RESPOND: a patient-centred programme to prevent secondary falls in older people presenting to the emergency department with a fall—protocol for a mixed methods programme evaluation

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ABSTRACT

Background Programme evaluations conducted alongside randomised controlled trials (RCTs) have potential to enhance understanding of trial outcomes. This paper describes a multi-level programme evaluation to be conducted alongside an RCT of a falls prevention programme (RESPOND).

Objectives (1) To conduct a process evaluation in order to identify the degree of implementation fidelity and associated barriers and facilitators. (2) To evaluate the primary intended impact of the programme: participation in fall prevention strategies and the factors influencing participation. (3) To identify the factors influencing RESPOND RCT outcomes: falls, fall injuries and emergency department (ED) re-presentations.

Methods/design 528 community-dwelling adults aged 60–90 years presenting to two EDs with a fall will be recruited and randomly assigned to the intervention or standard care group. All RESPOND participants and RESPOND clinicians will be included in the evaluation. A mixed methods design will be used and a programme logic model will frame the evaluation. Data will be sourced from interviews, focus groups, questionnaires, clinician case notes, recruitment records, participant-completed calendars, hospital administrative datasets and audio-recordings of intervention contacts. Quantitative data will be analysed via descriptive and inferential statistics and qualitative data will be interpreted using thematic analysis.

Discussion The RESPOND programme evaluation will provide information about contextual and influencing factors related to the RESPOND RCT outcomes. The results will assist researchers, clinicians and policy makers regarding decisions about future falls prevention interventions. Insights gained may be applicable to a range of chronic conditions where similar preventive intervention approaches are indicated.

Trial registration number This programme evaluation is linked to the RESPOND RCT which is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000336684).

BACKGROUND

Falls are a serious problem among community-dwelling older people and represent the leading cause of emergency department (ED) presentations for older adults.[1] Following an ED presentation for a fall, up to half of cases will experience subsequent falls, often resulting in detrimental physical and psychological consequences.[2–5] Various falls prevention approaches have reduced falls within the clinical trial setting.[6] However, there was a significant increase in age-standardised fall-related hospitalisation rates for older people from 1999–2000 to 2010–2011, according to Australian data.[7] Similarly, a recent US study estimated that the number of fall-related injuries treated in ED increased from 1.6 million in 2001 to 2.4 million in 2012 and may increase to 5.7 million by the year 2030 for adults aged 65 and over.[8] These upward trends suggest that favourable trial results are not being sufficiently translated to practice.

Falls are often the result of a complex mix of physiological, medical, behavioural and environmental risk factors.[9] Individual characteristics, such as socio-demographic factors, are also associated with risk of falling.[10] Effective falls risk management is a multi-component process, with best practice guidelines recommending early screening to detect risk factors and implementation of tailored interventions taking into account individual preferences in order to address the necessary changes.[11–13] Key components influencing the success or failure of a programme are the rate of participation in and adherence to recommended falls prevention strategies among those receiving the intervention.[11] Adherence to multifactorial interventions has varied, ranging from 28% to 95% for individual components.[14] Lack of perceived personal relevance may partially explain poor participation rates, and has been expressed by up to 34% of older adults when provided with details of evidence-based falls prevention strategies.[15] Conversely, acceptability of interventions, including perceived relevance and benefit, and involvement in decision-making, has been shown to facilitate participation.[16] In addition, health literacy contributes to the capacity of an individual to partake in preventative health programmes.[17] As 50% of older Australians are likely to have inadequate health literacy,[18] this may be a substantial factor related to participation in falls prevention strategies. Given the number of inter-related factors involved, it is often difficult to identify the key individual characteristics, participatory factors and programme components responsible for facilitating or inhibiting a reduction in falls from clinical trial results alone.

Understanding of trial results can be enhanced by conducting a programme evaluation.[19][20] Evaluations can be conducted on a number of levels including process (the degree of, and factors that influence, implementation fidelity),[21][22] impact (changes in specific participant behaviours, knowledge or skills)[23] and outcome (whether or not a programme achieved its goals, and why).[24] Comprehensive programme evaluations are especially pertinent for multicentre trials where there is a risk that the same programme may be implemented and received in different ways.[19] However, despite the value of conducting comprehensive programme evaluations alongside falls prevention trials, there is limited evidence of this occurring.

Elements of process evaluation have been reported alongside three randomised controlled trials (RCTs) of falls prevention programmes targeting cognitively intact older adults who have presented to the ED with a fall.[3][25][26] None of the three trials demonstrated a significant reduction in falls between the intervention and standard care groups. However, evaluation of process factors allowed for some explanation of the trial results. Two of the studies reported adherence to falls prevention strategies, with comparison between the intervention and control groups.[3][26] A referral-based intervention reported that adherence was highest for occupational therapy, physiotherapy and podiatry, and lowest for written and oral advice. In addition, control group contamination included 17% of standard care participants referred to physiotherapy and 4% to falls clinics.[3] Similarly, a Dutch study involving a geriatric assessment and multifactorial intervention reported that control group contamination was a possible factor influencing trial results.[26] In contrast, a process evaluation of a Dutch version of the successful British PROFET trial did not report participation in falls prevention strategies for the control group, despite discussing the possibility that the lack of contrast between groups may have been a factor explaining the lack of favourable trial results.[25] However, the evaluation did comprise a number of additional process evaluation elements, allowing the authors to conclude that the multidisciplinary programme was largely implemented according to protocol, and was acceptable to those delivering and receiving the programme. The authors concluded that lack of effectiveness was potentially due to the relatively low number of referrals and recommendations ensuing from the suggestion to contact their general practitioner (GP) for ongoing management.

No impact evaluations of RCTs of falls prevention programmes targeting older adults presenting to the ED with a fall have been conducted. However, a non-randomised pretest post-test study evaluated the impact of peer-presented education sessions on falls-related attitude, knowledge and behaviour of older people.[23] The study demonstrates the value of conducting an impact evaluation, as a number of recommendations were made for effective targeting of future falls prevention programmes. Evaluations of factors associated with RCT outcomes are also not evident in the current literature related to falls prevention programmes targeting older people presenting to the ED with a fall. Identification of associations between certain participant characteristics and trial outcomes can provide insight into which subgroups of participants the intervention is most, and least, effective for. One German RCT of an intervention comprising a geriatric assessment and home visit conducted a subgroup analysis and found that the intervention was most effective for participants who reported having had two or more falls during the year before recruitment into the study.[27] Although falls history is an important factor to consider, evaluation of a number of other participant characteristics, such as health status, socio-demographic and health literacy factors, may provide deeper understanding of trial outcomes.[10][17][18]

This paper describes a mixed methods process, impact and outcome evaluation to be conducted alongside an RCT of a falls prevention programme—RESPOND. RESPOND is a patient-centred intervention designed to improve older persons' participation in falls prevention strategies through delivery of patient-centred education and behaviour change strategies. The proposed evaluation intends to provide insight into the contextual and influencing factors related to the RESPOND RCT outcomes. Results of this study may be applicable to other falls prevention programmes, as well as a range of chronic conditions where similar preventive intervention approaches are indicated.

OBJECTIVES
1. For the process evaluation we will:
   A. Assess the degree to which RESPOND was implemented as planned.
   B. Identify barriers and facilitators to implementation from the perspectives of those delivering and receiving the intervention.
2. For the impact evaluation we will:
   A. Identify whether RESPOND increases participation in falls prevention strategies, and factors influencing participation among the intervention group, compared with standard care.
   B. Determine the degree to which participant characteristics and RESPOND programme factors are associated with participation in falls prevention strategies.
3. For the outcome evaluation we will:
   A. Determine the degree to which participant characteristics, participatory and RESPOND programme factors influence falls, fall injuries and ED re-presentations.

METHODS/DESIGN
Study design
Overview and purpose of the logic model
The evaluation will be conducted alongside an RCT of the RESPOND programme and will apply a convergent parallel mixed methods design.[28] Data collected as part of the RCT will be used in addition to data collected specifically for programme evaluative purposes. A logic model (figure 1) that outlines each component of the RESPOND programme was mapped as a framework to guide and inform the evaluation. The model articulates relationships between inputs (resources available for the programme), activities conducted with these resources, outputs (products of the programme activities), impacts (specific changes in participants' behaviour) and outcomes (fundamental change occurring as a result of the programme).

Levels of evaluation and how they relate to the logic model
Three levels of evaluation will be conducted: (1) process, (2) impact and (3) outcome. The process evaluation relates to implementation fidelity and corresponds with the inputs, activities and outputs in the logic model. The impact evaluation focuses on factors related to achieving the primary intended behavioural change: increased participation in falls prevention strategies. The outcome evaluation will identify subgroups for which the RESPOND programme is most and least effective in terms of reducing falls, fall injuries and ED re-presentations. The impact and outcome evaluations correspond with their respective columns in the logic model. The evaluation plan is summarised in table 1.

RESPOND RCT

Study design details of the RESPOND RCT are described elsewhere.[29] In summary, a single-blind multicentre RCT of the RESPOND falls prevention programme, compared with standard care, will be conducted. The comparator group will continue to receive standard care from all health professionals involved in their management within the ED and primary care setting during the 12-month follow-up.

Participants and setting

All participants in the RESPOND RCT will contribute to the programme evaluation. The RCT will recruit 528 community-dwelling persons aged 60–90 years who present over a 12-month period to two tertiary referral EDs in Perth and Melbourne, Australia, with a fall and who are planned to be discharged directly home from the hospital within 72 h.

RESPOND RCT outcomes and data collection

A number of outcomes will be reported for the RESPOND RCT. However, for the purpose of the programme evaluation, factors related to only three trial outcomes will be analysed. These outcomes are falls, fall injuries and ED re-presentations per person-year in the 12 months after recruitment. A fall is defined as per the WHO: 'an event resulting in a person coming to rest inadvertently on the ground, floor or other lower level'.[30] A fall injury is any physical harm resulting from a fall.

Hospital administrative data will be audited to determine the number of ED presentations that occur during the 12-month follow-up. Participants in both groups of the trial will complete monthly calendars documenting details of any falls, fall injuries and ED presentations on a daily basis. All participants will receive a monthly telephone call from a RESPOND outcome assessor to verify information recorded on calendars. The outcome assessors will be blinded to group allocation.

The RESPOND intervention

The key inputs, activities and intended outputs of the RESPOND programme are summarised in the logic model (figure 1). The RESPOND intervention comprises four modules related to evidence-based falls risk factors and their associated management strategies. The risk factors targeted in RESPOND are: strength and/or balance impairment; vision impairment; long-term use of benzodiazepines or z-drugs; and poor bone health. The intervention will be delivered by health professionals experienced in falls prevention and trained in motivational interviewing and behaviour change strategies. They will provide education and coaching to participants in the intervention group via an initial face-to-face home visit and follow-up telephone calls. Education and coaching will focus on positive health messages and participant-centred care to optimise participant engagement and participation in strategies to decrease falls.

Planned dosage of intervention

The dosage according to protocol is an initial 45 min face-to-face session within 2 weeks of ED discharge, with the first coaching phone call made within 2 weeks of the initial visit and the second within 3 months. Remaining phone calls will occur at intervals that allow progress towards goals. There will be a minimum of two follow-up phone calls with each call lasting approximately 45 min. Each participant will receive an average of 10 h of coaching over a 6-month period.

Objective 1: process evaluation

The degree to which RESPOND was implemented as planned

Assessment of implementation fidelity aims to document how the intervention is delivered and received, and compare this with intended implementation. For this objective, the domains to be evaluated are: the reach, delivery of (in terms of content and dosage) and adherence to the RESPOND intervention.

Reach refers to the proportion of intended target audience who participate in an intervention.[31] Hospital admitted episode and ED administrative data will be audited to identify the number of potentially eligible study participants and reported in the RESPOND RCT outcome paper. The process evaluation will add to this by identifying the proportion of eligible participants who declined to participate in the trial and the reasons stated for
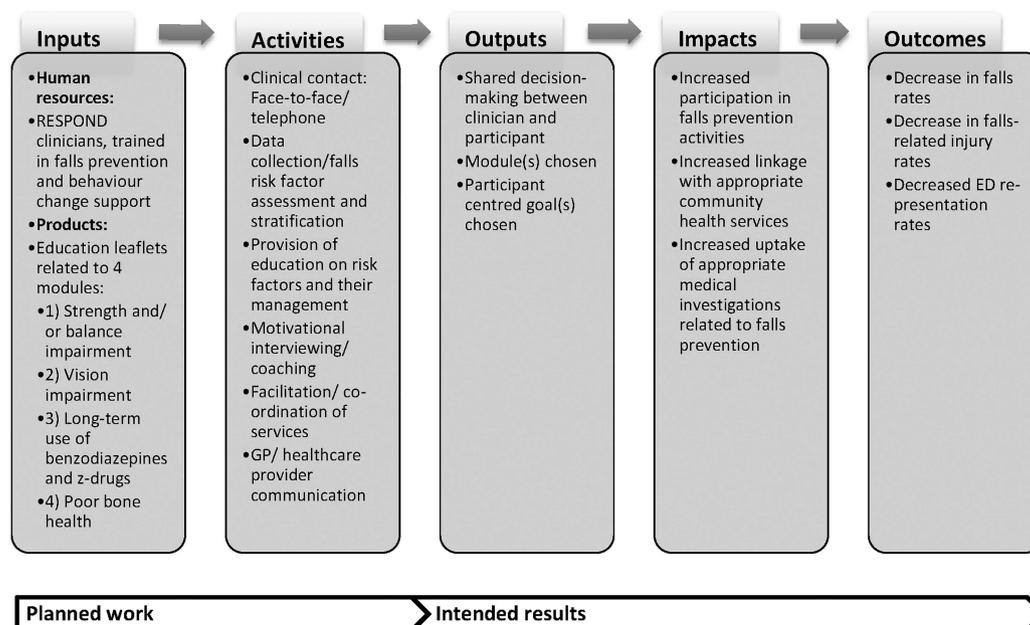

Figure 1 RESPOND programme logic model. ED, emergency department; GP, general practitioner.

Table 1 RESPOND programme evaluation plan

Objective	Evaluation component	Data source	Timing of data collection
1. Process evaluation			
(a) Assess the degree to which RESPOND was implemented as planned	Implementation fidelity: reach	Recruiter records	Recruitment
		Hospital administrative data	12 months
	Implementation fidelity: content	Clinician records	6 months
		Audio-recordings of clinician–participant contacts	6 months
	Implementation fidelity: dosage	Clinician records	6 months
	Implementation fidelity: adherence	Clinician records	6 months
(b) Identify barriers and facilitators to implementation from the perspectives of those delivering and receiving the intervention	Barriers and facilitators, acceptability, perceived relevance, perceived benefit	Participant questionnaire (intervention)	6 months
	Barriers and facilitators to achieving RESPOND goals	Participant focus groups (intervention)	6 months
		RESPOND clinician interviews	12 months
		Clinician records	6 months
	RESPOND clinician training and support	RESPOND clinician interviews	12 months
2. Impact evaluation			
(a) Identify whether RESPOND increases participation in falls prevention strategies, and factors influencing participation among the intervention group compared with standard care	Participation in falls prevention strategies	Participant-completed calendars (intervention and standard care)	6 and 12 months
		Participant questionnaire (intervention and standard care)	12 months
(b) Determine the degree to which participant characteristics and RESPOND programme factors are associated with participation in falls prevention strategies	Participant characteristics	Hospital administrative data	Baseline
		FROP-Com	Baseline
		Health Literacy Questionnaire	Baseline
		Initial clinician interview with participant	Baseline
	Programme factors	As per objective 1a	6 months
	Participation in falls prevention strategies	As per objective 2a	6 and 12 months
3. Outcome evaluation			
(a) Determine the degree to which participant characteristics, participatory and RESPOND programme factors influence falls, fall injuries and ED re-presentations	Participant characteristics	As per objective 2b	Baseline
	Participation in falls prevention strategies	As per objective 2a	6 and 12 months
	Programme factors	As per objective 1a	6 months
	Falls and falls injuries	Participant-completed calendars (intervention and standard care)	6 and 12 months
	ED re-presentations	Participant-completed calendars (intervention and standard care)	6 and 12 months
		Hospital administrative data	12 months

ED, emergency department; FROP-Com, Falls Risk for Older People—Community setting.

declining. This includes differentiation between declining to participate in a research project and declining to participate in a falls prevention programme. The primary reason stated by patients for declining to participate is also captured. This information will be collected by RESPOND recruiters. Reasons expressed for exiting the study prematurely will also be collected by RESPOND clinicians and outcome assessors as appropriate.

Evaluation of delivery will be divided into two subcategories: content and dosage. Content refers to the delivery of each individual component of the RESPOND programme tailored to the individual participant. This includes the provision of education related to falls risk factors and their management, application of motivational interviewing techniques, shared decision-making leading to choice of module(s) and goal setting, and coordination of referrals to appropriate community services (as per 'activities' and 'outputs' in figure 1). Clinician–participant contacts will be audio-recorded, where written consent has been obtained, in order to evaluate the proportion of key RESPOND elements delivered. In all, 10% of randomly selected intervention audio-recordings will be used for analysis. The degree of participatory decision-making will be evaluated by applying the Rochester

Participatory Decision-Making Scale.[32] This tool relates closely to the focus of RESPOND as a patient-centred programme and includes items such as the clinician clearly explaining the relevant issues, discussing uncertainties, clarifying agreement, examining barriers and asking open ended questions. This tool has been found to be valid and reliable in a study of physician–patient communication with primary care physicians.[32] Other RESPOND components, such as provision of education and application of motivational interviewing techniques, will be evaluated using qualitative methods (see analysis for details). The proportion and type of discussions that occur beyond the scope of RESPOND during the intervention contacts will be also be evaluated through analysis of the audio-recordings.

Dosage of intervention delivered will be evaluated for all intervention participants and compared with the planned dosage of delivery (detailed above). This will include information related to the timing, frequency and total number of intervention contacts made by the RESPOND clinician per participant, as well as total duration of participation in the intervention (maximum 6 months). Dosage data will be obtained from clinician records.

Adherence refers to the extent to which the intervention participants actively engage with and act on agreed recommendations.[31] Data collection will include the number and type of modules chosen, the number and type of goals chosen, and management strategies chosen to address the goals. Participant-reported achievement of agreed actions to address goals will be captured and recorded by RESPOND clinicians for all intervention participants.

Barriers and facilitators to implementation

In order to understand the reasons for the degree of implementation fidelity established above, barriers and facilitators will be identified from the perspectives of those delivering and receiving the intervention. This will include exploring domains such as acceptability of the programme content, including the modules and written and verbal education provided; programme delivery in terms of dosage and delivery mode (combination of home visit and telephone contacts); and the patient-centred health-coaching delivery style. Perceived benefit and perceived relevance of the RESPOND programme will also be evaluated.

Data will be collected from a number of sources. As part of the intervention delivery, clinicians will ask participants to identify barriers and facilitators to achieving RESPOND goals. This will be recorded in clinician notes, in the form of 'tick box' options including commonly identified barriers and facilitators.[16] Additional free text options will ensure barriers and facilitators beyond preanticipated responses are captured.

All intervention participants will also receive a questionnaire on completion of the RESPOND programme (6 months from commencement). This will seek feedback related to evaluation domains including barriers and facilitators to participation in the RESPOND programme, acceptability of the content, dosage, delivery mode, and perceived benefit and relevance of the programme. The survey instrument will be developed by the research team and will include a series of statements with 5-point Likert scale response options (strongly agree to strongly disagree). Additional free text options will be included in the questionnaire. The questionnaire will be posted or emailed (depending on the preferred communication method of the participant identified at recruitment). The timing of the questionnaire aims to reduce the potential for recall bias.

RESPOND clinicians will be individually interviewed at 12 months from commencement of the trial using a semistructured interview template in order to ascertain information related to their experience delivering the RESPOND programme. Evaluation domains that will be explored will be similar to those explored in the intervention participant questionnaires to allow for triangulation of evaluation domains. In addition, opinions related to the content, timing and frequency of RESPOND training and support will be sought. All consenting RESPOND clinicians employed throughout the trial period (a minimum of five) will be included in the programme evaluation. As data from the perspective of those delivering the intervention are qualitative, this sample size is considered to be sufficient for the purpose of analyses.

RESPOND intervention participants who have completed the programme will be invited to take part in a focus group. Focus groups consisting of 8–10 participants will be conducted at both trial sites using a semi-structured template exploring the evaluation domains included in the participant questionnaire. Quota sampling will ensure a broad range of participants according to socio-demographic and health status factors and will consider (but not be limited to): gender, age and falls risk profile. Falls risk profile will be determined and categorised as mild, moderate or high as per the Falls Risk for Older People—Community

setting (FROP-Com) which will be administered to all participants at baseline.[33] [34] The sample size for the focus groups will ensure saturation of themes has been reached. In the instance of certain socio-demographic groups of participants being unable to attend focus groups, purposive sampling will be conducted to target missed groups, and individual telephone interviews will be conducted, following the same semistructured template as described above for focus groups. All interviews and focus groups will be audio-recorded and field notes taken. It is expected that at least four focus groups will be required per RCT site (eight in total).

Objective 2: impact evaluation
Participation in falls prevention strategies

An increase in participation in falls prevention strategies is the key intended impact of the RESPOND programme. Measurement of participation will be consistent for all impact and outcome evaluation objectives and is defined as the rate of GP; physiotherapy; occupational therapy; falls clinic/ specialist; geriatrician; optometrist; and ophthalmologist appointments attended by RESPOND participants (control and intervention). This information will be captured alongside RESPOND RCT data, in the participant-completed monthly calendars and telephone calls. These specific strategies were chosen as they correlate with management strategy options recommended in the RESPOND falls risk factor education modules. Estimation of participation in falls prevention strategies is powered to detect a significant difference in participation rates between the intervention and control groups in the 12-month follow-up. Assuming a control group participation rate of 5.7 appointments attended per person-year,[3] [26] the minimum percentage change in participation that can be detected with 80% power at the 5% level of significance is 12.5% when taking into account the sample size for the RESPOND RCT (n=528).

Data related to specific falls prevention strategies, such as vitamin D tests, duel-energy X-ray absorptiometry scans and home environment assessments are not captured in the calendars as these may prompt behaviour change in the control participants and therefore be a potential source of contamination. In addition, as RESPOND is focused on four evidence-based risk factors and corresponding management strategies, participants may be involved in other falls prevention strategies beyond the scope of RESPOND. In order to capture this additional participatory data, a questionnaire will be sent to all participants (intervention and control) at 12 months. The questionnaire will ask a series of open and closed questions related to participation in a broad spectrum of falls prevention strategies including vitamin D tests and supplementation; duel-energy X-ray absorptiometry scans; home environment assessments; consultation with medical specialists; and participation in home and/or community-based exercise. Perceived barriers and facilitators to participation in falls prevention strategies will also be explored. Data from the 12-month questionnaire will provide valuable insight into standard care available in the community. The timing of this questionnaire aims to reduce the chance of influencing participant behaviour during the trial period.

Participant characteristics, RESPOND programme factors and their influence on participation in falls prevention strategies

This component of the impact evaluation will identify relationships between certain participant characteristics, RESPOND programme factors, and higher or lower levels of participation in falls prevention strategies. Key participant characteristics will be identified at baseline and will include: age; gender; lives alone; level of independence; falls risk status; falls history; employment

status; comorbidities; and health literacy. Falls risk status, falls history (past 12 months) and comorbidities will be determined by the FROP-Com. Health literacy will be determined by the Health Literacy Questionnaire.[35] Whether the participant lives alone, employment status and level of independence will be determined at baseline assessment through clinician interview with the participant. Age and gender will be determined from hospital records at the point of recruitment. Exploratory analysis will be undertaken to determine if there are any other significant factors associated with participation in falls prevention strategies. RESPOND programme factors include the intensity, frequency and duration of intervention delivered, modules chosen and goals achieved. This information will be available from the process evaluation detailed above (objective 1). Participation will be assessed by combining data pertaining to health service utilisation (as described in objective 2a).

Objective 3: outcome evaluation
Participant characteristics, participatory and RESPOND programme factors and their influence on falls, fall injuries and ED re-presentations

It is important to understand for whom a falls prevention programme is best and least effective for in terms of achieving trial outcomes. This allows for increased effectiveness and efficiency in future application of the programme. This analysis will identify the associations among participant characteristics and participatory factors (as determined in the impact evaluation), RESPOND programme factors (as determined in the process evaluation) and the main outcomes for the RESPOND RCT, falls, fall injuries and ED re-presentations, to enhance the understanding and value of the trial results. Data related to these three trial outcomes will be obtained from RESPOND RCT data collected via participant calendars, verified with monthly phone calls from an outcome assessor, and hospital administrative data (as described above for RESPOND RCT outcomes and data collection).

Inter-site comparison
An inter-site comparison will be conducted for each objective in order to determine site-specific similarities and differences. As the trial includes two Australian states, state-specific variations, such as geographical, political and economic factors, as well as hospital specific variations such as organisational structure, funding, and culture may influence the success of the RESPOND RCT. An inter-site comparison will allow for conclusions related to the generalisability of the programme to a wider population.

Data analysis and synthesis
Quantitative analysis

The data will be analysed in two separate stages: primary and a secondary analysis. The primary analysis will compare the participation in falls prevention strategies between the control and intervention groups at 6 and 12 months post baseline. Differences between groups will be compared using negative binomial regression. Secondary analyses include descriptive statistics of process measures (reach, delivery and adherence), such as mean, SD, frequency and proportion to be calculated as appropriate. We will assess differences in participation, falls, fall injuries and ED re-presentations across covariates by adding a treatment group by covariate interaction term to the negative binomial regression models. Covariates to be considered in the analysis include: age; gender; lives alone; level of independence; falls risk status; falls history; employment status; comorbidities;

and health literacy. A variable for adjustment by site will be included in all analyses. A significance level of $p < 0.05$ will be used. Stata software will be used to analyse quantitative data.

Qualitative analysis

Qualitative data will be transcribed and coded by two members of the research team and thematic analysis will be used to analyse the data. An inductive approach will be used to analyse focus groups, interviews, qualitative aspects of questionnaires, and free text options in recruiter and clinician notes. Both a deductive and inductive approach will be used to analyse the intervention audio-recordings. A deductive approach will be applied to determine the degree to which RESPOND clinicians adhere to key RESPOND activities, as per the logic model (figure 1). This includes provision of education, application of motivational interviewing techniques and facilitation and coordination of services. An inductive approach will allow for identification and analysis of clinician–participant interactions beyond the scope of RESPOND. If at any stage consensus cannot be reached, a third researcher will review those aspects.[36] NVivo software will be used to facilitate management of the qualitative data and analysis.

Integration of quantitative and qualitative data

Quantitative and qualitative data will be triangulated, summarised and interpreted. The extent to which, and in what ways, results from the two types of data converge, diverge, relate to each other and/or produce a more complete understanding will be reported and discussed.

Ethics
Ethics approval was obtained from each of the participating hospitals, Alfred Health (HREC 439/13) and Royal Perth Hospital (REG 13-128), Monash University Human Research Ethics Committee (MUHREC CF13/3869-201300) and Curtin University HREC (HR 43/ 2014). Ethics approval covers both the RESPOND RCT and programme evaluation.

DISCUSSION
This paper details a mixed methods programme evaluation to be conducted alongside an RCT of a patient-centred falls prevention programme—RESPOND. The evaluation aims to address the lack of comprehensive multi-level evaluations conducted alongside RCTs of falls prevention programmes targeting older adults attending the ED with a fall. The results of this evaluation will assist in explaining the RESPOND RCT results, including subgroup analyses identifying factors associated with better or worse outcomes, in order to effectively and efficiently target limited resources for future falls prevention research and practice. Insights into the coaching style of programme delivery, including education, patient-centred decision-making and motivational interviewing, have potential to be transferable beyond the realms of falls prevention and may contribute to policy and practice for a range of chronic conditions where similar preventive intervention approaches are indicated.

There are a number of methodological strengths to this programme evaluation. Using a mixed methods design which incorporates both quantitative and qualitative data allows for a richer understanding of the RESPOND programme than either method alone. Conducting the evaluation alongside an RCT has the advantage of planning for timely and appropriate data collection, in synergy with RCT data collection. In addition, the study design allows for comparison between the control and intervention group, providing information on the relative

benefits of the RESPOND intervention above current standard care provided to patients.

Triangulation of data from both the clinician and participant perspectives will allow for insights into any similarities or discrepancies between the viewpoints of those delivering and receiving the programme, increasing internal validity of the study. The use of audio-recordings of intervention contacts in addition to participant and clinician reported data will reduce the impact of recall and reporting bias, further adding to the validity of the findings. Furthermore, an inter-site comparison will facilitate conclusions related to the generalisability of the programme.

CONCLUSION

This multi-level programme evaluation will add value to the RESPOND RCT results and address the current gaps in literature related to comprehensive programme evaluations of falls prevention programmes. The results of this study will inform health service decision makers regarding implementation of policies and practice for falls prevention initiatives for older adults who require an ED attendance. Insights gained will potentially be applicable to a range of chronic conditions where similar preventive intervention approaches are indicated.

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REFERENCES

1 Samaras N, Chevalley T, Samaras D, et al. Older patients in the emergency department: a review. Ann Emerg Med 2010;56:261–9.
2 Bloch F, Jegou D, Dhainaut JF, et al. Do ED staffs have a role to play in the prevention of repeat falls in elderly patients? Am J Emerg Med 2009;27:303–7.
3 Russell MA, Hill KD, Day LM, et al. A randomized controlled trial of a multifactorial falls prevention intervention for older fallers presenting to emergency departments. J Am Geriatr Soc 2010;58:2265–74.
4 Salter A, Khan KM, Donaldson M, et al. Community-dwelling seniors who present to the emergency department with a fall do not receive Guideline care and their fall risk profile worsens significantly: a 6-month prospective study. Osteoporos Int 2006;17:672–83.
5 Scheffer AC, Schuurmans MJ, Van Dijk N, et al. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. Age Ageing 2008;37:19–24.
6 Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. Cochrane Database Syst Rev 2012;9:CD007146.
7 Bradley C. Trends in hospitalisations due to falls by older people, Australia: 1999–00 to 2010–11 Australian Institute of Health and Welfare (AIHW). Injury research and statistics no. 84. Cat. no. INJCAT 160. Canberra: AIHW, 2013.
8 Orces CH, Alamgir H. Trends in fall-related injuries among older adults treated in emergency departments in the USA. Inj Prev Published Online First: 10 Jun 2014. doi:10.1136/injuryprev-2014-041268
9 Deandrea S, Lucenteforte E, Bravi F, et al. Risk factors for falls in community-dwelling older people: a systematic review and meta-analysis. Epidemiology 2010;21:658–68.
10 Bloch F, Thibaud M, Dugué B, et al. Episodes of falling among elderly people: a systematic review and meta-analysis of social and demographic pre-disposing characteristics. Clinics 2010;65:895–903.
11 Shubert TE, Smith ML, Prizer LP, et al. Complexities of fall prevention in clinical settings: a commentary. Gerontologist 2013;54:550–8.
12 Australian Commission on Safety and Quality in Health Care (ACSQHC). Preventing falls and harm from falls in older people: best practice guidelines for Australian community care. Australia: Commonwealth of Australia, 2009.
13 National Institute for Health and Care Excellence (NICE). Falls: assessment and prevention of falls in older people. UK: NICE, 2013.
14 Nyman SR, Victor CR. Older people's participation in and engagement with falls prevention interventions in community settings: an augment to the Cochrane systematic review. Age Ageing 2012;41:16–23.
15 Haines TP, Day L, Hill KD, et al. "Better for others than for me": a belief that should shape our efforts to promote participation in falls prevention strategies. Arch Gerontol Geriatr 2014;59:136–44.
16 Bunn F, Dickinson A, Barnett-Page E, et al. A systematic review of older people's perceptions of facilitators and barriers to participation in falls-prevention interventions. Ageing Soc 2008;28:449–72.
17 Manning D, Dickens C. Health literacy: more choice, but do cancer patients have the skills to decide? Eur J Cancer Care (Engl) 2006;15:448–52.
18 Bush RA, Boyle FM, Ostini R. Risks associated with low functional health literacy in an Australian population. Med J Aust 2010;192:478–9.
19 Oakley A, Strange V, Bonell C, et al. Process evaluation in randomised controlled trials of complex interventions. BMJ 2006;332:413–16.
20 Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655.
21 Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. Implement Sci 2007;2:40.
22 Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. Implement Sci 2010;5:67.
23 Deery HA, Day LM, Fildes BN. An impact evaluation of a falls prevention program among older people. Accid Anal Prev 2000;32:427–33.
24 Nutbeam D. Evaluating health promotion—progress, problems and solutions. Health Promot Int 1998;13:27–44.

25 Bleijlevens MH, Hendriks MR, van Haastregt JC, et al. Process factors explaining the ineffectiveness of a multidisciplinary fall prevention programme: a process evaluation. *BMC Public Health* 2008;8:332.

26 de Vries OJ, Peeters GM, Elders PJ, et al. Multifactorial intervention to reduce falls in older people at high risk of recurrent falls: a randomized controlled trial. *Arch Intern Med* 2010;170:1110–17.

27 Nikolaus T, Bach M. Preventing falls in community-dwelling frail older people using a home intervention team (HIT): results from the randomized Falls-HIT trial. *J Am Geriatr Soc* 2003;51:300–5.

28 Creswell JW, Clark VLP. *Designing and conducting mixed methods research*. 2nd edn. USA: SAGE Publications, 2007.

29 Barker A, Cameron P, Hill K, et al. RESPOND–A patient-centred program to prevent secondary falls in older people presenting to the emergency department with a fall: Protocol for a multi-centre randomised controlled trial. *Inj Prev* Published Online First: 23 Jun 2014. doi:10.1136/injuryprev-2014-041271

30 World Health Organization (WHO). *WHO Global Report on Falls Prevention in Older Age*. *Secondary WHO Global Report on Falls Prevention in Older Age* 2007, page

1. http://www.who.int/violence_injury_prevention/other_injury/falls/en/index.html (accessed Nov 2013).

31 Steckler AB, Linnan L, Israel B. *Process evaluation for public health interventions and research*. San Francisco: Jossey-Bass, 2002.

32 Shields CG, Franks P, Fiscella K, et al. Rochester participatory decision-making scale (RPAD): reliability and validity. *Ann Fam Med* 2005;3:436–42.

33 Russell MA, Hill KD, Blackberry I, et al. The reliability and predictive accuracy of the falls risk for older people in the community assessment (FROP-Com) tool. *Age Ageing* 2008;37:634–9.

34 Russell MA, Hill KD, Day LM, et al. Development of the Falls Risk for Older People in the Community (FROP-Com) screening tool. *Age Ageing* 2009;38:40–6.

35 Osborne RH, Batterham RW, Elsworth GR, et al. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;13:658.

36 Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15:398–405.

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RESPOND: a patient-centred programme to prevent secondary falls in older people presenting to the emergency department with a fall —protocol for a mixed methods programme evaluation

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