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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020726
Article Type:	Protocol
Date Submitted by the Author:	20-Nov-2017
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
Keywords:	older adults, tailored education, falls prevention, hospital discharge, health behaviour

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Manuscripts

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: protocol for a process evaluation.

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

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45
46 **There are no relationships, conditions or circumstances that present a**
47 **potential conflict of interest.**
48
49

50
51
52 **Acknowledgement of any presentation of this material:**
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54 This material has not been presented to anyone or anywhere.
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Acknowledgment of financial support

Authors CN, SM, TH, MEM, JF-C, CE-B, D-CAL, LF, AMH have received funding from the National Health and Medical Research Council (Australia) for a trial to reduce falls and regain independence in older people after hospital discharge (Project App no:1078918). However, this grant funding has not been received directly to the authors rather to the institutions they represent. The authors have not received financial support for this study.

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WORD COUNT

Abstract: 293

Manuscript: 3557

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 be 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.

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3 **Ethics and dissemination** Results will be presented in peer-reviewed journals and at
4 conferences worldwide. This study is approved by hospital and university Human Research
5 Ethics Committees.
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9 **Trial Registration:** This study is nested within the larger “Back to My Best” clinical trial
10 (ANZCTR - ACTRN12615000784516)
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14 **Strengths and limitations of this study**

- 15
16
17 • This process evaluation will be nested within a larger RCT representing a broad cohort
18 of older adults recruited from three public metropolitan rehabilitation hospitals in
19 Australia.
20
- 21 • While the main trial aims to reduce falls following hospital discharge by increasing
22 older adults’ engagement in falls prevention strategies, this study will assess their
23 response to the tailored falls prevention education intervention during their post-
24 discharge recovery.
25
- 26 • It will determine if providing tailored falls prevention education can facilitate
27 capability, opportunity, and motivation for older adults to engage in falls prevention
28 strategies at home after hospital discharge.
29
- 30 • The prospective design, robust data collection and the convergent embedded mixed
31 method design uses triangulation to describe the effects of the education on engagement
32 in falls prevention strategies, to outline barriers to engagement and provide a more
33 holistic understanding of the factors that mediate the effectiveness of the intervention.
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- 35 • A possible limitation is that the participants have been drawn from a high-risk
36 population that may still be affected by their illness
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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

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3 these trials have suggested they produce limited positive outcomes and do not significantly
4 reduce adverse events including falls. [25-29]
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9 Older people have been found to have low levels of awareness of the risk of falls, despite their
10 increased falls risk during the post-discharge period. [30, 31 Previous research has also shown
11 that older adults have reduced knowledge about how best to prevent falls after they return
12 home from hospital. [32, 33] A recent study showed that older people understood and
13 effectively engaged in their discharge plan, yet experienced unanticipated problems, such as
14 difficulty taking medications, uncontrolled pain, poor dietary intake and fragmented social
15 supports, indicating that more support may be required. [34] A pilot randomised controlled trial
16 (RCT) demonstrated that tailored education was received positively by older adults and
17 resulted in increased engagement in falls prevention strategies after discharge, [35] and a recent
18 systematic review found that falls prevention programs that contained a patient education
19 component were effective in reducing rate of falls after hospital discharge. [36] However, there
20 has been no RCTs to date to show that using patient education alone can reduce falls after
21 discharge.
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39 An RCT in which this study is nested, [37] (n=390) is the first trial being undertaken to
40 evaluate whether providing tailored falls prevention education, that includes individual health
41 professional consultations in hospital and after discharge in addition to usual care, reduces falls
42 rates in older adults after discharge from hospital.
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50 Tailored health education aims to change individuals' health behaviours. [38, 39] When this
51 education is used as an intervention, it presents a challenge for identifying effective
52 components, and therefore reporting of findings, and subsequent replication. [40, 41] The
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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

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3 falls prevention education in addition to usual care, compared to those that received a social
4 intervention in addition to usual care; and b) to identify the opportunity (social and physical
5 environment) surrounding the participant that made the behaviour possible, by exploring the
6 barriers and facilitators identified by older adults to engage in falls prevention strategies in the
7 six months following hospital discharge
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13 14 15 16 **METHOD**

17 18 19 **Design**

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

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44 The study is nested within the larger “Back to My Best” clinical trial (ANZCTR -
45 ACTRN12615000784516). [37] Ethics approvals have been obtained from Human Research
46 Ethics Committee of North Metropolitan Health Service and South Metropolitan Health
47 Service with reciprocal approval from The University of Notre Dame Australia and Curtin
48 University. Participant information forms are provided at the time of consent at baseline in
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3 hospital as a part of the RCT and all participants will provide written informed consent to
4 participate in the study.
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10 **Setting and Participants**

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

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

42 *Quantitative*

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44 Primary outcome: engagement in falls prevention strategies in the six months after discharge.
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46 Falls prevention strategies measured are those suggested to the participant as a part of the
47 tailored education intervention, which is based on current evidence for falls prevention,
48 provided prior to discharge. Each participant has been encouraged to engage in a falls
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3 prevention plan which has been tailored by the delivering therapists. This intervention has been
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5 described in full elsewhere. [37] Strategies are defined as:

- 6
7 i. Receiving assistance (both formal and informal assistance) with activities of daily
8
9 living (ADL). Activities of daily living are defined according to the Katz index of
10
11 Independence in Activities of Daily Living, [50] and include toileting, showering, and
12
13 eating.
14
15 ii. Receiving assistance with instrumental activities of daily living (IADL). Instrumental
16
17 ADL are defined using the Lawton index, [51] and include home cleaning, shopping,
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19 transport.
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22 These two outcomes will be measured using yes/no responses and also frequency (days per
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24 week and hours of total assistance per week) and type of assistance (whether paid formal
25
26 services from home care provider or informal family or friends' assistance to the participant).
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31 iii. Engagement in exercises, including all type and frequency (hours per week and number
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33 of times per week) and where completed such as at home, in a healthcare centre, with or
34
35 without provider assistance.
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37 iv. Home modifications, such as installation of equipment or rails, or alteration of home
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39 layout, including whether assessment was provided by an occupational therapist and the
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41 level of assistance obtained to make these modifications.
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44 These primary outcomes will be measured in hospital (baseline) by recruiters for the main RCT
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46 (who are blinded to group allocation), then measured at six-months following hospital
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48 discharge through a structured phone survey by a trained research assistant who is also blinded
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50 to group allocation. These surveys have been modified from previous surveys used in falls
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52 prevention trials, including the pilot trial which evaluated these outcomes. [18, 33, 35, 52, 53]
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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

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3 the participants to reflect on their previous responses. Questions will be framed around barriers
4 and enablers to engaging in falls prevention strategies, graduated return to independence and
5 engaging in exercise. This may be physical opportunity provided by their environment
6 including access and social supports, or cultural milieu including stigmas or fears that dictate
7 older adult decision-making. [42]
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16 Demographic data will be gathered in hospital at baseline by recruiters during a face to face
17 interview as a part of the RCT. These data will include age, gender, diagnosis, length of stay in
18 hospital, history of falls prior to hospitalisation and during hospital stay, presence of visual
19 impairment, presence of hearing impairment, number and type of medications, signs of
20 depression (measured using Geriatric Depression Scale), [57] and use of walking aids.
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29 Other data is also collected at baseline during the face to face interview then again at six-
30 months after discharge using a structured phone survey. These variables are living situation
31 (home alone, with partner, other situation), level of indoor and outdoor mobility, including any
32 use of walking aids, functional mobility measured using Katz and Lawton's Scales [50, 51],
33 and health related quality of life measured using the Assessment of Quality of Life tool
34 (AQoL) [58].
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44 Additionally, as part of the main trial, data are collected regarding the intervention provision by
45 the educators. These data include the number of education sessions provided to each
46 intervention group participant, the duration, and whether an action plan was completed. These
47 data will also be used during sensitivity analyses, to assist to explain participants knowledge,
48 motivation, and engagement in falls prevention strategies after discharge.
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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

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3 previously received monthly phone monitoring of falls data from the RCT, so the researcher
4 has established a genuine rapport and reciprocity with the participants.[60] To ensure quality
5 data collection that is sufficient to answer the study aim, the semi-structured survey has been
6 piloted to ensure the questions are easily understood and screened for blind spots, bias, and
7 potentially sensitive questions. [47] Each interview will be recorded and transcribed verbatim.
8 [60, 61]. Additional interviews will be completed as necessary until data saturation has
9 occurred. [47, 59, 61] The researcher will keep a journal to record observations and reflections
10 regarding data collection and procedure. [60]

23 **Statistical Analysis**

26 *Quantitative data*

28 Quantitative data will be analysed using Stata (Stata Statistical Software: College Station, TX:
29 StataCorp LP) [62] and intention to treat analysis will be undertaken when examining potential
30 influence of group allocation on process outcomes based on the trial randomisation. [63].

34 Primary and secondary outcomes will be summarized using descriptive statistics. The primary
35 analysis will compare engagement with each strategy between the control and intervention
36 groups for six months post-discharge from hospital, using regression models that will control
37 for baseline measures of engagement and be conducted with adjustment for potential covariates
38 consistent with the prior pilot study for this trial. [37] Similarly, secondary analyses will
39 compare the aforementioned secondary outcomes to examine potential between group
40 differences using regression models that will control for baseline and be conducted with
41 adjustment for potential covariates consistent with the prior pilot study for this trial. [37]

51 Sensitivity analyses will also be conducted to examine whether the trial findings are robust to
52 planned analysis choices (e.g., intention-to-treat versus as treated analyses, or adjusted versus
53 unadjusted regression models). The significance level for analyses will be set at 0.05, and the

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

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12 Qualitative data from researcher field notes, phone interview transcriptions and participant
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14 open-ended answers to structured questions in the quantitative survey will be used, with the
15
16 intent to triangulate the different data sources and gain a multi-layered understanding of the
17
18 findings. [45, 47, 59] Interpretive phenomenological analysis (IPA) will be used to describe
19
20 and interpret participants' behaviours regarding engagement in falls prevention strategies. [64]
21
22 Briefly, following IPA guidelines' the two researchers will independently produce detailed
23
24 interpretive coding of how and why the participants experienced barriers or enablers to
25
26 engaging falls prevention strategies since hospital discharge. These coded data will then be
27
28 examined by the two researchers together to identify emergent themes then re-examined to
29
30 ascertain if it described the data collected and if all coded data were captured within these
31
32 identified emergent themes. [64] Member-checking will occur by the first researcher returning
33
34 to a sample of participants to ask them how accurately their realities have been represented in
35
36 the final interpretations. [61] To add rigor, a third researcher who is not involved in data
37
38 collection, will then be invited to scrutinize the data and to arbitrate any differences between
39
40 coding and themes, and review final interpretations. [48, 61] Purposive sampling for qualitative
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42 data collection will be finalised and justified by consensus between all three researchers
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44 referring to the findings to confirm saturation of themes. [64]
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51 Finally, quantitative and qualitative data will be synthesised to enrich the interpretation of the
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53 findings with the aim of adding validity to the study. [45, 48, 61, 64]. An overview of the
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3 procedure for primary and secondary quantitative and qualitative data collection and statistical
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5 analysis is presented in Figure 2.
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8 9 **DISCUSSION**

10 Older people are known to have increased rates of falls and functional decline following
11
12 hospital discharge, [10-13]. Falls related injuries among these older adults are associated with
13
14 readmission and substantial economic health care costs. [7-9] This study will seek to
15
16 understand whether providing tailored education facilitates older adults' engagement in falls
17
18 prevention strategies following hospital discharge. Recent studies investigating readmissions
19
20 have found that patients are unprepared to manage their physical limitations during their
21
22 immediate recovery after hospital discharge. [34, 65, 66] These investigations have shifted
23
24 from a hospital-centric model to a patient-centred approach to understand the lived experience
25
26 of older adults as they transition from hospital to home. [67, 68] This is important because
27
28 other systematic reviews of discharge planning have identified that while readmissions may be
29
30 reduced with such interventions, the impact on health outcomes for the patients is uncertain.
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39 This process evaluation will assess older adults' response to the tailored falls prevention
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41 education programme, and investigate how the intervention was received and interpreted by the
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43 older participant during their post-discharge recovery. [70-73] When delivering interventions
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45 that seek to facilitate health behaviour change, it is also important to understand the process by
46
47 which behaviour changes and the mediating factors. [41] This provides evidence to develop a
48
49 sound basis for defining effective intervention components. [68] The application of the
50
51 framework of the COM-B model to the findings, [42] will assist to characterise how the
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53 intervention altered motivation, capability or opportunity. Additionally, secondary analysis of
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3 barriers or enablers to engagement will be mapped onto the COM-B model and subsequently
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5 identify more precise determinants of engagement.
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9 This study has strengths and limitations that warrant consideration. A strength is that the
10 participants are a broad cohort recruited from a representative sample of three public
11 metropolitan rehabilitation hospitals in Australia. The delivery of a falls prevention education
12 intervention just prior to discharge with follow-up sessions by telephone during one month
13 after hospital discharge has previously shown promising effects on older adult engagement in
14 falls prevention strategies in a pilot trial. [35] Other strengths include the prospective design,
15 robust data collection and the convergent embedded mixed method design, which combines the
16 advantages of both quantitative and qualitative data. [61]
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28 A possible limitation is that the participants have been drawn from a high-risk population that
29 may still be affected by their illness. To minimise bias, the primary and secondary data will not
30 be collected until six months post-discharge. We are also relying on self-reported data at six
31 months, and this will be cross-checked with baseline data including from medical files and
32 researcher notes. Participants are only contacted by phone and not interviewed face to face,
33 however we have found in our earlier trials [18, 35] that this allows more complete responses
34 as older people especially if unwell are not always able to attend a clinic setting.
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46 **Conclusion**

47 We will clarify whether providing tailored falls prevention education can positively change
48 health behaviour. We will also explore older adults' knowledge of falls prevention strategies
49 and motivation to engage falls prevention strategies following hospital discharge. Findings will
50 enable generation of robust recommendations for clinicians and researchers about the role of
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3 tailored falls prevention education at the point of hospital discharge. Ultimately, we aim to
4 understand if providing older adults with tailored education enables them to change their health
5 behaviour in the post discharge period and if this engagement in relevant strategies reduces
6 falls after hospital discharge.
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11 12 13 14 **DECLARATIONS**

15 16 17 **Consent for publication**

18 Not applicable
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23 24 **Competing interests**

25 None to declare
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30 31 **Funding**

32 This study is funded by the National Health and Medical Research Council (Australia) as part
33 of the main “Back to My Best” (ANZCTR-ACTRN12615000784516; Project App
34 no:1078918). SM receives career funding support from the National Health and Medical
35 Research Council (Australia).
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43 44 **Authors contributions**

45 AMH, CN, SM and TH conceptualised the current study design and resultant research protocol
46 with ongoing expertise and support from JN, CE-B, MEM and JF-C. AMH and CN lead trial
47 management including data collection and management and site procedure, in consultation
48 with TH, MEM, CE-B and LF. AMH, CN and SM lead statistical analyses with support from
49 TH, JN, D-CAL and JF-C. CN led the drafting of all sections of the manuscript in consultation
50 with AMH, SM, JN, CE-B, MEM, LF and D-CAL. All authors critically revised the
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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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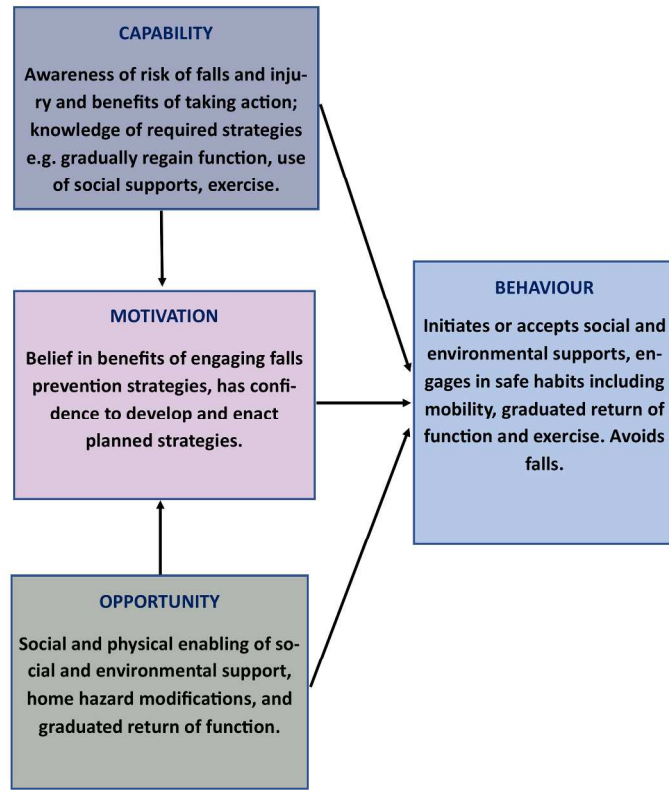
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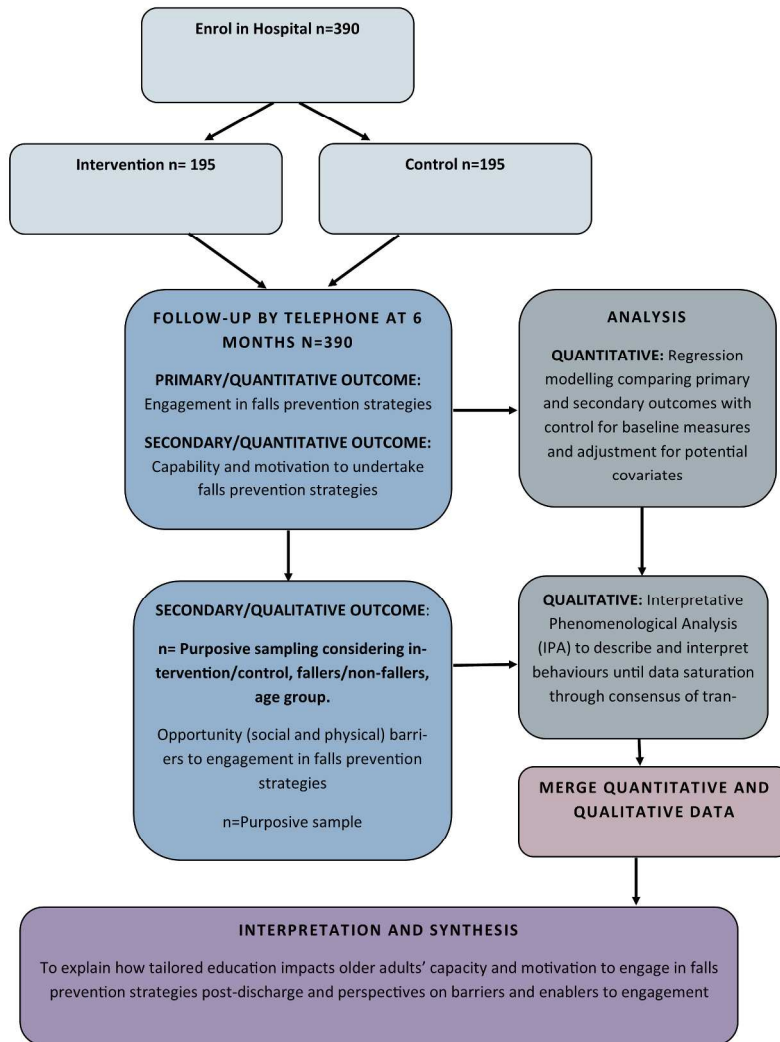
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Figure 1. COM-B system applied to falls prevention behaviour post-discharge



209x297mm (300 x 300 DPI)

Figure 2. Study Procedure



209x297mm (300 x 300 DPI)

BMJ Open

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020726.R1
Article Type:	Protocol
Date Submitted by the Author:	28-Feb-2018
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
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Geriatric medicine, Patient-centred medicine, Rehabilitation medicine, Qualitative research
Keywords:	older adults, tailored education, falls prevention, hospital discharge, health behaviour

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Manuscripts

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.

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38 **There are no relationships, conditions or circumstances that present a**
39 **potential conflict of interest.**

40 41 42 43 44 **Acknowledgement of any presentation of this material:**

45
46 This material has not been presented to anyone or anywhere.

47 48 49 50 **Acknowledgment of financial support**

51
52 Authors SM, TH, MEM, JF-C, CE-B, D-CAL, LF, AMH have received a grant from the
53
54 National Health and Medical Research Council (Australia) to conduct a trial which investigates
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3 how to reduce falls and promote independence in older people after hospital discharge (Project
4 App no:1078918). CN receives a post graduate student stipend as part of the grant. This grant
5
6 funding has not been received directly to the authors rather to the institutions they represent.
7
8 The authors have not received financial support for this study. SM receives career funding
9
10 support from the National Health and Medical Research Council (Australia)
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35 **WORD COUNT**

36 Abstract: 298

37 Manuscript: 3895

38 References: 52
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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.

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3 **Ethics and dissemination** Results will be presented in peer-reviewed journals and at
4 conferences worldwide. This study is approved by hospital and university Human Research
5 Ethics Committees.
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9 **Trial Registration:** This is a process evaluation for the “Back to My Best” clinical trial, which
10 is registered through the Australian New Zealand Clinical Trials Registry
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12 (ACTRN12615000784516)
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16 17 18 **Strengths and limitations of this study**

- 19 • This is a process evaluation of a RCT representing a broad cohort of older adults
20 recruited from three public metropolitan rehabilitation hospitals in Australia.
21
- 22 • The education intervention delivered in the RCT is being evaluated for its effect on falls
23 rates following hospital discharge. This process evaluation will assess participants’
24 response to the education, which aims to increase older adults’ engagement in falls
25 prevention strategies after they are discharged from hospital.
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- 27 • It will determine if providing falls prevention education can facilitate capability,
28 opportunity, and motivation for older adults to engage in falls prevention strategies at
29 home after hospital discharge.
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- 31 • The prospective design, robust data collection and the convergent embedded mixed
32 method design uses triangulation to describe the effects of the education on engagement
33 in falls prevention strategies, to outline barriers to engagement and provide a more
34 holistic understanding of the factors that mediate the effectiveness of the education.
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- 36 • A possible limitation is that the participants have been drawn from a high-risk
37 population that may still be affected by their illness
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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]

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5 Older people have been found to have low levels of awareness of their falls risks and the
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7 benefits of falls prevention strategies, despite their increased falls risk during the post-
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9 discharge period. [22-24] A recent study showed that older people understood and effectively
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11 engaged in their discharge plan, yet experienced unanticipated problems, such as difficulty
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13 taking medications, uncontrolled pain, poor dietary intake and fragmented social supports,
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15 indicating that more support may be required. [25] A pilot randomised controlled trial (RCT)
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17 demonstrated that tailored education was received positively by older adults and resulted in
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19 increased engagement in falls prevention strategies after discharge, [26] and a recent systematic
20
21 review found that falls prevention programs that contained a patient education component were
22
23 effective in reducing rate of falls after hospital discharge. [27] However, there has been no
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25 RCTs to date to show that using patient education alone can reduce falls after discharge. An
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27 RCT, [28] is the first trial being undertaken to evaluate whether providing tailored falls
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29 prevention education, that includes individual health professional consultations in hospital and
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31 after discharge in addition to usual care, reduces falls rates in older adults after discharge from
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33 hospital. The protocol for the RCT has been published previously. [28]
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39 The education intervention has been developed using the framework of the Capability
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41 Opportunity Motivation Behaviour (COM-B) model of health behaviour change. [29] The aim
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43 of the education is to increase engagement in falls prevention strategies, therefore it is
44
45 important to understand the intended effect on this intermediate outcome of engagement in falls
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47 prevention strategies. It is yet to be determined if providing tailored falls prevention education
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49 can facilitate capability, opportunity, and motivation for older adults to engage in falls
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51 prevention strategies at home after hospital discharge. (Figure 1)
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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

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

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

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

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3 iv. Home modifications, such as installation of equipment or rails, or alteration of home
4 layout, including whether assessment was provided by an occupational therapist and the
5 level of assistance obtained to make these modifications.
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9 These primary outcomes will be measured in hospital (baseline) by recruiters for the RCT (who
10 are blinded to group allocation), then measured at six-months following hospital discharge
11 through a structured phone survey by a trained research assistant who is also blinded to group
12 allocation. These surveys have been modified from previous surveys used in falls prevention
13 trials, including the pilot trial which evaluated these outcomes. [13, 26, 37]
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22 The secondary quantitative outcome measures are:

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24 i. Participants perceived levels of capability (knowledge and awareness) about falls
25 prevention after discharge, such as awareness of risk of falls, awareness of injury and
26 benefits of engaging falls prevention strategies; measured through a structured phone
27 survey using Likert scales, [38] at baseline and at six-month follow up.
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33 ii. Motivation, such as beliefs in benefits of engaging strategies, confidence to engage
34 strategies; develops and enacts plan to engage strategies.
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37 These secondary outcomes will be measured alongside the primary outcomes, using the
38 methods described above. Survey items for secondary outcomes will be measured using five-
39 point Likert scales, [38] (strongly agree to strongly disagree). Items are based on the domains
40 of the COM-B, [29] and modified from previous surveys which have evaluated capability,
41 motivation and confidence regarding falls prevention. [13, 26, 37]
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- 48 iii. Motivation to engage in exercise will be additionally measured using the Self-Efficacy
49 for Exercise scale (SEE). [39]
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3 The Self-Efficacy for Exercise scale (SEE), [39] a 9-item scale that rates older peoples'
4 response to a statement about barriers to exercise (scores range from 0=not very confident to
5 10=very confident; with a total possible score of 90).
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10 11 *Qualitative*

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13 The secondary qualitative outcomes relate to opportunity (described as being both social and
14 physical in the COM-B framework), [29] and include both barriers and enablers that
15 participants encounter when seeking to engage in falls prevention strategies. These secondary
16 outcomes will be measured by completing semi-structured in-depth phone interviews at the
17 conclusion of the observation period. Questions will be guided by participant responses gained
18 from earlier structured phone interviews, using open-ended questions designed to encourage
19 the participants to reflect on their previous responses. Questions will be framed around barriers
20 and enablers to engaging in falls prevention strategies, graduated return to independence and
21 engaging in exercise. This may be physical opportunity provided by their environment
22 including access and social supports, or cultural milieu including stigmas or fears that dictate
23 older adult decision-making. [29]
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40 Demographic data will be gathered in hospital at baseline by recruiters during a face to face
41 interview. These data will include age, gender, diagnosis, length of stay in hospital, history of
42 falls prior to hospitalisation and during hospital stay, presence of visual impairment, presence
43 of hearing impairment, number and type of medications, signs of depression (measured using
44 Geriatric Depression Scale), [40] and use of walking aids.
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53 Other data is also collected at baseline during the face to face interview then again at six-
54 months after discharge using a structured phone survey. These variables are living situation
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3 (home alone, with partner, other situation), level of indoor and outdoor mobility, including any
4 use of walking aids, functional mobility measured using Katz and Lawton's Scales [5, 36], and
5 health related quality of life measured using the Assessment of Quality of Life tool (AQoL)
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7 [41].
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13 Additionally, as part of the education intervention, data are collected regarding the delivery of
14 the program by the educators. These data include the number of education sessions provided to
15 each intervention group participant, the duration, and whether an action plan was completed.
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17 These data will also be used during sensitivity analyses, to assist to explain participants'
18 knowledge, motivation, and engagement in falls prevention strategies after discharge.
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26 **Data collection and procedure**

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29 Baseline surveys for primary and secondary outcomes are conducted by a trained research
30 assistant who is blinded to group allocation, then participants are randomly allocated to
31 intervention or control group. The RCT protocol, including randomisation, blinding, and the
32 intervention procedure has been described in detail elsewhere. [28] Briefly, participants receive
33 tailored falls prevention education by trained physiotherapist educators during a one-to one
34 interaction in hospital. The education assists the participant to prepare a tailored plan to initiate
35 after hospital discharge. The participants are then followed up by phone after discharge by the
36 educators once a month for three months, to further assist them to enact their plan, and address
37 any barriers that may have arisen since discharge.
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51 At six-months following hospital discharge, the structured phone survey will be conducted to
52 collect quantitative follow up data, after which the participant will be invited to participate in a
53 semi-structured in-depth phone interview to collect qualitative data that measures the
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3 secondary outcome which explores opportunity (barriers and enablers) to engagement in falls
4 prevention strategies.
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9 Purposive sampling for qualitative data collection will occur after the six-month period and
10 following completion of primary and secondary quantitative data collection. The sample
11 selected will represent the cohort, with consideration of age, diagnosis, gender, falls history,
12 and whether intervention or control group. Purposive sampling will be finalised and justified
13 by referring to data and theoretical saturation and confirmed through consensus of a second
14 researcher reviewing the transcribed narrative data.[42] A phone interview was selected to
15 collect data, rather than a focus group, or face to face interview, as the participants have
16 previously received monthly phone monitoring of falls data from the RCT, so the researcher
17 has established a genuine rapport and reciprocity with the participants.[43] To ensure quality
18 data collection that is sufficient to answer the study aim, the semi-structured survey has been
19 piloted to ensure the questions are easily understood and screened for blind spots, bias, and
20 potentially sensitive questions. [33] Each interview will be recorded and transcribed verbatim.
21 Additional interviews will be completed as necessary until data saturation has occurred. The
22 researcher will keep a journal to record observations and reflections regarding data collection
23 and procedure. [43]
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45 **Statistical Analysis**

46 *Quantitative data*

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48 Quantitative data will be analysed using Stata (Stata Statistical Software: College Station, TX:
49 StataCorp LP) [44] and intention to treat analysis will be undertaken when examining potential
50 influence of group allocation on process outcomes based on the trial randomisation. [45].
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56 Primary and secondary outcomes will be summarized using descriptive statistics. The primary
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3 analysis will compare engagement with each strategy between the control and intervention
4 groups for six months post-discharge from hospital, using regression models that will control
5 for baseline measures of engagement and be conducted with adjustment for potential covariates
6 consistent with the prior pilot study for this trial. [26] Similarly, secondary analyses will
7 compare the secondary outcomes to examine potential between group differences using
8 regression models that will control for baseline and be conducted with adjustment for potential
9 covariates consistent with the prior pilot study for this trial. [26] Sensitivity analyses will also
10 be conducted to examine whether the trial findings are robust to planned analysis choices (e.g.,
11 intention-to-treat versus as treated analyses, or adjusted versus unadjusted regression models).
12 The significance level for analyses will be set at 0.05, and the sample size was determined by
13 primary trial effect analysis, which has previously been described. [28]
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30 *Qualitative data*

31 Qualitative data from researcher field notes, phone interview transcriptions and participant
32 open-ended answers to structured questions in the quantitative survey will be used, with the
33 intent to triangulate the different data sources and gain a multi-layered understanding of the
34 findings. [32, 33] Interpretive phenomenological analysis (IPA) will be used to describe and
35 interpret participants' behaviours regarding engagement in falls prevention strategies. [46]
36 Briefly, following IPA guidelines' the two researchers will independently produce detailed
37 interpretive coding of how and why the participants experienced barriers or enablers to
38 engaging falls prevention strategies since hospital discharge. These coded data will then be
39 examined by the two researchers together to identify emergent themes then re-examined to
40 ascertain if it described the data collected and if all coded data were captured within these
41 identified emergent themes. [46] Member-checking will occur by the first researcher returning
42 to a sample of participants to ask them how accurately their realities have been represented in
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3 the final interpretations. [42] To add rigor, a third researcher who is not involved in data
4 collection, will then be invited to scrutinize the data and to arbitrate any differences between
5 coding and themes, and review final interpretations. [46] Purposive sampling for qualitative
6 data collection will be finalised and justified by consensus between all three researchers
7 referring to the findings to confirm saturation of themes. [46]
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15 Finally, quantitative and qualitative data will be synthesised to enrich the interpretation of the
16 findings with the aim of adding validity to the study. [33, 42]. An overview of the procedure
17 for primary and secondary quantitative and qualitative data collection and statistical analysis is
18 presented in Figure 2.
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26 **DISCUSSION**

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28 Older people are known to have increased rates of falls and functional decline following
29 hospital discharge. [7, 8] Recent studies investigating readmissions have found that patients are
30 unprepared to manage their physical limitations during their immediate recovery after hospital
31 discharge. [24, 25] These investigations have shifted from a hospital-centric model to a patient-
32 centred approach to understand the lived experience of older adults as they transition from
33 hospital to home. [47] This is important because other systematic reviews of discharge
34 planning have identified that while readmissions may be reduced with such interventions, the
35 impact on health outcomes for the patients is uncertain. [48]
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48 Previous observational studies have suggested that to promote participation in evidenced-based
49 falls prevention strategies, therapists may need to convince older adults that they are at risk of
50 falls, [23] with guidance on what specific strategies are likely to have a personally beneficial
51 falls prevention effect. [22] Tailored health education aims to change individuals' health
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3 behaviours. [29, 30] When this education is used as an intervention, it presents a challenge for
4 identifying effective components, and therefore reporting of findings, and subsequent
5 replication. [31, 32]
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11 This process evaluation will seek to understand whether providing tailored education facilitates
12 older adults' engagement in falls prevention strategies following hospital discharge. The
13 application of the framework of the COM-B model to the findings, [29] will assist to
14 characterise how the intervention altered motivation, capability or opportunity. Additionally,
15 secondary analysis of barriers or enablers to engagement will be mapped onto the COM-B
16 model and subsequently identify more precise determinants of engagement. [49] Capability
17 includes an individual's psychological and physical capacity to engage in falls prevention
18 strategies behaviour. Opportunity, both social and physical, includes those factors that lie
19 outside the individual that make the behaviour possible, such as being able to access home
20 assistance or modifications. [29] Motivation includes all processes that inspire and direct
21 behaviour, such as believing that it would be good to exercise. [29]
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37 This study has strengths and limitations that warrant consideration. A strength is that the
38 participants are a broad cohort recruited from a representative sample of three public
39 metropolitan rehabilitation hospitals in Australia. The delivery of a falls prevention education
40 intervention just prior to discharge with follow-up sessions by telephone during one month
41 after hospital discharge has previously shown promising effects on older adult engagement in
42 falls prevention strategies in a pilot trial. [26] Other strengths include the prospective design,
43 robust data collection and the convergent embedded mixed method design, which combines the
44 advantages of both quantitative and qualitative data. [32, 43]
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3 A possible limitation is that the participants have been drawn from a high-risk population that
4 may still be affected by their illness. To minimise bias through possible prompting of
5 participants, data regarding engagement in falls prevention strategies following hospital
6 discharge, will not be collected until six months post-discharge. We are also relying on self-
7 reported data at six months. Participants are only contacted by phone and not interviewed face
8 to face, however we have found in our earlier trials [1, 26] that this allows more complete
9 responses as older people, especially if unwell, are not always able to attend a clinic setting.
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20 **Conclusion**

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

Consent for publication

Not applicable

Competing interests

None to declare

Funding

Authors SM, TH, MEM, JF-C, CE-B, D-CAL, LF, AMH have received a grant from the National Health and Medical Research Council (Australia) to conduct a trial which investigates how to reduce falls and promote independence in older people after hospital discharge (Project App no:1078918). CN receives a post graduate student stipend as part of the grant. This grant funding has not been received directly to the authors rather to the institutions they represent. The authors have not received financial support for this study. SM receives career funding support from the National Health and Medical Research Council (Australia).

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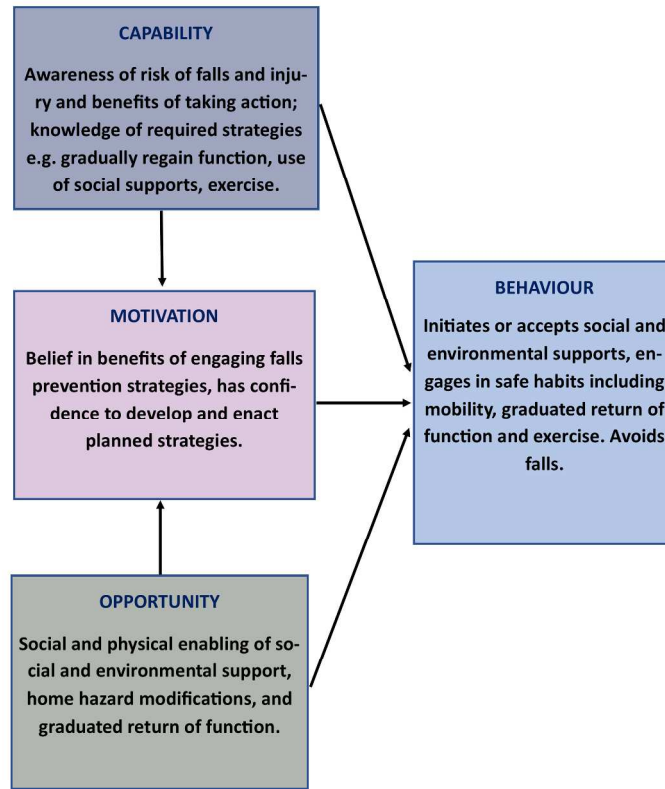
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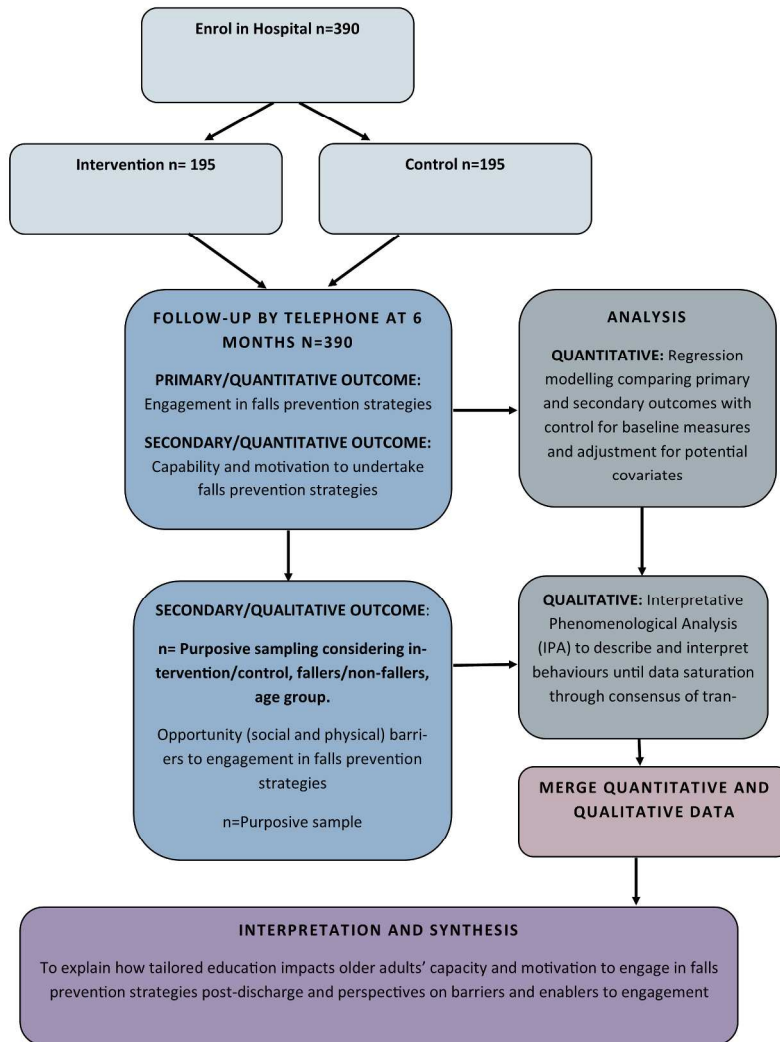
Figure 1. COM-B system applied to falls prevention behaviour post-discharge



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Figure 2. Study Procedure



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