models). The significance level for analyses will be set at 0.05, and the sample size was determined by primary trial effect analysis, which has previously been described. [28]

Qualitative data

Qualitative data from researcher field notes, phone interview transcriptions and participant open-ended answers to structured questions in the quantitative survey will be used, with the intent to triangulate the different data sources and gain a multi-layered understanding of the findings. [32, 33] Interpretive phenomenological analysis (IPA) will be used to describe and interpret participants' behaviours regarding engagement in falls prevention strategies. [46] Briefly, following IPA guidelines' the two researchers will independently produce detailed interpretive coding of how and why the participants experienced barriers or enablers to engaging falls prevention strategies since hospital discharge. These coded data will then be examined by the two researchers together to identify emergent themes then re-examined to ascertain if it described the data collected and if all coded data were captured within these identified emergent themes. [46] Member-checking will occur by the first researcher returning to a sample of participants to ask them how accurately their realities have been represented in

the final interpretations. [42] To add rigor, a third researcher who is not involved in data collection, will then be invited to scrutinize the data and to arbitrate any differences between coding and themes, and review final interpretations. [46] Purposive sampling for qualitative data collection will be finalised and justified by consensus between all three researchers referring to the findings to confirm saturation of themes. [46]

Finally, quantitative and qualitative data will be synthesised to enrich the interpretation of the findings with the aim of adding validity to the study. [33, 42]. An overview of the procedure for primary and secondary quantitative and qualitative data collection and statistical analysis is presented in Figure 2.

DISCUSSION

Older people are known to have increased rates of falls and functional decline following hospital discharge. [7, 8] Recent studies investigating readmissions have found that patients are unprepared to manage their physical limitations during their immediate recovery after hospital discharge. [24, 25] These investigations have shifted from a hospital-centric model to a patient-centred approach to understand the lived experience of older adults as they transition from hospital to home. [47] This is important because other systematic reviews of discharge planning have identified that while readmissions may be reduced with such interventions, the impact on health outcomes for the patients is uncertain. [48]

Previous observational studies have suggested that to promote participation in evidenced-based falls prevention strategies, therapists may need to convince older adults that they are at risk of falls, [23] with guidance on what specific strategies are likely to have a personally beneficial falls prevention effect. [22] Tailored health education aims to change individuals' health

behaviours. [29, 30] When this education is used as an intervention, it presents a challenge for identifying effective components, and therefore reporting of findings, and subsequent replication. [31, 32]

This process evaluation will seek to understand whether providing tailored education facilitates older adults' engagement in falls prevention strategies following hospital discharge. The application of the framework of the COM-B model to the findings, [29] will assist to characterise how the intervention altered motivation, capability or opportunity. Additionally, secondary analysis of barriers or enablers to engagement will be mapped onto the COM-B model and subsequently identify more precise determinants of engagement. [49] Capability includes an individual's psychological and physical capacity to engage in falls prevention strategies behaviour. Opportunity, both social and physical, includes those factors that lie outside the individual that make the behaviour possible, such as being able to access home assistance or modifications. [29] Motivation includes all processes that inspire and direct behaviour, such as believing that it would be good to exercise. [29]

This study has strengths and limitations that warrant consideration. A strength is that the participants are a broad cohort recruited from a representative sample of three public metropolitan rehabilitation hospitals in Australia. The delivery of a falls prevention education intervention just prior to discharge with follow-up sessions by telephone during one month after hospital discharge has previously shown promising effects on older adult engagement in falls prevention strategies in a pilot trial. [26] Other strengths include the prospective design, robust data collection and the convergent embedded mixed method design, which combines the advantages of both quantitative and qualitative data. [32, 43]

A possible limitation is that the participants have been drawn from a high-risk population that may still be affected by their illness. To minimise bias through possible prompting of participants, data regarding engagement in falls prevention strategies following hospital discharge, will not be collected until six months post-discharge. We are also relying on self-reported data at six months. Participants are only contacted by phone and not interviewed face to face, however we have found in our earlier trials [1, 26] that this allows more complete responses as older people, especially if unwell, are not always able to attend a clinic setting.

Conclusion

This process evaluation will assess older adults' response to a tailored falls prevention education programme and investigate how the intervention was received and interpreted by the older participant during their post-discharge recovery. When delivering interventions that seek to facilitate health behaviour change, it is also important to understand the process by which behaviour changes and the mediating factors. [50, 51] This provides evidence to develop a sound basis for defining effective intervention components. [52] We will clarify whether providing tailored falls prevention education can positively change health behaviour. We will also explore older adults' knowledge of falls prevention strategies and motivation to engage falls prevention strategies following hospital discharge. Findings will enable generation of robust recommendations for clinicians and researchers about the role of tailored falls prevention education at the point of hospital discharge. Ultimately, we aim to understand if providing older adults with tailored education enables them to change their health behaviour in the post discharge period and if engagement in relevant strategies reduces falls after hospital discharge.

DECLARATIONS

Consent for publication

Not applicable

Competing interests

None to declare

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Authors contributions

AMH, CN, SM and TH conceptualised the current study design and resultant research protocol with ongoing expertise and support from JN, CE-B, MEM and JF-C. AMH and CN lead trial management including data collection and management and site procedure, in consultation with TH, MEM, CE-B and LF. AMH, CN and SM lead statistical analyses with support from TH, JN, D-CAL and JF-C. CN led the drafting of all sections of the manuscript in consultation with AMH, SM, JN, CE-B, MEM, LF and D-CAL. All authors critically revised the manuscript for important intellectual content and read and approved of the final version of the manuscript.

FIGURE LEGEND

Figure 1. COM-B system applied to falls prevention behaviour post-discharge

Figure 2. Study Procedure

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Figure 1. COM-B system applied to falls prevention behaviour post-discharge

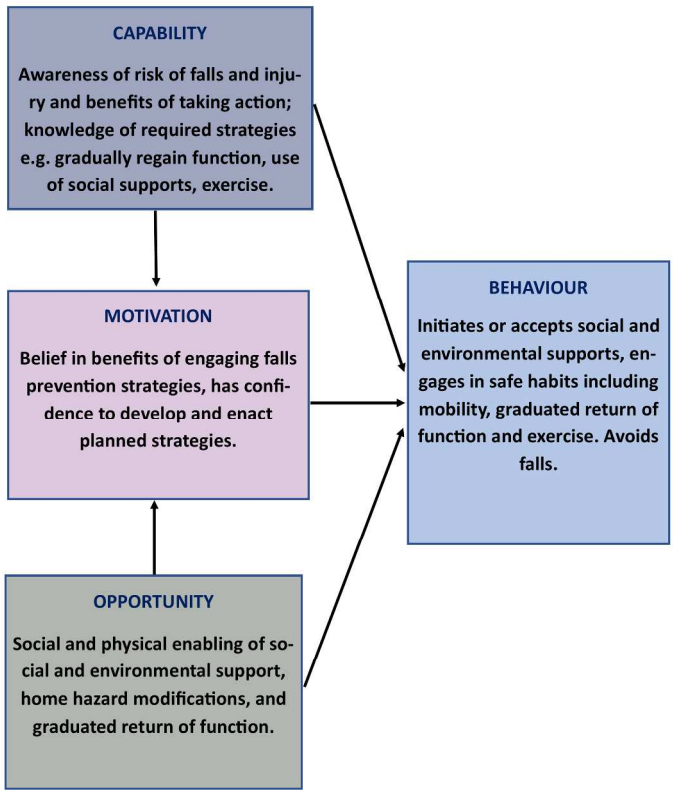

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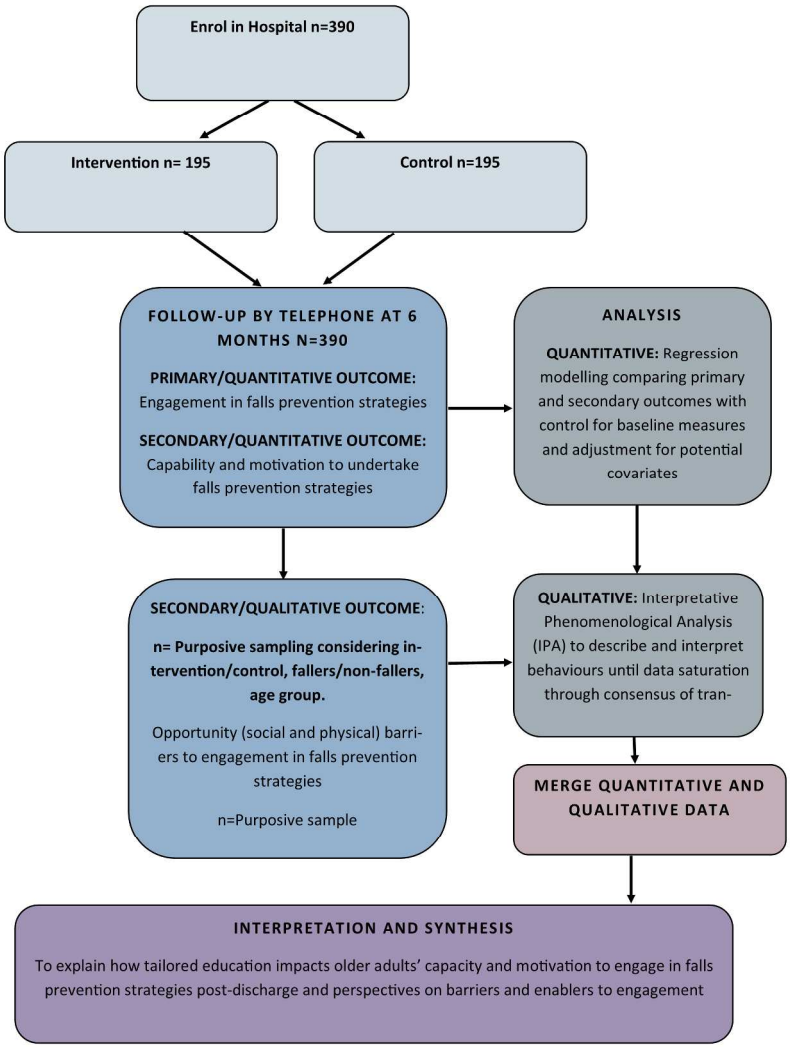
Figure 2. Study Procedure



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