MONASH University

# A Program Evaluation of a Falls Prevention Program for Older Adults


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# ABSTRACT

Falls are the leading cause of emergency department (ED) presentations for older people. Falls can be multifactorial in nature and prevention initiatives are often complex. Randomised controlled trials (RCTs) are the gold standard for establishing the effectiveness of interventions. Effect sizes from RCTs, however, lack information on which components worked, how, why, and for whom. This limits the ability to effectively and efficiently replicate the intervention or apply the intervention in different contexts. In addition, health literacy is increasingly recognised as influencing health outcomes. The role of health literacy in programs for those presenting to ED with a fall has not previously been explored.

The aim of this doctoral study was to address the lack of knowledge related to the critical success factors for falls prevention programs for older people who present to ED with a fall by conducting a comprehensive program evaluation of a successful falls prevention program: RESPOND. Secondary aims were to analyse the measurement properties of the Health Literacy Questionnaire (HLQ), determine the level of health literacy ability of the RESPOND cohort, and explore the associations between health literacy and RESPOND impacts and outcomes.

The aims were addressed by conducting three studies:

1) a mixed methods process evaluation of RESPOND (to determine the degree of implementation fidelity and associated barriers and facilitators);

2) an impact and outcome evaluation (sub-group analyses exploring factors associated with participation in falls prevention strategies and RESPOND RCT outcomes); and

3) analysis of the measurement properties of the HLQ using RESPOND RCT baseline data.

The process evaluation determined that RESPOND was delivered in a timely and person-centred manner, at a much lower dose than planned. Most participants received their first intervention session within one month of hospital discharge. RESPOND participants and clinicians reported that implementation was facilitated using gain-framed and personally relevant health messages. Complex health and social issues were the main barriers to participation. The impact and outcome evaluation indicated a trend towards increased participation in falls prevention activities in the intervention group compared with usual care. A history of previous falls was associated with an increase in falls, fall injuries, and ED re-presentations, after adjusting for other participant characteristics and RESPOND program factors. The HLQ overall, had good measurement properties when administered to the RESPOND cohort, providing detailed information on nine distinct components of health literacy.

This research identified key factors that influenced implementation of the RESPOND RCT: person-centred program delivery; participation in falls prevention strategies; and dose and timeliness of intervention. Health literacy may influence participation and falls outcomes, but the mechanism remains unclear. Measurement

of health literacy, using the HLQ, is recommended in order to tailor programs accordingly. The findings of this program evaluation may assist researchers, clinicians, or policy makers wishing to implement RESPOND, or similar programs, in their clinical or community settings.

# PUBLICATIONS DURING ENROLMENT

## Chapter 3

**Morris RL**, Brand CA, Hill KD, Ayton DR, Redfern J, Nyman SR, Lowthian JA, Hill AM, Etherton-Beer CD, Flicker L, Hunter PC, Barker AL. 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. Injury Prevention. 2016 Apr 1;22(2):153-60

## Chapter 4

**Morris RL**, Hill KD, Ackerman IN, Ayton DR, Arendts G, Brand C, Cameron P, Etherton-Beer CD, Flicker L, Hill AM, Hunter P, Lowthian JA, Nyman SR, Morello R, Redfern J, Smit DV, Barker AL. A mixed methods process evaluation of a person-centred falls prevention program. BMC Health Services Research. 2019 Dec;1;19(1):906

## Chapter 6

**Morris RL**, Soh SE, Hill KD, Buchbinder R, Lowthian JA, Redfern J, Etherton-Beer CD, Hill AM, Osborne RH, Arendts G, Barker AL. Measurement properties of the Health Literacy Questionnaire (HLQ) among older adults who present to the emergency department after a fall: a Rasch analysis. BMC Health Services Research. 2017 Dec;17(1):605

## Appendix 4

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## Appendix 5

Richtering SS, **Morris RL**, Soh SE, Barker A, Bampi F, Neubeck L, Coorey G, Mulley J, Chalmers J, Usherwood T, Peiris D. Examination of an eHealth literacy scale and a health literacy scale in a population with moderate to high cardiovascular risk: Rasch analyses. PLoS One. 2017 Apr 27;12(4):e0175372

# PRESENTATIONS ARISING FROM THIS THESIS

**Morris RL**. Barriers and facilitators to delivering an effective falls prevention program: an interdisciplinary allied health perspective. 3rd Victorian Allied Health Research Conference. March 2019. Melbourne, Australia. [Oral presentation]

**Morris RL**. Process evaluation of an effective falls prevention programme: learnings from the RESPOND trial. 19th British Geriatrics Society (BGS) Falls and Postural Stability Conference. September 2018. Leeds, UK. [Oral presentation]

**Morris RL**. Be Your Best: RESPOND falls prevention project. The Centre of Research Excellence in Patient Safety Seminar: Optimising Exercise Programs for Older People To Improve Balance And Prevent Falls. June 2018. Melbourne, Australia. [Oral presentation – invited speaker]

**Morris RL**. Preventing falls among community-dwelling older people: opportunities and challenges. Melbourne Ageing Research Collaboration (MARC) Falls Forum. February 2018. Melbourne, Australia. [Oral presentation – invited speaker]

**Morris RL**. Barriers and Facilitators to Implementation of the RESPOND Falls Prevention Program: a Qualitative Study. 7th Biennial Conference of the Australian and New Zealand Falls Prevention Society. November 2016. Melbourne, Australia. [Oral presentation]

**Morris RL**. Key ingredients for successful falls prevention programs—did we get it right? The Centre of Research Excellence in Patient Safety Seminar: Promoting Health and Preventing Falls in Older Adults. September 2016. Melbourne, Australia. [Oral presentation – invited speaker]

**Morris RL**; Ayton DR; Hill KD; Brand CA; Redfern J; Nyman SR; Lowthian JA; Hill AM; Etherton-Beer CD, Flicker L; Hunter PC; Arendts G; A Forbes ; Smit De V; Barker AL. Clinician and patient perspectives of the RESPOND falls prevention program: a qualitative analysis. International Federation on Ageing (IFA): 13th Global Conference. June 2016. Brisbane, Australia. [Poster presentation]

**Morris RL**. Measuring the impact of health literacy: Implications for clinical practice. The Centre of Research Excellence in Patient Safety Seminar: Hot topics in managing an ageing population. September 2015. Melbourne, Australia. [Oral presentation – invited speaker]

**Morris RL**, Brand CA, Hill KD, Ayton DR, Redfern J, Nyman SR, Lowthian JA, Hill AM, Etherton-Beer CD, Flicker L, Hunter PC, Barker AL. RESPOND: a patient-centred program to prevent secondary falls in older people presenting to the emergency department with a fall-protocol for a mixed methods program evaluation. Australasian College for Emergency Medicine (ACEM) Conference. December 2014. Melbourne, Australia. [Poster presentation]

**Morris RL**, Brand CA, Hill KD, Ayton DR, Redfern J, Nyman SR, Lowthian JA, Hill AM, Etherton-Beer CD, Flicker L, Hunter PC, Barker AL. RESPOND: a patient-centred program to prevent secondary falls in older people presenting to the emergency department with a fall-protocol for a mixed methods program evaluation. 6th Australian and New Zealand Falls Prevention Conference. November 2014. Sydney, Australia. [Poster presentation]

## PRIZE ARISING FROM THIS THESIS

"**Best platform presentation**" awarded to: **Morris RL**. Process evaluation of an effective falls prevention programme: learnings from the RESPOND trial. 19th British Geriatrics Society (BGS) Falls and Postural Stability Conference. September 2018. Leeds, UK. [Oral presentation]

# THESIS INCLUDING PUBLISHED WORKS DECLARATION

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes three original papers published in peer reviewed journals. The core theme of the thesis is health promotion. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the School of Public Health and Preventive Medicine under the supervision of Associate Professor Ilana Ackerman (from 2017 to 2019), Professor Keith Hill (2013 to 2019), Doctor Darshini Ayton (2015 to 2019), and Associate Professor Anna Barker (2013 to 2017).

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of chapters 3, 4 and 6 my contribution to the work involved the following:

| Thesis chapter | Publication title | Status | Nature and % of student contribution | Co-author names. Nature and % of co-author contribution | Co-authors Monash student |
|---|---|---|---|---|---|
| 3 | 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 | Published | Review of the literature, development of the study design, manuscript preparation and revision.<br><br>60% | Anna Barker: study concept and design, input into manuscript; 7%<br>Keith Hill: study concept and design, input into manuscript; 5%<br>Darshini Ayton: study design, input into manuscript; 5%<br>Caroline Brand: study design, input into manuscript; 4%<br>Julie Redfern: study design, input into manuscript; 3%<br>Samuel Nyman: study design, input into manuscript; 3%<br>Judy Lowthian: study design, input into manuscript; 3%<br>Anne-Marie Hill: study design, input into manuscript; 3%<br>Leon Flicker: study design, input into manuscript; 3%<br>Christopher Etherton-Beer: study design, input into manuscript; 2%<br>Peter Hunter: study design, input into manuscript; 2% | None of the co-authors are Monash students |
| 4 | A mixed methods process evaluation of a person-centred falls prevention program | Published | Study design, data collection, data analysis, interpretation, manuscript preparation and revision.<br><br>60% | Keith Hill: study concept and design, data interpretation, input into manuscript: 4%<br>Ilana Ackerman: data interpretation, input into manuscript: 4%<br>Darshini Ayton: study design, data collection and interpretation, input into manuscript: 4%<br>Anna Barker: study design, data interpretation, input into manuscript; 4%<br>Glenn Arendts: study design, data interpretation, input into manuscript; 2%<br>Caroline Brand: study design, data interpretation, input into manuscript; 2%<br>Peter Cameron: study design, data interpretation, input into manuscript; 2%<br>Christopher Etherton-Beer: study design, data interpretation, input into manuscript; 2%<br>Leon Flicker: study design, data interpretation, input into manuscript; 2%<br>Anne-Marie Hill: study design, data interpretation, input into manuscript; 2%<br>Peter Hunter: study design, data interpretation, input into manuscript; 2%<br>Judy Lowthian: study design, data interpretation, input into manuscript; 2%<br>Renata Morello: data analysis and interpretation, input into manuscript; 2%<br>Samuel Nyman: study design, data interpretation, input into manuscript; 2%<br>Julie Redfern: study design, data interpretation, input into manuscript; 2%<br>De Villiers Smit: study design, data interpretation, input into manuscript; 2% | None of the co-authors are Monash students |

| Thesis chapter | Publication title | Status | Nature and % of student contribution | Co-author names. Nature and % of co-author contribution | Co-authors Monash student |
|---|---|---|---|---|---|
| 6 | Measurement properties of the health literacy questionnaire (HLQ) among older adults who present to the emergency department after a fall: a Rasch analysis | Published | Review of the literature, development of the study design, data collection, data analysis, interpretation, manuscript preparation and revision.<br><br>60% | Anna Barker: study concept and design, data interpretation, input into manuscript; 7%<br>Keith Hill: study concept and design, data interpretation, input into manuscript; 5%<br>Sze-Ee Soh: study design, data interpretation, input into manuscript; 5%<br>Rachelle Buchbinder: data interpretation, input into manuscript; 5%<br>Richard Osborne: data interpretation, input into manuscript; 5%<br>Judy Lowthian: data interpretation, input into manuscript; 3%<br>Julie Redfern: data interpretation, input into manuscript; 3%<br>Anne-Marie Hill: data interpretation, input into manuscript; 3%<br>Christopher Etherton-Beer: data interpretation, input into manuscript; 2%<br>Glenn Arendts: data interpretation, input into manuscript; 2% | None of the co-authors are Monash students |

I have added page numbers to published papers in order to generate a consistent presentation within the thesis.

**Student name**: Rebecca Morris

Student signature: Rebecca Morris Date: 5 December 2019

I hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author, I have consulted with the responsible author to agree on the respective contributions of the authors.

**Main Supervisor name**: Ilana Ackerman

Main Supervisor signature: Ilana Ackerman Date: 3 December 2019

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# CONTENTS

# LIST OF FIGURES

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# LIST OF TABLES

This list excludes tables and figures in published papers (Chapters 3, 4, and 6).

# ABBREVIATIONS

| | |
|---|---|
| ABS | Australian Bureau of Statistics |
| ACSQHC | Australian Commission on Safety and Quality in Health Care |
| AIHW | Australian Institute of Health and Welfare |
| BCT | Behaviour change theory |
| CFA | Confirmatory factor analysis |
| CI | Confidence interval |
| COM-B | Capability, opportunity, motivation - behaviour |
| COPD | Chronic obstructive pulmonary disease |
| CTT | Classical test theory |
| DALY | Disability-adjusted life years |
| ED | Emergency department |
| FROP-Com | Falls Risk for Older People - Community version |
| GP | General Practitioner |
| HLQ | Health Literacy Questionnaire |
| IQR | Interquartile range |
| IRR | Incidence rate ratio |
| IRSAD | Index of Relative Socio-economic Advantage and Disadvantage |
| IRT | Item response theory |
| MI | Motivational interviewing |
| MRC | Medical Research Council |
| p | Probability value |
| RCT | Randomised controlled trial |
| RPAD | Rochester Participatory Decision-making Scale |
| RR | Risk ratio |
| SD | Standard deviation |
| SEIFA | Socio-Economic Indexes for Areas |
| SES | Socioeconomic status |
| UK | United Kingdom |
| US | United States (of America) |
| WHO | World Health Organization |

# 1 INTRODUCTION

## 1.1 SUMMARY OF THE PROBLEM

In a healthcare system with finite resources, and in the context of an ageing population, there is increasing pressure for effective and efficient preventive health programs targeting older people. Falls and their negative consequences on the individual and their families, society, and economy are a serious and growing issue.[3] Falls are the leading cause of emergency department (ED) presentations for older adults.[4, 5] Following ED presentation after a fall, approximately half of older adults experience subsequent falls,[6] hospitalisation, or substantial functional decline in the ensuing year.[7]

Clinical practice guidelines focusing on falls prevention for older community-dwelling people recommend the use of multifactorial interventions that involve an assessment of individual risk factors, followed by interventions targeted to the identified risk factors.[8-10] However, the evidence regarding these interventions is conflicting when applied to people who present at ED with a fall.[11, 12] Multifactorial interventions, by definition, are complex.[13] They involve multiple interacting components that equate to more than the sum of their parts.[14] When program results are not favourable, a program evaluation approach is necessary to differentiate between whether the program design was inherently flawed, or whether it was not implemented as planned. When programs are effective, a program evaluation can determine the key active ingredients and indicate how, why, and for whom they work.[14] Information generated from program evaluations can aid refinement of programs for implementation in other settings.[13, 15]

Health literacy is increasingly associated with participation in preventive health programs, and health outcomes.[16] Health literacy is related to an individual's ability to obtain, process, and understand health information and services, and make appropriate health decisions.[17] Health literacy is known to be low for the general population, and especially so for older people.[18] There is a growing body of evidence for a number of chronic conditions linking low health literacy to poor adherence to health initiatives and worse health outcomes.[16, 19, 20] Health literacy has not, however, been studied in the context of falls prevention programs for older people who present to ED with a fall. Furthermore, no health literacy measurement tool has been validated for use with people who have presented to ED after a fall. Comprehensive analysis of the measurement properties of a health literacy tool (the Health Literacy Questionnaire – HLQ) is necessary in order to determine whether the tool is appropriate for this patient group.

This thesis comprises three studies to address the problems outlined, using data from the parent randomised controlled trial (RCT) – RESPOND: a falls prevention program for older people who present to ED with a fall.

## 1.2 THESIS AIMS

The primary aim of this thesis is to identify the critical success factors for the RESPOND RCT by conducting a comprehensive program evaluation. A secondary aim is to explore the concept of health literacy among the RESPOND cohort, by describing baseline health literacy and evaluating the Health Literacy Questionnaire (HLQ) for use with this patient group.

## 1.3 THESIS OBJECTIVES

The objectives of this thesis are:

1. To conduct a process evaluation of the RESPOND RCT (implementation fidelity and barriers and facilitators to implementation).
2. To conduct an impact evaluation (factors associated with participation in falls prevention strategies) and outcome evaluation (sub-group analyses of key RESPOND RCT outcomes) of the RESPOND RCT.
3. To analyse the measurement properties of the HLQ using RESPOND RCT baseline data.

## 1.4 THESIS SYNOPSIS

This thesis comprises three studies, each relating to one of the three objectives:

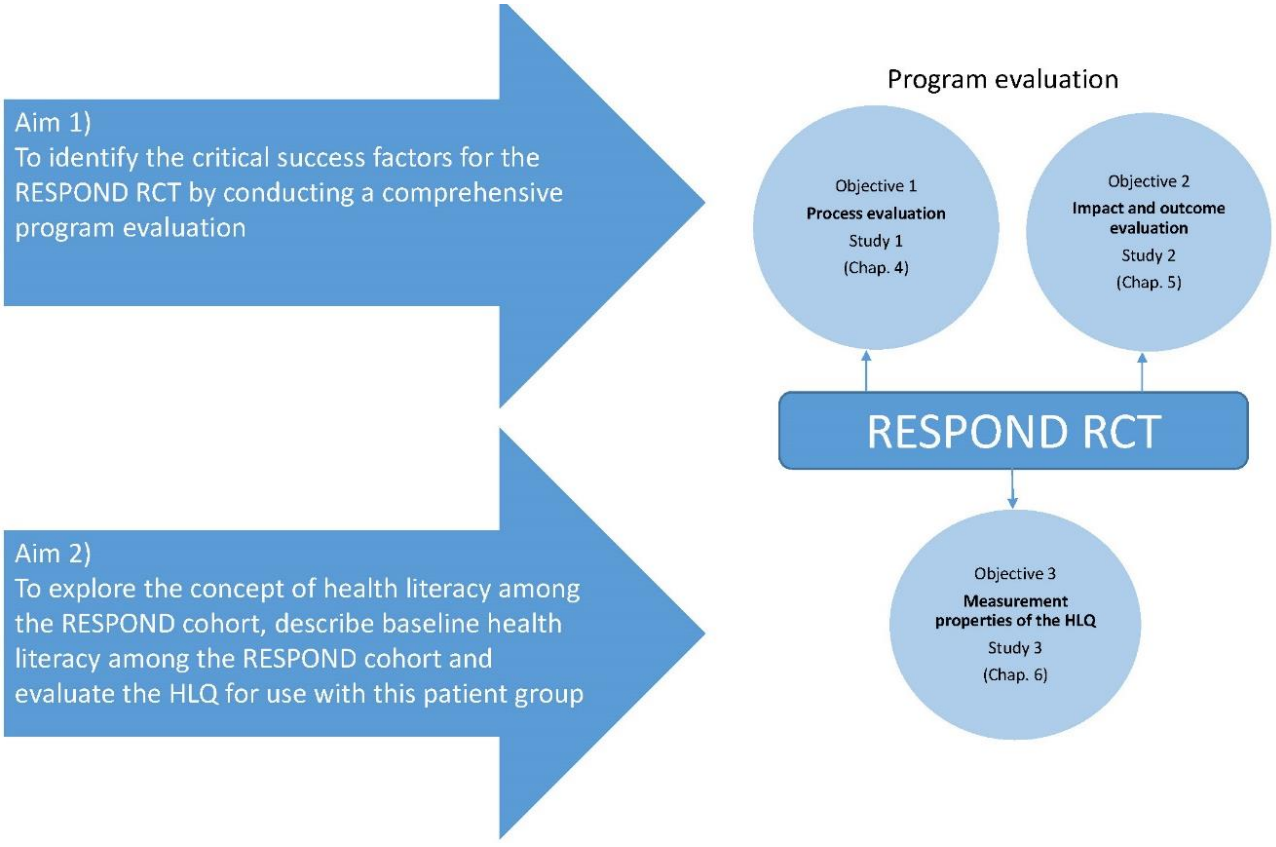


**Figure 1.1: Thesis aims, objectives, and studies**

## 1.5 THESIS CHAPTER SUMMARY

**Table 1.1: Summary of thesis chapter content and objectives**

| Chapter | Content | Objectives |
|---|---|---|
| 1 | Introduction | To identify the issues to be addressed, and outline the thesis aims and objectives |
| 2 | Background | To provide context for the thesis, appraising the current literature related to falls, program evaluation, and health literacy |
| 3 | RESPOND program evaluation: methods (published paper) | To detail the methods for studies 1 and 2: the process, impact, and outcome evaluation of the RESPOND RCT |
| 4 | RESPOND process evaluation (published paper) | To determine the degree of implementation fidelity of the RESPOND RCT, and identify the barriers and facilitators to implementation |
| 5 | RESPOND impact and outcome evaluation | To determine whether participant characteristics (including health literacy ability), and RESPOND program factors, are associated with the intended impact (participation in falls prevention), or outcomes (rate of falls, fall injuries, and ED presentations) |
| 6 | Measurement properties of the HLQ (published paper) | To describe the health literacy ability of the RESPOND cohort, using the HLQ, and analyse the measurement properties of the HLQ |
| 7 | Thesis discussion and conclusion | Synthesis of thesis findings, clinical implications, future research directions, strengths and limitations, and thesis conclusion |

# 2 BACKGROUND

## 2.1 THE AGEING POPULATION

The proportion of older people (those aged 65 years and over) in Australia has been increasing over the last century. One in 25 people in Australia were aged 65 or over in 1911, increasing to one in six in 2016.[21] This trend is expected to continue: by 2057 it is projected that there will be 8.8 million older people in Australia (22% of the population); and by 2097, 12.8 million people (25%) will be aged 65 and over.[22] An ageing population is not exclusive to Australia – between 2015 and 2050 the proportion of the world's population over 60 years of age is forecast to nearly double from 12% to 22%.[23]

Longevity has the potential to provide many additional opportunities to enjoy life and contribute to society. However, there is little evidence that older people today are experiencing older age in better health than the previous generation.[23] Older age can be characterised by the emergence of a number of complex non-specific health states that are characteristic of later life, and have been termed 'geriatric syndromes'[24]. These include multiple morbidities, cognitive impairment, malnutrition, impaired homeostasis, chronic inflammation, and frailty, and are often associated with poor outcomes such as reduced quality of life, hospitalisations, residential aged care facility admissions, and mortality.[25] Frailty is a health state related to the ageing process in which multiple body systems gradually lose their in-built reserves.[26] The British Geriatric Society lists falls as one of five frailty syndromes.[26]

Further health trends impacting older people include the increased prevalence of chronic diseases. Dementia is a leading cause of death and disability and it is estimated that between 2010 and 2050 the number of Australians with dementia will triple.[27] The cognitive deficits associated with dementia can severely limit an individual's ability to engage in preventive health initiatives, such as falls prevention programs. Furthermore, 87% of Australians aged 65 and over have been diagnosed with at least one chronic disease.[28] Chronic diseases most commonly include arthritis, asthma, back pain, cancer, cardiovascular disease, chronic obstructive pulmonary disease (COPD), and diabetes. The burden of chronic disease is increasingly impacted by a further global trend towards increased overweight and obesity, with worldwide obesity almost tripling since 1975.[29] The prevalence of obesity in European older adults has already reached epidemic proportions[30] and the majority of older Australians (80% of men and 69% of women age 65-74 years) are overweight or obese.[31]

This complex health picture for many older adults presents a potential reduction in quality of life for those affected, as well as their families and friends, and has substantial societal implications and challenges. Changing health profiles, an increased demand for medical and non-medical health services, and rising health costs are driving the need for new models of health care delivery. This is reflected in the World Health Organization (WHO) 'Global strategy and action plan on ageing and health', which encompasses

'Aligning health systems with the needs of older populations' as a major global objective.[32] Similarly, the Australian Government has highlighted aged care initiatives as a priority in their Corporate Plan 2018-2019, with the aim of providing support and services to promote greater independence, mobility, and autonomy, in order to reduce or delay the need for more complex aged care support services.[33] Given the growing number of older people globally, it is imperative that potentially preventable health issues, such as falls, are addressed.

## 2.2 THE BURDEN OF FALLS AMONG OLDER ADULTS

### 2.2.1 Prevalence and incidence of falls

Falls are variously defined in clinical practice and in the literature. Throughout this thesis, the widely used WHO definition has been used: "a fall is defined as an event which results in a person coming to rest inadvertently on the ground or floor or other lower level".[34]

Falls are a common issue for older people. Falls are the main cause of injury related disability-adjusted life years (DALYs) globally for older people and were responsible for 27.5 million DALYs (95% uncertainty level 23.4–31.9 million) from 1990 to 2013 – an increase of 21% over this time period.[35] Data from the United Kingdom (UK) and New Zealand suggest that approximately 28-35% of people aged 65 and over living in the community fall each year.[36-38] Studies from the UK, the Netherlands and the United States (US) show that this increases to 32-42% for those over 70 years of age.[39-41]

The incidence of falls is variable among countries and cultures. For example, in China the overall median annual incidence is estimated as 18% – a figure well below that commonly reported in studies of Caucasian older people.[42] This may in part reflect the different cultural approaches to falls, falls reporting mechanisms, falls management strategies, and varying healthcare systems and services. A recent systematic review and meta-analysis of Asian falls prevention strategies identified stark differences between Asian and non-Asian countries in terms of the environment, lifestyle, social and family structures, and differing perceptions, beliefs and behaviours towards falls prevention.[43] This poses implications for effective translation of successful falls prevention programs across countries and cultures.

There is further variability in accuracy according to data collection methods. An Australian study found a 20% reduction in the number of falls reported by community-dwelling older women using a retrospective question, compared with prospective data collection.[44] Self-report data can be problematic due to recall bias and perceived stigmatisation associated with being a 'faller,' potentially leading to under-reporting.[45]

Variability in the incidence of falls is demonstrated across community, hospital, and aged care settings. One third of community-dwelling people aged over 65 fall each year,[46, 47] rising to 50% for those over 80.[48] At least half of residential aged care facility residents fall at least once a year.[49] Falls are the most commonly reported type of patient safety incident from hospitals in England, with over 250,000 falls recorded each year.[50] A

multi-site Australian RCT reported that 5% of patients admitted to hospital during the 14 month trial period experienced an in-hospital fall.[51] While falls across all settings and health status are problematic and need to be addressed, this thesis focuses on falls among cognitively intact older community-dwelling Australians.

### 2.2.2 The consequences of falls

The rate of age-adjusted falls-related hospitalisations in Australia continues to increase by approximately 3% per year, despite strong research evidence of effective approaches to reduce risk of falling.[52] Falls can have detrimental physical and psychological consequences for the individual, their family and friends, as well as negative impacts on society as a whole. Most fall-related injuries are minor, such as abrasions, lacerations, bruises, strains, and sprains, but can still cause significant pain and discomfort as well as psychological issues such as fear of falling and loss of confidence.[53-55] Older adults who experience falls also report increased anxiety and depression and reduced quality of life.[56, 57] This can result in self-restricted activity levels leading to a reduction in physical function and social interactions, which can further increase falls risk.[58]

More severe fall-related injuries can have debilitating long term consequences.[59] Approximately 10% of falls result in a fracture.[41, 47] The largest proportion (26%) of fall-related injuries that resulted in hospitalisation for Australians aged 65 and older in 2012–13 were injuries to the hip and thigh. Fractures of the neck of the femur accounted for the majority of these (74%).[60] Peri-prosthetic hip fractures (fractures that occur around an implanted hip replacement prosthesis, commonly due to a fall) account for 20% of hip arthroplasty revisions, which are associated with serious potential surgical risks and complications.[61]

Hospitalisations for fall-related head injuries in Australia increased at a rate of 7% per year from 2002-03 to 2012-13.[60] Over the period from 2007 to 2016, low falls (falls from standing, or no more than one metre in height) accounted for 28% of traumatic spinal cord injuries in Victoria, Australia, with an average increase of 9% per year (95% CI, 4–15%).[62] Falls are associated with a threefold increase in the likelihood of being admitted to a residential aged care facility after adjusting for other factors, indicating a substantial loss of independence with activities of daily living.[63] The mortality rate for those who have sustained fall-related injuries is high, especially for hip fractures and head injuries.[64] A recent systematic review and meta-analysis of factors affecting mortality in older trauma patients found that low level falls were associated with an almost threefold increase in mortality, compared with motor vehicle collisions (cumulative odds ratio 2.88, 95% CI 1.26–6.60).[65]

Older people who have been injured as a result of a fall often require long stays in hospitals, frequently involving more than one episode of admitted patient care.[60] Transitions between acute and sub-acute hospital departments, as well as community-based therapy and rehabilitation, are often required.[60] The average total length of in-patient stay per fall injury case is estimated to be 10 days.[52] Older adults are often accompanied by family members or friends to appointments and outpatient therapy, and supported post hospitalisation, which has a societal impact owing to loss of work-time or other daily activities not only for

the patient, but also their carers.[66] Despite this resource-intense support for those who have experienced a fall, relatively few regain pre-fracture levels of mobility, and/or independent mobility after serious injury such as a hip fracture.[7]

Falls among older people represent a substantial and increasing economic burden. In the US the direct cost of fall-related injuries increased from USD$30.3 billion to USD$31.3 billion in the three years from 2012 to 2015.[67] By 2051, the Australian total annual health costs from fall-related injuries is predicted to increase almost threefold, compared with costs in 2001, to AUD$1375 million per annum.[68] In Western Australia (WA) the estimated cost of falls to the health system was AUD$86.4 million in 2001-2002, with more than half of this attributable to hospital inpatient treatment. This is projected to increase to AUD$181 million in 2021.[69] This upward trend in economic cost of falls for older community-dwelling people was also found in Victoria, with an estimated AUD$213 million spent on falls in 2005-2006, rising to AUD$237 million in 2007-2008.[70] The lifetime treatment costs associated with falls among older people in New South Wales (NSW) is estimated at AUD$559 million.[71] Taken together, these substantial and increasing costs (and projections of future high economic burden) highlight the need for effective policy and practice for falls and fall injury prevention.

### 2.2.3 Falls resulting in emergency department presentations

Despite the wide-reaching impact of falls on the whole healthcare system, this thesis focuses on the substantial and unsustainable burden of falls on hospital emergency departments (EDs). The ED is a critical point of access to healthcare for many older people who have had a fall.[66] Falls are the leading cause of hospital ED presentations for older people.[72, 73] In 2014, approximately 2.8 million older adults presented to an ED in the US with a fall. One study found that among those over the age of 70, one in six ED presentations was because of a fall, with ED staff attending to an average of 4.4 fall cases a day. On average, 8.8 hours per falls-related ED presentation were spent waiting for and receiving care.[66] This is longer than an average medical, nursing, or allied health worker shift and highlights the burden of falls injuries in a busy, time-pressured environment with limited staffing resources. Data from one Australian hospital showed that the direct medical costs associated with ED presentations after a fall and subsequent hospitalisation totalled AUD$11.2 million over a two year period (2007-2009).[66] There is also a high rate of recurrent falls for people presenting to ED with falls and being discharged home. Up to a third of those who present to ED with a fall will fall again within 6 months,[7, 74] and approximately half will fall again within one year.[6, 75]

Current guidelines recommend that older people should receive multi-factorial interventions following an injurious fall. This includes exercise programs, home modifications and medication reviews based on risk factors identified in individual assessment.[9, 10, 46] Management of older people presenting to ED is sub-optimal, however, with only 3% of older patients presenting to an Australian ED with a fall receiving guideline-recommended care.[76] A Canadian study reported a similar outcome, with only 4% of older people presenting to ED with a fall receiving guideline care.[74] The challenges associated with the ED, including time pressures and competing priorities for ED staff, make this clinical environment a difficult place to initiate falls

prevention assessment and intervention. One Victorian study reported that 45% of older people are discharged directly home from ED.[77] This provides an opportunity for risk assessment and initiation of secondary falls prevention strategies.[6] Initiatives involving increased multi-disciplinary allied health team activity within ED and post ED discharge for older people have been reported, with some focusing on falls prevention. A systematic review and meta-analysis of ED to community transition strategies for older people found that despite a variety of models being implemented internationally, there is limited evidence for their effectiveness in reducing ED re-presentations, unplanned hospitalisations, or mortality.[78] Given the increasing burden of older people presenting to the ED with a fall, and the serious personal, societal and economic consequences, this appears to be a missed opportunity for implementing effective strategies to reduce future falls.

### 2.2.4 Falls risk factors

The ability to transfer and walk safely depends on integration and coordination among sensory (vision, vestibular, proprioception), central and peripheral nervous, cardiopulmonary, musculoskeletal, and other systems.[24] Demonstrating the wicked nature of falls, over 400 falls risk factors have been identified.[79] These have been synthesised in a systematic review that included 74 studies investigating risk factors for falls among community-dwelling older people.[80] Falls risk factors can broadly be categorised as either intrinsic or extrinsic.[81] Intrinsic risk factors include physiological changes such as impaired balance, vision, strength, or cognitive changes.[82] Extrinsic factors include environmental issues (such as inadequate lighting, unsecured mats, and slippery floors), hazardous activities (such as climbing a ladder), as well as medication use.[80, 81] Most falls occur as a result of an interaction between intrinsic and extrinsic factors, and the presence of multiple factors increase the risk of falls.[83] Falls risk factors can be further classified as modifiable (reversible or changeable characteristics) or non-modifiable (such as age and sex). Modifiable risk factors are of most interest when aiming to reduce the rate of falls and associated negative consequences, as these can be targeted and potentially reduced or eliminated.[84]

Lord *et al* proposed an alternative classification of falls risk factors, dividing risk factors into sociodemographic, balance and mobility, sensory and neuromuscular issues, psychological, medical and environmental factors, and medication use.[85] The odds ratios (ORs) estimating the association between these risk factors and the likelihood of falls were generally higher for recurrent fallers than all fallers. Deandrea *et al*. (2010) found the strongest falls risk factors were: history of falls (OR = 2.8 for all fallers; OR = 3.5 for recurrent fallers), gait problems (OR = 2.1; 2.2), walking aids use (OR = 2.2; 3.1), vertigo (OR = 1.8; 2.3), Parkinson's disease (OR = 2.7; 2.8), and antiepileptic drug use (OR = 1.9; 2.7).[80] Table 2.1 summarises the risk factors most strongly associated with falls for all fallers (not limited to recurrent fallers) from Deandrea *et al.*'s systematic review.[80] Risk of falling also increases with age: in the US in 2014, 27% of adults aged 65 to 74 years and 37% of adults 85 years or older reported a fall.[86] Approximately 15% of falls result from a major external event that would cause most people to fall. A similar percentage of falls result from a single

identifiable event such as syncope (fainting). However, most result from an interaction of multiple falls risk factors (for example, a person with poor balance and vision who trips on a mat which results in a fall).[53]

**Table 2.1: Falls risk factors**

| Sociodemographic factors | Psychological & medical factors | Medication use | Mobility/ sensory factors |
|---|---|---|---|
| Advanced age | Vertigo | Sedatives | Gait problems |
| Female | Parkinson's disease | Antihypertensives | Visual impairment |
| Living alone | Fear of falling | Antiepileptics | Hearing deficit |
| History of falls | Comorbidity | Polypharmacy | *Strength and balance deficit |
| Physical disability | Self-perceived poor health status | | |
| Use of a walking aid | | | |

This table is adapted from Deandrea *et al*.[80]

*Given the heterogeneity of measurement of strength and balance, Deandrea *et al* did not include these risk factors in their review.[80] Impaired strength and balance, however, have frequently been identified as risk factors for falls.[53, 87]

#### *2.2.4.1* Falls risk screening

Falls risk screens are tools used to identify an individual's level of risk of falling, usually classified as low, moderate, or high risk.[9] These tools are often brief (three to five items) and quick to administer. Validated multiple-item falls risk screening tools for community-dwelling older people include the FROP-Com (Falls Risk for Older People - Community version) fall screening test and the Elderly Fall Screening Test (EFST).[88, 89]

The simplest falls risk screen involves enquiring whether an older person has experienced any falls in the last 12 months. Although this is a strong predictor of future falls, this method provides limited information. However, knowledge of an individual's falls history may prompt an assessment of balance and mobility status. Various valid and reliable quick tests can be used to gain more detailed information about balance and mobility, such as the Timed Up and Go (a measure of speed of performance during functionally important tasks which potentially threaten balance),[90] and Sit-To-Stand (a functional measure of lower limb strength).[91]

This screening process is distinct from comprehensive falls risk assessments that facilitate falls prevention interventions to be tailored to identified modifiable risk factors.[92] A number of multifactorial falls risk assessment tools are available for use in community settings.[9] These include the QuickScreen which is a multifactorial, reliable, and valid tool based on the sensorimotor functional model for falls prediction. Items measured are: previous falls, medication use, vision, peripheral sensation, lower limb strength, balance, and coordination,[93] and the FallScreen — Physiological Profile Assessment which is a validated five item tool that provides detailed information on the physiological domains contributing to postural stability: vision, peripheral sensation, lower limb strength, reaction time, and body sway.[94]

The FROP-Com is one tool recommended in the Australian Falls Prevention Best Practice Guidelines.[95] It includes detailed assessment of 13 falls risk factors: falls history, medication use, medical conditions, sensory

loss, feet and footwear, cognitive status, continence, nutrition, environmental factors, functional behaviour, function, balance, and gait/physical activity. It was developed based on data from a sample of older people presenting to Emergency Departments after a fall. High inter- and intra-rater reliability has been reported and the tool has moderate accuracy to predict those at risk of future falls.[96, 97] This is the falls risk assessment tool used in the studies in this thesis.

## 2.3 FALLS PREVENTION PROGRAMS

### 2.3.1 Types of falls prevention interventions

Falls prevention can be categorised as a single intervention, such as exercise to improve balance, or a combination of strategies, such as exercise and adjustment of medication.[87] A combination of program components can be delivered as a multifactorial intervention based on assessment of an individual's falls risk factors, or as a multiple component intervention where the same combination of strategies are given to all participants.[53] Interventions that contain a combination of components, whether in trials or in real-world community or hospital settings, are known as complex interventions. Complex interventions are commonly defined as interventions that comprise multiple interacting components.[98] These components may include the number and type of behaviour changes required, the degree of flexibility or tailoring of the intervention allowed, and contextual issues such as the number and type of organisations involved.[13]

### 2.3.2 Evidence for falls prevention programs

Systematic reviews show that overall there is good evidence of effect for falls prevention interventions for community-dwelling older people.[53, 87, 99, 100] There is high quality evidence that exercise reduces the rate of falls.[87, 99, 100] The magnitude of this reduction varies from 19% for Tai Chi (rate ratio 0.81, 95% CI 0.67 to 0.99), to 34% (rate ratio 0.66, 95% CI 0.50 to 0.88) for multiple types of exercise, most commonly comprising balance and functional exercises, plus resistance exercises.[99] Programs that involve a moderate to high challenge to balance and include a large total dose of exercise (more than three hours per week) have particularly good effect.[100] However, when these exercise parameters were introduced to older adults recently discharged from hospital,[101] this led to an increase in the number of falls, falls injuries, and proportion of fallers. This has implications for safety considerations and may require an initially reduced dose and intensity of exercise, with increased supervision, for those immediately post-hospital discharge.[102]

Home safety assessment and modification interventions were found to be effective in reducing rate of falls (rate ratio 0.81, 95% CI 0.68 to 0.97), particularly for those at high risk of falling, for community-dwelling older people.[87] This evidence is conflicting, however, according to the findings of a more recent systematic review that synthesised evidence of effective falls prevention interventions for older adults following recent hospital discharge.[102] Naseri *et al*. found limited evidence that home hazard modifications reduced falls

outcomes, although the intervention was more effective among a subgroup of participants who had a history of frequent falls.[102]

Withdrawal of psychotropic medication reduces the rate of falls (rate ratio 0.34, 95% CI 0.16 to 0.73) but not risk of falling.[87] Vitamin D supplementation interventions also had mixed results, with a high dose being associated with higher rates of fall-related outcomes.[103] A recent systematic review and meta-analysis of vitamin D supplementation concluded that there is little justification to use vitamin D supplements to maintain or improve musculoskeletal health.[104] This review has been criticised for excluding significant high quality studies which have shown vitamin D supplementation to be of benefit to subgroups of older people, especially those with low vitamin D levels, and those in residential care settings.[105] Medication review and education for older people, conducted by their general practitioner (GP), is associated with a reduction in falls.[106] This may be because medication review addresses issues besides drug use, including postural hypotension, and increases doctors' awareness of falls.

Mixed results have been reported for management of visual issues, with some interventions significantly increasing the rate of falls, while others reduce the rate of falls.[87] Cataract surgery for first eye surgery has been shown to be effective at reducing the rate of falls and risk of fractures.[107] An Australian RCT found that when regular users of multifocal glasses used single lens glasses, falls were significantly reduced among those who regularly took part in outside activities.[108]

Multifactorial interventions (where component interventions differ based on individual risk assessment) and multiple component interventions (where the same component interventions are provided to all people) for older people living in the community reduce falls rates compared with a control group.[53] This builds on the findings of a previous review that found that multifactorial interventions that include individual falls risk assessment reduces the rate of falls (rate ratio 0.76, 95% CI 0.67 to 0.86).[87] Multifactorial interventions may, however, make little or no difference to the number of fallers, recurrent falls, fall-related fractures, fall-related hospitalisations, or quality of life.[53]

### 2.3.3 Falls prevention programs for those presenting at ED with a fall

Despite the strong body of evidence for falls prevention for community-dwelling older adults, when specifically examining interventions for those presenting to an ED with a fall, the evidence is conflicting.[11, 12] To date, 12 RCTs of falls preventions programs for older people who present to an ED with a fall have been conducted, from six different European and Australasian countries.[1, 6, 75, 109-117] This includes the RESPOND trial that forms the basis of this thesis.[1, 2]

Nearly all (11 of 12) of these studies included a falls prevention education component[1, 6, 75, 109-116] and referral to healthcare services,[1, 6, 75, 109-114, 116, 117] most included home modifications,[75, 109-115] half included exercise[1, 110, 111, 114-116] and five targeted adjustment to medication.[1, 75, 110, 115, 116] Three studies included the intervention being delivered via a mix of telephone calls and home visits.[1, 109, 111]

The methodological quality of these studies varied from moderate to high quality. A limitation common to all 12 studies was the inability to blind the therapists or participants, which reflects the nature of therapy-based trials, and three of the studies did not blind the outcome assessors to group allocation.[75, 113, 115] Methodological strengths for all the 12 studies include characteristics of the RCT design, such as random allocation to either the intervention or control group, and between-group comparisons for statistical analysis.

Pooled effects of these RCTs showed no reduction in the rate of falls with the use of multifactorial falls prevention programs for older people who present to ED with a fall (rate ratio (RR) 0.78, 95%CI 0.58 to 1.05).[11] A sub-group analysis, however, demonstrated that interventions that included treatment of risk factors, rather than just referral-based intervention, showed a clinically important reduction in the rate of falls (RR 0.78, 95%CI 0.58 to 0.93).[11]

The systematic review evidence specific to those who have presented to ED with a fall, or have recently been discharged from hospital [11, 12] conflicts with that of the more general population of community-dwelling older people who have experienced a fall.[53, 87, 100, 102] This may reflect the varying care needs of different populations. People who present to ED after a fall are generally older, frailer, and have more complex health and social issues than those who do not present at ED.[66, 118] This suggests that a modified approach to falls prevention is required to meet the needs of those who present at ED with a fall.

#### *2.3.3.1 RESPOND: a falls prevention program*

RESPOND is a falls prevention program for older people who present to an ED with a fall, with the tag line "*Respond to the first fall to prevent the second*".[1, 2] All data used in the studies that comprise this thesis are derived from an RCT of the RESPOND program. The multifactorial intervention included offering a selection of one or more of only four evidence-based modules, rather than attempting to address all identified falls risk factors. These four modules each comprised a key risk factor and selection of corresponding management strategies. The RESPOND modules were: Better Strength and Balance (targeting physical strength and balance deficits); Better Eyesight (targeting visual impairment); Better Bones (for those with poor bone density); and Better Sleep (relating to long-term use of sedatives, specifically benzodiazepines or z-drugs). The program was delivered with one initial home visit and subsequent telephone coaching calls over six months, with the use of motivational interviewing to aid person-centred module choice and goal setting, with individualised falls risk education and linkage to existing community-based services. For example, a chosen goal may involve discussion with the participant's GP to determine whether they need a serum Vitamin D test; booking an appointment with their local optometrist for a vision test; or commencing a strength and balance exercise program. The program was intended to be delivered by a RESPOND clinician (allied health practitioner or nurse) using gain-framed, positive health messages and motivational interviewing techniques.

Adherence to falls prevention initiatives is notoriously low. Only half of community-dwelling older people are likely to be adhering to recommended falls prevention interventions at 12 months.[119] Improved health outcomes depend on behaviour change, and engaging individuals closely in their own personal health and well-being.[120] Motivational interviewing (MI) is a behaviour change technique (BCT) increasingly being applied to public health settings. MI is defined as a 'person-centred method of guiding to elicit and strengthen personal motivation for change'.[121] The spirit of MI involves a collaborative approach, evoking the participant's motivation to change rather than trying to instil it.[122] Systematic reviews have shown that MI leads to more favourable results for a broad range of behavioural problems and diseases, and may lead to improvements in physical activity for people with chronic disease, compared with traditional approaches where advice is given in a didactic or paternalistic way by the healthcare professional.[123, 124]

A further technique designed to encourage participation in health promoting behaviours is the use of gain-framed messages, which emphasise the potential positive outcomes of adhering to healthy behaviours. This is opposed to loss-framed messages which emphasise the disadvantages of non-adherence.[125] Threatening health-promoting information may be less effective for those who the message has high relevance.[126] Emphasis on perceived benefits of preventive activities, rather than perceived risk of harm, is recommended for promoting uptake of falls intervention strategies.[127] However, there may be a place for both styles of message framing, with some older people believing that warnings about falls risks and consequences may be necessary to elicit behaviour change.[128]

The planned impact of the RESPOND program was increased participation in falls prevention strategies, which in turn was intended to produce the following key outcomes: reduction in the rate of falls; fall-related injuries; ED re-presentations; and hospitalisations. As such, MI techniques, using gain-framed health messages were used by the RESPOND clinicians to maximise adherence to the program and participation in appropriate falls prevention strategies. The gain-framed messages were also apparent in the colourful RESPOND paper information pamphlets which corresponded with each of the four modules and encouraged participants to 'Be Your Best' (Figure 5.1).

While detailed information about the RESPOND RCT participants and methods will be provided in subsequent chapters, a brief overview of the study is provided here. In order to test the effectiveness of RESPOND, an RCT was conducted between March 2014 and July 2016, recruiting patients from two Australian hospital EDs.[1, 2] Baseline data were collected, including falls risk status using the FROP-Com, and health literacy ability, using the Health Literacy Questionnaire (HLQ). Participants were community-dwelling people aged 60-90 years presenting to the ED with a fall and planned for discharge home within 72 hours. There were 430 people included in the primary outcome analysis; randomised to the RESPOND group (n=217) or to the control group (n=213). The control group received standard care including any investigations, assessments or referrals organised by ED staff. At 12-month follow-up, the rate of falls per person-year was 1.15 in the RESPOND group and 1.83 in the control (incidence rate ratio [IRR] 0.65; 95% CI 0.43 to 0.99). The rate of fractures was

0.05 in the RESPOND group and 0.12 in the control (IRR 0.37; 95% CI 0.15 to 0.91). There was no difference in fall injuries, ED presentations or hospitalisation outcomes between groups.[1]

## 2.4 PROGRAM EVALUATION IN HEALTHCARE

RCTs are accepted as the gold standard research methodology for determining the effect of an intervention and answering the question "did it work?"[98] However, for complex interventions, such as RESPOND, RCT results alone cannot provide information to answer the questions "how did it work?", "why did it work?", "who did it work for?", and "where else might it work?"[14, 129]

Evaluation is broadly defined as "the process by which we judge the worth or value of something".[130] In a health system with finite resources, and increasingly strained health budgets, it is important to have accurate information in order to make decisions regarding appropriate allocation of funds, and optimise the efficiency of health services. Information generated from program evaluations is useful for governments, policy makers, researchers, healthcare managers and clinicians, stakeholders and funding bodies, as well as the patients and communities receiving the health services. Program evaluation is considered to be the bridge between research and clinical practice, facilitating translation of evidence into practice.[131] In recognition of this, the Productivity Commission has called for improved healthcare evaluation in Australia.[132]

There are numerous existing frameworks to guide program evaluations of health programs, with varying categorisation of key stages and components.[133-135] Broadly, program evaluations comprise three distinct components: formative, process, and summative evaluations.[133, 134]

### 2.4.1 Formative evaluation

The formative phase refers to answering questions related to the relevance of the identified health problem, and the practicality of different intervention methods.[136] This usually includes a needs assessment, or gap analysis, prior to program design and delivery, and informs the implementation design and strategy.[137] With the RESPOND RCT, this phase of evaluation was conducted by the trial investigators prior to commencement of this PhD project and therefore is not detailed in this thesis.

### 2.4.2 Process evaluation

Process evaluations explore the functioning of an intervention. They can provide insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. A process evaluation nested inside a trial can be used to assess fidelity and quality of implementation, clarify causal mechanisms, and identify contextual factors associated with outcomes.[13, 98] At another level, it opens the door through which studies can be repeated, refined, and widely disseminated by defining the conditions which need to be created for success in achieving program objectives.[15] Process

evaluations are especially valuable alongside multi-site trials, where the same intervention may be implemented and received in different ways.[14]

The necessary components of a process evaluation have been extensively debated and synthesised in different models, guidelines, and frameworks.[98, 138-141] Despite varying categorisation of process components, common threads can be identified throughout the literature.

Implementation fidelity is a major component of process evaluation and measures the degree to which an intervention was implemented as planned.[139] The degree of implementation fidelity is usually determined by comparison with a pre-determined standard, or protocol.[138] Several aspects of program delivery can be measured.[141] There is no consensus on the necessary components for evaluation of implementation fidelity. This may reflect the fact that each program is unique, and a 'one size fits all' approach is not appropriate in the context of diverse multifactorial interventions. Consistently cited implementation components are: reach (the proportion of intended target audience who participate in an intervention);[141] adherence (compliance with recommended strategies);[73] and dose (the amount of intervention provided).[138]

Moore *et al* developed the UK Medical Research Council (MRC) guidance for process evaluation of complex interventions.[98] Their guidance was informed by review and synthesis of influential evaluation theories and frameworks and is intended to be used for process evaluation of public health interventions.[98] In addition to factors related to implementation fidelity, they proposed that participant responses to and interactions with the intervention are critical to determine, as part of a construct they termed 'mechanism of impact'. This has parallels with the concept of 'acceptability' and 'participant responsiveness' detailed in previous frameworks,[139, 142] and closely aligns with the concept of 'perceived relevance'.[139] Carroll *et al*. proposed that if a participant does not perceive the intervention to be personally relevant, then they are unlikely to engage in the program, resulting in low implementation fidelity.[139] In addition to participant responses, other mechanisms of impact include mediators (intermediate processes which explain subsequent changes in outcomes), and unintended pathways or consequences.[98]

Finally, contextual factors are a key process evaluation component.[98, 138] Context includes anything external to the intervention that acts as a barrier or facilitator to its implementation, or its effects.[98] This may include the attitudes and beliefs of those delivering or receiving the intervention, pre-existing circumstances and skills, or organisational norms and resources.[143-145] Implementation may vary from one context to another, or an intervention may have different effects in different contexts, even if implementation remains consistent.[146] Identification and understanding of contextual factors, are therefore critical to interpreting the findings of an evaluation, and generalising beyond it.[98]

### 2.4.3 Summative evaluation

Summative evaluation is the assessment of the impacts and outcomes of implemented programs. It is used to determine if the program objectives were met and usually occurs after program implementation.[134] The

definitions of impact and outcome vary in the evaluation literature, [133] and the two terms have been used interchangeably. Impacts are also sometimes labelled as short term or intermediate outcomes.[142] Impact evaluation in health promotion refers to immediately observable program effects.[147]

For the purpose of this thesis, the term 'impact evaluation' will be used to refer to the intermediate effect that a health program has on the individuals involved.[148] The impact of interest in this thesis is participation in falls prevention activities. Outcome evaluation shall be defined as determining whether the long-term goal of program has been achieved. [148] The outcomes to be evaluated in this thesis are the rate of falls, fall injuries, and ED re-presentations.

A further type of summative evaluation is economic evaluation. This provides valuable information related to the cost-effectiveness of a program, to determine whether a program represents good value for money and aiding decision-making for allocation of limited funds (see Appendix A: RESPOND economic evaluation protocol). Economic evaluation is, however, beyond the scope of this thesis and will be reported separately by the RESPOND project team. A recent systematic review of economic evaluations of falls prevention programs for older people found that home assessment programs were the most cost effective type of program for community-dwelling older adults (incremental cost-effectiveness ratios (ICERs)<USD$40,000/ quality adjusted life year (QALY)), although when a higher willingness-to-pay threshold of USD$100,000 was applied, the majority of the remaining program types (exercise, multifactorial, other) were also cost-effective.[149] The willingness-to-pay threshold is the maximum amount society is willing to pay for gaining one additional QALY following an intervention. A willingness-to-pay range of USD$50,000-$100,000 per QALY is commonly used in the US, particularly for decisions about public reimbursement of pharmacological treatments.[150, 151] When the ICER is lower than the threshold, the program is considered more cost-effective than the control intervention.

## 2.5 PROGRAM EVALUATION OF FALLS PREVENTION PROGRAMS

This section provides a synthesis of the program evaluation components reported for falls prevention RCTs that have targeted older people who presented to ED with a fall. There are 12 published RCTs, as detailed above in section 2.3.3 'Falls prevention programs for those presenting at ED with a fall'. Excluding RESPOND, none of the remaining 11 RCTs conducted a comprehensive multi-level mixed methods program evaluation alongside the trial. Elements of program evaluation have been reported to varying degrees for these trials, with one study conducting a detailed process evaluation alongside the RCT.[112, 152]

Table 2.2 details the process factors reported for each of the 11 RCTs. The process factors reported are: reach, adherence, dose, and timeliness of intervention delivery. Acceptability of the program and whether or not barriers and facilitators to implementation are reported is also examined. Given the variability in defining impact and outcome evaluations, these evaluation components are not reported in this table.

### 2.5.1 Reach

The majority of studies reported the proportion of the intended target audience who participated in an intervention of the study.[6, 75, 110, 112, 113, 115-117] For the three studies that did not report reach,[109, 111, 114] the number of participants screened for eligibility, and participant flow through the studies was reported, as required by the CONSORT guidelines for reporting RCTs.[153] The lack of information, however, relating to the proportion of older people who presented at ED and came into contact with the study, limits the conclusions that can be drawn for the outcomes of these studies. Understanding the degree to which a program reaches those in need is vital in order to determine whether a program sufficiently addresses an unmet public health need, which in turn has implications for understanding program cost-effectiveness and for considering healthcare budget implications.[140]

### 2.5.2 Adherence

Participant adherence to, or participation with, program components was reported in seven studies.[6, 109, 112, 114, 115, 117, 152] In these studies, the uptake of referrals and/or falls prevention recommendations ranged from 7% to 100%.[11] Where adherence was reported, however, there was variability in the level of detail provided. This may reflect the high degree of heterogeneity in specific interventions delivered. An Australian referral-based intervention that used targeted referrals to existing community services and health promotion recommendations reported that adherence was highest for occupational therapy (69%), physiotherapy (65%) and podiatry sessions (64%) although overall adherence to recommendations was low (46%).[6] In addition, control group contamination included 17% of standard care participants who were referred to physiotherapy and 4% to falls clinics.[6] Collection of adherence information was valuable in understanding potential reasons for the lack of effect of the intervention, compared with usual care.

In contrast, a Danish study that offered older people multidisciplinary assessment of falls risk factors, followed by implementation of appropriate risk management strategies, reported 'acceptance' of suggested strategies.[116] For example, acceptance ranged from 71% for suggestions to use a gait aid to address impaired balance, to 99% of participants accepting the advice to have their medications reviewed.[116] This information suggests that the participants were willing to consider change. Adherence to these suggestions, however, was not recorded. This limits the ability to differentiate between whether the trial was not effective at preventing further falls because of an inherently poor program design, or whether the program was not adhered to as intended.

A successful British trial (PROFET) comprising a medical and occupational therapy assessment with referral to healthcare services significantly decreased the risk of further falls compared with usual care.[75] However, the study did not report details related to the referral or recommendations resulting from the assessments. This lack of process information limits the capacity to make sound judgement regarding the critical success

factors for this trial, and also reduces the repeatability of this program in other settings. This posed a challenge to Hendricks *et al*. when attempting to recreate the PROFET trial in the Netherlands.[112]

### 2.5.3 Timeliness

The timeliness of the intervention received may help to explain trial results. Five studies reported the duration between baseline assessment and receiving the first intervention session, with timing ranging from two weeks to two months.[6, 109, 112, 113, 116] One RCT that found no differences between groups reported that many services were not received until up to four months after their initial assessment.[6] This delay suggests that timeliness in delivering the intervention may be a factor related to program success. A systematic review of falls prevention programs for those who have attended ED with a fall suggests that delivering the intervention within one month of the index fall may lead to more favourable results.[12]

### 2.5.4 Dose

Most studies reported elements of dose.[75, 109, 110, 112-114, 116] This refers to the study reporting sufficient information about the quantity of intervention provided. Dose was variously reported, which probably reflects the variability in program designs and components. For example, Russell *et al*. referred participants to existing community services (as opposed to providing an intervention), following a baseline falls risk assessment.[6] As such, it is challenging to record the dose of intervention received. Gates *et al*. suggested that high intensity interventions that provide direct action (rather than referral-based interventions) may be more effective.[12] The number of intervention sessions was recorded for most studies and ranged from one to 16 sessions.[75, 109-114, 116, 117] The duration of the intervention was recorded in three studies and ranged from two to six months.[109, 114, 115] A systematic review of the impact of exercise program characteristics on preventing falls suggested that an adequate dose involves at least one home visit or telephone call per month and more than two home visits in total.[154]

### 2.5.5 Mechanisms of impact and contextual factors

Beyond these basic process factors, only one study reported limited elements of mechanism of impact and contextual factors – acceptability and barriers (not facilitators) to the program.[152] Furthermore, mixed methods, incorporating both quantitative and qualitative data, are considered important for process evaluations in order to best understand the complex factors influencing program implementation, such as acceptability, barriers and facilitators.[98, 155] None of the 11 studies used a mixed methods design, thus limiting our ability to understand mechanisms for the trial results.

**Table 2.2: Process evaluation components of RCTs of falls prevention programs for older people who present to ED with a fall**

| | Process evaluation component | | | | | | |
|---|---|---|---|---|---|---|---|
| | Reach[a] | Adherence[b] | Dose[c] | Timeli-ness[d] | Accept-ability[e] | Barriers[f] | Facilitators[g] |
| **Study** | | | | | | | |
| Chu (2017)[109] | | ✓ | ✓ | ✓ | | | |
| Close (1999)[75] | ✓ | | ✓ | | | | |
| Davison (2005)[110] | ✓ | | ✓ | | | | |
| Harper (2017)[111] | | | | | | | |
| Hendriks (2008)[112, 152] | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Lightbody (2002)[113] | ✓ | | ✓ | ✓ | | | |
| Matchar (2017)[114] | | ✓ | ✓ | | | | |
| Russell (2010)[6] | ✓ | ✓ | | ✓ | | | |
| Shaw (2003)[115] | ✓ | ✓ | | | | | |
| Vind (2009)[116] | ✓ | | ✓ | ✓ | | | |
| Whitehead (2003)[117] | ✓ | ✓ | | | | | |

[a]Reach: The proportion of intended target audience who participate in an intervention[141]
[b]Adherence :Compliance with, or participation in, key intervention components[73]
[c]Dose: The quantity of intervention delivered[98]
[d]Timeliness: Time from baseline assessment until first intervention session[11]
[e]Acceptability: The degree to which those involved in the program perceive it to be satisfactory[13]
[f]Barriers: Factors that hinder the delivery or receipt of a program[98]
[g]Facilitators: Factors that aid, or enable program implementation[98]

## 2.6 HEALTH LITERACY

There is a strong body of evidence linking health literacy to health outcomes.[156-168] The term 'health literacy' was first introduced in the 1970s. [169] A recent systematic review identified and synthesised 17 definitions,[170] and found that the WHO definition was one of three most frequently cited: "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health".[17] This is the definition of health literacy used in this thesis.

Low health literacy has been reported to be associated with increased mortality,[171-173] hospitalisation,[174] lower use of preventive healthcare services,[175] poor adherence to prescribed medications,[158] and difficulty communicating with health professionals, including engaging in participatory decision-making.[176, 177] Poorer knowledge about disease processes and self-management skills has also been found among people with chronic conditions such as COPD, asthma, diabetes, cardiovascular disease and arthritis.[162, 178, 179] The financial impacts of low health literacy have been estimated to range from USD$30 billion to USD$73 billion in 1998.[180] A 2009 review estimated that limited health literacy accounted for an additional 3-5% of total healthcare cost annually, or up to an additional USD$7,798 per year for individual patients.[181] Health literacy

studies commonly include participants with chronic conditions such as COPD, asthma, diabetes, cardiovascular disease and arthritis.[162, 178, 179]

Suboptimal health literacy is a common problem worldwide, especially among older adults. Sixty percent of Australians, and two-thirds of US citizens over the age of 65 lack basic health literacy skills.[182, 183] Functional literacy is also important. It is through these skills of reading and writing that those who are literate are able to participate more fully in society, with low functional literacy associated both directly and indirectly with a range of poor health outcomes.[184] Estimates of the proportion of the population in Organisation for Economic Co-operation and Development (OECD) countries lacking functional literacy skills range from 7% to 47%. In developing countries, these figures are much higher.[184]

In response to this issue, health literacy has become an increasingly important focus in modern healthcare. In developing and developed countries, health and social policies ensure health literacy is considered as a key factor for optimising people's ability to manage their health, and to maximise equitable access to health services.[18, 185] In the US the Health and Medicine Division identified health literacy as a health priority.[18] Similarly, in Europe, health literacy is highlighted as a critical component of population health through patient empowerment.[186, 187] The Australian Commission on Safety and Quality in Health Care (ACSQHC) emphasises that organisations need to align health literacy with the concept of person-centred care and integrate health literacy into healthcare planning and evaluation.[188]

The mechanisms linking health literacy to health outcomes have been extensively debated.[16, 20, 189] It has been suggested that health literacy influences patient outcomes through the individual's ability to engage in self-management skills, or participate in shared decision-making during healthcare interactions.[177] Lee *et al* devised a simple model with four key interrelated constructs linking health literacy to health outcomes: (1) disease and self-care knowledge; (2) health risk behaviour; (3) preventive care and physician visits; and (4) compliance with medication.[189] These factors all concern cognitive capabilities, skills and behaviours which reflect an individual's capacity to function in the role of a patient within the healthcare system. Paasche-Orlow and Wolf expanded on this idea and suggested that the ability to utilise healthcare is influenced by the person's navigation skills, self-efficacy, perceived barriers, and degree of participation in decision-making, as well as the health system's complexity.[20] They also acknowledged the healthcare provider's role in linking an individual's health literacy level to health outcomes, with the clinicians' communication skills and teaching ability, and degree of person-centred care delivered seen as important factors.[20] Figure 2.1 presents an overview of the mechanisms linking health literacy to falls prevention strategies, adapted from Lee *et al.*[189] and Paashe-Orlow & Wolf's[20] models.

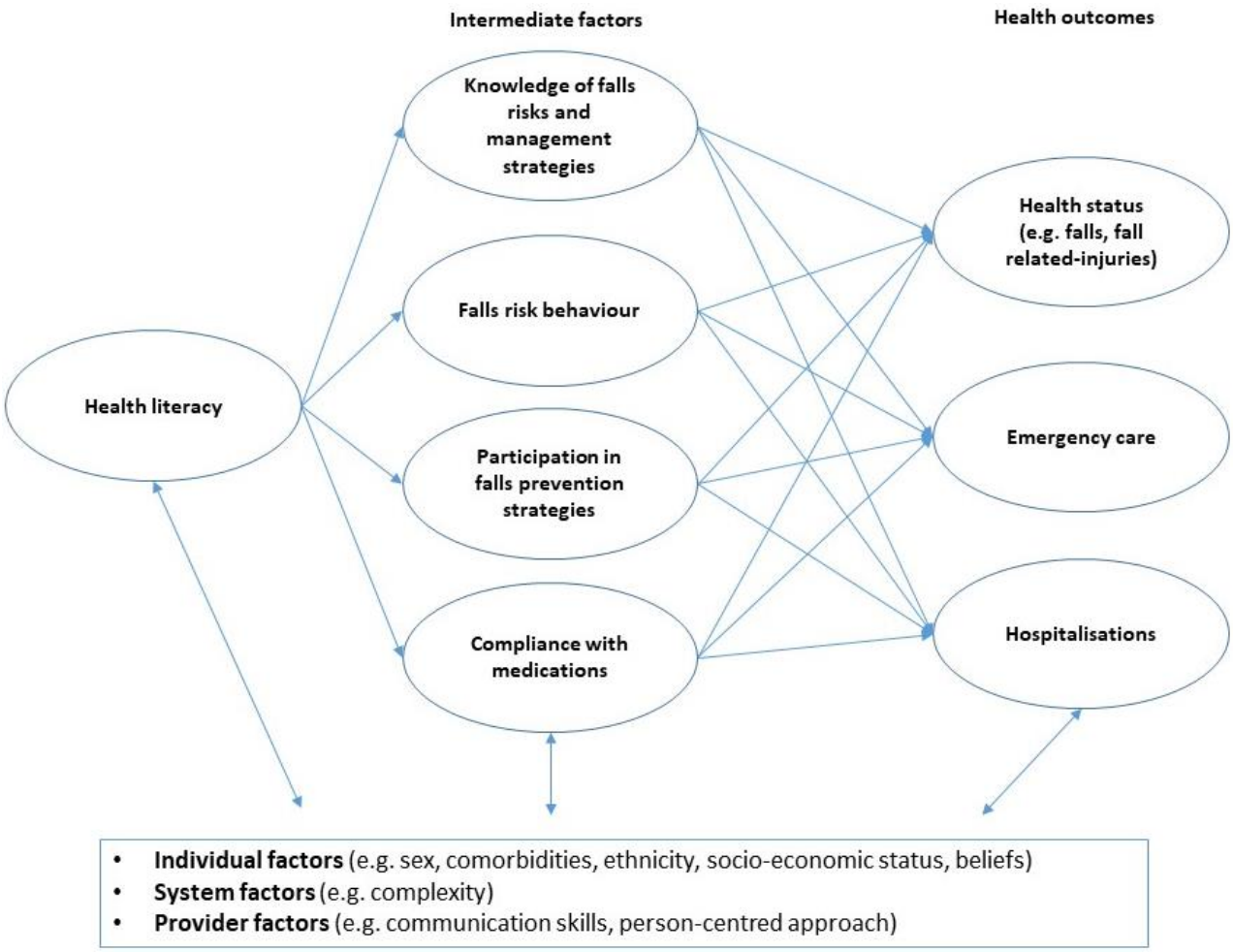


**Figure 2.1: Mechanisms linking health literacy to health outcomes**

Adapted from Lee *et al*.'s,[189] and Paashe-Orlow & Wolf's[20] models linking health literacy to health outcomes.

### 2.6.1 Health literacy and falls prevention

Despite the demonstrated links between health literacy and health outcomes, and resulting international drives to address this, research on health literacy in the context of falls prevention is still very much in its infancy. A recent qualitative study exploring the views and experiences of older adults with varying health literacy levels who had attended a falls clinic[190] found that tailoring communication to older adults' individual attributes and preferred learning styles was essential. They concluded that health professionals should be aware of patients' individual health literacy needs prior to commencing falls prevention rehabilitation.[190] A US study found that for males, the number of falls and injuries decreased with higher health literacy.[191] The authors recommended that falls prevention education materials be developed with health literacy ability in mind. Soh *et al*. studied the profiles of clients who used personal response systems (a form of assistive technology for falls prevention).[192] Although they did not measure health literacy in their study, they recommended that assessors for personal response systems consider the health literacy of eligible clients in order to tailor their discussions about falls prevention interventions to meet the needs of the individual.[192]

Consideration of health literacy when designing and implementing falls prevention programs for older adults has the potential to improve clinician-patient communication, treatment adherence, health outcomes, and quality of life.[191] According to the terminology used for the MRC process evaluation guidance, health literacy has the potential to be a significant 'mechanism of impact'[98] within falls prevention program implementation. Health literacy is, however, not mentioned in the ACSQHC's falls prevention guidelines for community, hospital, or residential aged care settings.[9, 193, 194] Furthermore, no previous studies have evaluated health literacy in the context of older people who present to an ED with a fall.

### 2.6.2 Measurement of health literacy

The accurate measurement of health literacy is essential for translating policy into preventive health practice. This allows for better identification of patient groups most in need of educational support; assists in tailoring interventions; and provides metrics to evaluate progress.[195]

Health literacy is a complex and multi-faceted concept, which poses challenges for its measurement.[196] There are many measurement tools available, measuring different components of health literacy, with varying validity and reliability.[197] Widely used of measures for testing individual health literacy ability include the Rapid Estimate of Adult Literacy in Medicine (REALM), which tests reading ability and pronunciation; The Health Education Impact Questionnaire (heiQ): an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions,[198] the Test of Functional Health Literacy in Adults (TOFHLA), which tests reading comprehension and numeracy;[199] and the Newest Vital Sign (NVS), which is a short clinical screening tool that assesses reading comprehension and numeracy using an ice cream label.[200] However, these tools generate very different results when administered concurrently,[201] and have been shown to have substantial psychometric weaknesses.[197, 202, 203] A critical appraisal of 19 health literacy indices showed that the underlying constructs varied widely across instruments, that they were not based on a specific conceptual framework, and that they did not encapsulate the full breadth of the health literacy construct.[202] These issues reduce the validity of these tools and limit their usefulness in clinical practice.

#### *2.6.2.1 The Health Literacy Questionnaire*

The Health Literacy Questionnaire (HLQ) was developed to address issues identified with previous tools and is now widely used. The HLQ is recommended by the ACSQHC as it measures individual health literacy ability more broadly than other more commonly used tools.[188] The HLQ contains 44 items that cover nine conceptually distinct areas of health literacy:[204]

1. Feeling understood and supported by healthcare providers (four items);
2. Having sufficient information to manage my health (four items);
3. Actively managing my health (five items);

4. Social support for health (five items);

5. Appraisal of health information (five items);

6. Ability to actively engage with healthcare providers (five items);

7. Navigating the healthcare system (six items);

8. Ability to find good health information (five items);

9. Understand health information well enough to know what to do (five items).

The measurement properties of the HLQ have been extensively evaluated, and the tool has been validated for a number of settings and languages, including French, Dutch, German, Slovakian, Norwegian, and Danish.[204-211] What is valid in one clinical population, however, may not be so in another. It is necessary that the measurement properties of a tool are sensitive to and appropriate for the context in which the tool is used. No health literacy tool has been validated specifically for a population of older people who have experienced a fall. Older people who experience a fall that leads to an ED attendance are often more frail, with more health and social complexities, compared with those who do not attend the ED after a fall.[1] Given the unique profiles of this patient population, it is imperative that an appropriate health literacy tool is utilised if individual health literacy information is to be used and acted upon in a meaningful manner. The HLQ was selected for use in the series of studies reported in this thesis.

## 2.7 RATIONALE FOR THE PhD RESEARCH

Falls are a serious, prevalent, and increasing issue for older community-dwelling people in Australia and around the world. Those who present at ED with a fall are known to be receiving suboptimal care that does not meet contemporary falls management guidelines. This places these individuals at high risk of subsequent ED presentations for future falls. In complex programs, such as multifactorial falls prevention interventions, a program evaluation approach is essential for appraising and understanding the 'black box' of intervention components and their interactions. No comprehensive mixed methods program evaluation has been conducted alongside RCTs of falls prevention programs for older people who present at ED with a fall. Where evaluation components have been reported, the data were inconsistently defined and reported. Thus, the critical success factors for reducing falls, falls injuries, ED presentations, and other health outcomes remain unknown for this cohort. The first two studies in this thesis aim to address this gap in the literature through a comprehensive mixed methods program evaluation (process evaluation, and impact and outcome evaluation) of the successful RESPOND falls prevention program.

Health literacy may be one of many key factors contributing to patient outcomes following falls prevention programs. Despite strong evidence linking health literacy with health outcomes for many health conditions,

health literacy has not previously been evaluated in the context of older people who present at ED with a fall. Furthermore, analysis of the measurement properties of a health literacy tool has not previously been undertaken in this context. This information is important for determining whether the HLQ can be confidently used to evaluate health literacy in this patient group. The HLQ was used in the RESPOND trial, and a detailed evaluation of the HLQ for use among older people presenting to the ED after a fall is presented in study three of this thesis.

# 3 RESPOND PROGRAM EVALUATION PROTOCOL

This chapter comprises the published protocol for the RESPOND program evaluation.[212] This protocol details the methods used for studies one and two: a process evaluation, and impact and outcome evaluation of the RESPOND RCT, addressing the first two thesis objectives. The results of these studies are reported in subsequent chapters and allow for conclusions to be drawn regarding the primary aim of this thesis – what were the critical success factors for the RESPOND RCT?

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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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## 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).

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## 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

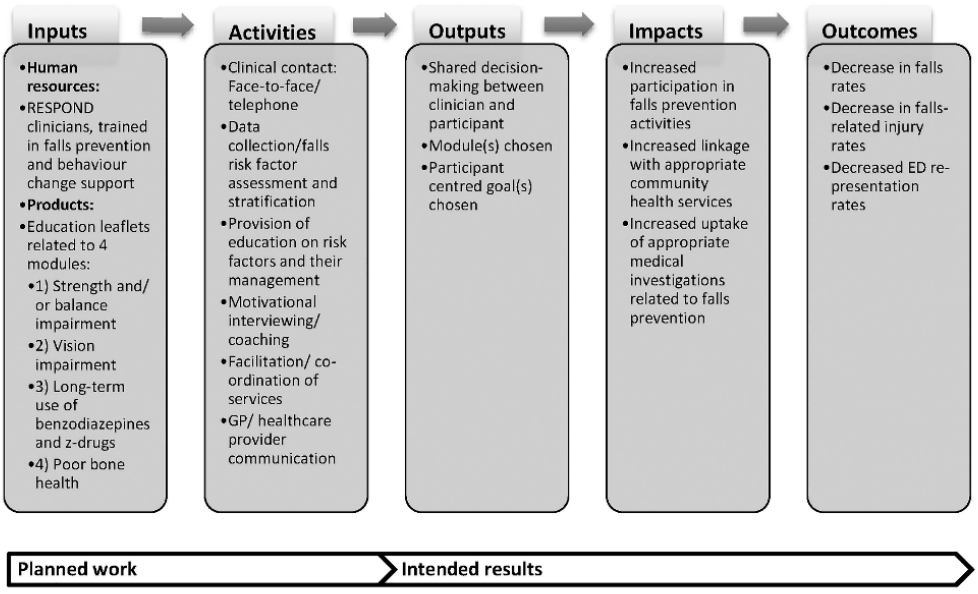


**Figure 1** RESPOND programme logic model. ED, emergency department; GP, general practitioner.

**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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# 4 RESPOND PROCESS EVALUATION

This chapter reports the results of the published mixed methods RESPOND RCT process evaluation.[213] This chapter describes study one and addresses objective one of this thesis. In combination with the impact and outcome evaluation (reported in Chapter 5) this process evaluation addresses the first aim of this thesis, through identification of the critical success factors for the RESPOND RCT.

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RESEARCH ARTICLE Open Access

# A mixed methods process evaluation of a person-centred falls prevention program

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## Abstract

**Background:** RESPOND is a telephone-based falls prevention program for older people who present to a hospital emergency department (ED) with a fall. A randomised controlled trial (RCT) found RESPOND to be effective at reducing the rate of falls and fractures, compared with usual care, but not fall injuries or hospitalisations. This process evaluation aimed to determine whether RESPOND was implemented as planned, and identify implementation barriers and facilitators.

**Methods:** A mixed-methods evaluation was conducted alongside the RCT. Evaluation participants were the RESPOND intervention group ($n = 263$) and the clinicians delivering RESPOND ($n = 7$). Evaluation data were collected from participant recruitment and intervention records, hospital administrative records, audio-recordings of intervention sessions, and participant questionnaires. The Rochester Participatory Decision-Making Scale (RPAD) was used to evaluate person-centredness (score range 0 (worst) - 9 (best)). Process factors were compared with pre-specified criteria to determine implementation fidelity. Six focus groups were held with participants ($n = 41$), and interviews were conducted with RESPOND clinicians ($n = 6$). Quantitative data were analysed descriptively and qualitative data thematically. Barriers and facilitators to implementation were mapped to the 'Capability, Opportunity, Motivation – Behaviour' (COM-B) behaviour change framework.

**Results:** RESPOND was implemented at a lower dose than the planned 10 h over 6 months, with a median (IQR) of 2.9 h (2.1, 4). The majority (76%) of participants received their first intervention session within 1 month of hospital discharge with a median (IQR) of 18 (12, 30) days. Clinicians delivered the program in a person-centred manner with a median (IQR) RPAD score of 7 (6.5, 7.5) and 87% of questionnaire respondents were satisfied with the program. The reports from participants and clinicians suggested that implementation was facilitated by the use of positive and personally relevant health messages. Complex health and social issues were the main barriers to implementation.

**Conclusions:** RESPOND was person-centred and reduced falls and fractures at a substantially lower dose, using fewer resources, than anticipated. However, the low dose delivered may account for the lack of effect on falls injuries and hospitalisations. The results from this evaluation provide detailed information to guide future implementation of RESPOND or similar programs.

**Trial registration:** This study was registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12614000336684 (27 March 2014).

**Keywords:** Falls prevention, fractures, older adults, emergency department, process evaluation, complex intervention, mixed methods

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## Background

Falls are the leading cause of hospital emergency department (ED) presentations for older people [1]. The evidence suggests that for fallers presenting to the ED, 13–33.3% will fall again within 6 months [2, 3], and 46–52% within 12 months [4, 5], highlighting the need for secondary falls prevention. In response to this clinical need, Barker et al. developed RESPOND: a falls prevention program targeting people presenting to ED with a fall to reduce their risk of subsequent falls ("*Respond to the first fall to prevent the second*") [6, 7]. RESPOND was designed to include the characteristics that appear to distinguish successful falls prevention, and other behaviour change programs, from others: interventions delivered at sufficient dose; in a timely manner; incorporating person-centred education and goal setting; using a telephone-based motivational coaching approach [7]. A randomised controlled trial (RCT) of RESPOND showed the program to be effective at reducing the rate of falls and fractures, compared with usual care. There was no difference in fall injuries (other than fractures), or hospitalisation outcomes between groups [6].

RCTs are the gold standard for establishing the effectiveness of an intervention [8]. However, RCT results alone do not provide information related to what worked, how, and why. RESPOND is a complex intervention, comprising numerous potential "active ingredients" where the combination of components comprise more than the sum of its parts [9]. Process evaluations conducted alongside clinical trials can determine the degree of implementation fidelity, clarify causal mechanisms (how and why it worked), and identify contextual factors (barriers and facilitators) associated with outcomes [8]. This information can guide researchers, clinicians and policy makers to successfully implement similar programs in different settings [10].

To date, information related to process factors for falls prevention RCTs is limited. Of eleven RCTs of falls prevention programs targeting older adults who present to an ED with a fall [4, 5, 11–19], elements of process evaluation, such as reach, adherence and timeliness of program delivery are inconsistently reported. Only one program conducted a detailed process evaluation alongside the RCT [17, 20]. The evaluation attributed lack of program effectiveness to an insufficient number of referrals and recommendations resulting from medical assessments, and participants' low compliance with advice [20]. No comprehensive process evaluation has been conducted on an RCT of a program that has been shown to reduce the rate of falls for older people who present to an ED with a fall, thus our understanding of critical success factors for reducing falls in this sub-optimally managed cohort remains limited. This process evaluation aimed to fill this gap in the literature by providing detailed insight into the RESPOND RCT results, and assist others in effectively translating the RESPOND program into real world settings, by addressing the following objectives:

1. To assess the degree to which RESPOND was implemented as planned; and
2. To identify barriers and facilitators to implementation from the perspectives of those delivering and receiving the intervention.

## Methods

### Study design

This paper reports a convergent parallel mixed-methods [21] process evaluation of the RESPOND RCT. Implementation fidelity is the degree to which an intervention is delivered as intended, and key components of evaluation of implementation fidelity have been variously categorised and defined [22]. For this study, components of implementation fidelity evaluated are: reach (the proportion of target cohort who participated in RESPOND); intervention participant adherence to minimum program requirements; RESPOND clinician adherence to key program components; and dose and timeliness of intervention delivered.

### Study setting and participants

A total of 541 community-dwelling adults aged 60–90 years, who had presented to one of two Australian public hospital EDs in Victoria and Western Australia with a fall, and had a planned discharge home within 72 h, were recruited to the RESPOND RCT. Exclusion criteria were: planned discharge to a residential aged care facility; current palliative care or terminal illness, requiring hands-on assistance to walk, non-English speaking, unable to use a telephone, a history of social aggression or psychosis, cognitive impairment (Mini Mental State Examination (MMSE) < 23) [23], or living > 50 km from the recruiting hospital. Recruited participants were randomised to either the RESPOND intervention or usual care and followed-up for 12 months. For those randomised to the intervention group, the first 6 months comprised the RESPOND program. RESPOND RCT details are published elsewhere [6, 7].

RESPOND process evaluation participants were the trial intervention participants ($n$ = 263) and the healthcare professionals delivering the program ($n$ = 7: three physiotherapists, two occupational therapists, one dietitian, and one nurse). This process evaluation corresponds with the inputs, activities and outputs detailed in the RESPOND program logic model [24], and interrogates the assumptions underlying the model and the linkages between program components and trial outcomes (Fig. 1).

### RESPOND intervention

Intervention participants received an initial home visit from a RESPOND clinician. At this visit a falls risk assessment

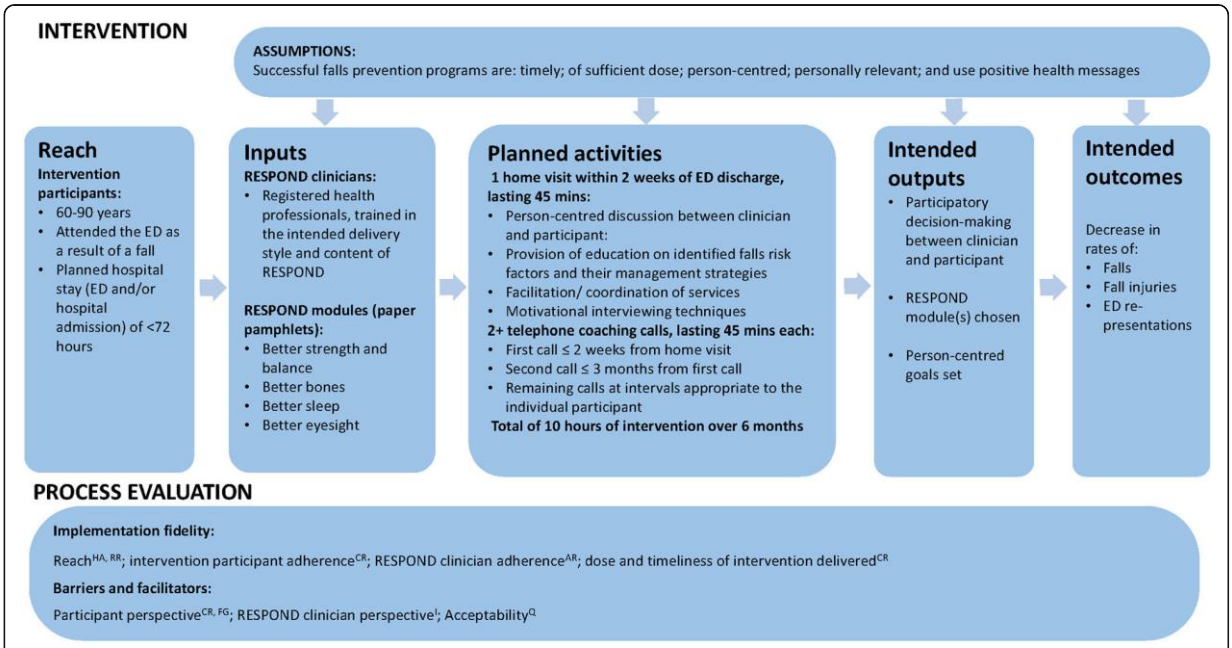


**Fig. 1** Key RESPOND intervention and process evaluation components. Process evaluation data sources: AR = audio-recordings of intervention sessions; CR = clinician records; FG = focus groups with intervention participants; HA = hospital administrative data; I = interviews with RESPOND clinicians; Q = intervention participant experience questionnaire; RR = recruitment records

was conducted, using a valid and reliable tool: Falls Risk for Older People – Community setting (FROP-Com) [25, 26], and the RESPOND intervention was introduced. RESPOND consisted of four evidence-based modules related to falls risk factors: Better Strength and Balance; Better Bones; Better Eyesight; and Better Sleep. Each RESPOND module had an associated pamphlet with the slogan: *"Be Your Best"*. These each provided positively framed health messages related to the interventions such as: *"Exercise… can help you feel revitalised, relaxed and help you get a good night's sleep"*; and *"With good eyesight you can…keep driving independently"*. Subsequent telephone coaching calls, using motivational interviewing approaches [27] were made by the RESPOND clinician over the 6 month intervention period. The timing, intended dose, and delivery style (person-centred education and goal setting, use of positive health messages, and motivational interviewing techniques), were pre-determined in the RCT protocol (summarised in Fig. 1) [7].

### *Clinician training*

A standard operating procedures manual guided consistent delivery of program content and intended delivery style across the two sites. The lead clinician attended a motivational interviewing course, and provided face-to-face training to the other clinicians, using a 'train the trainer' approach [28]. RESPOND clinicians shadowed their senior during intervention sessions prior to commencing their own intervention delivery. The lead clinician held regular meetings with RESPOND clinicians to discuss specific issues or achievements with program delivery, present case studies, and provide trial updates.

## Data collection

### *Implementation fidelity*

**Reach** Program reach was evaluated through the number of participants recruited into the RCT compared to the number of potentially eligible patients presenting to the recruiting hospital EDs (identified from hospital administrative data). Reasons for declining to participate were coded. Recruitment data were collected by the RESPOND trial recruitment team and entered directly into a web based database via an iPad.

**Intervention participant adherence** Participant adherence was defined as the proportion of participants who: i) had an initial home visit and at least two telephone coaching calls; ii) chose at least one RESPOND module to work through; and iii) set at least one goal. These data were recorded by the RESPOND clinicians in the project database.

**RESPOND clinician adherence** RESPOND clinician adherence to key RESPOND components was evaluated through analysis of intervention session audio-recordings. The clinicians were initially asked to audio-record all

intervention sessions, and part-way through the trial period this was changed to recording on a month on/month off basis in order to reduce clinician burden. This component of the study evaluated whether the clinicians: delivered the intervention in the spirit of participatory decision-making, using motivational interviewing (MI) techniques; provided education related to falls risks and their management strategies; and provided linkage to appropriate local community health services. Examples of community linkage included referral to a strength and balance exercise group; seeking advice from their general practitioner (GP) regarding withdrawal of sedative medication or having a vitamin D test; or making an appointment with an optometrist for a vision test.

Motivational interviewing skills evaluated were: Open-ended questions, Affirmations (statements and gestures that recognise client strengths and acknowledge behaviours that lead in the direction of positive change); Reflections (listening to the participant and then making statements to demonstrate understanding); and Summaries (synopsis of the conversation) – "OARS" [29].

Education, community linkage and motivational interviewing were assessed as either being present ("1") if there was an example of the clinician providing each component, or absent ("0"). Scoring guidelines were developed with definitions and examples for each component in order to assist with analysis.

Person-centeredness was analysed using the Rochester Participatory Decision-Making Scale (RPAD) [30]. This tool comprises nine aspects of participatory decision-making, each scoring "0" if no evidence of the item was present, "0.5" if some evidence, or a full point if strong evidence was present, with the exception of item 6, *'Clinician's medical language matches participant's level of understanding'*, which was scored: "-0.5" (clear mismatch), "0.5" (language mostly matches) or "1" (language clearly matches). The RPAD provides a total maximum score of nine.

**Dose and timeliness of intervention delivery** Data related to the RESPOND modules chosen, dose delivered (number of intervention sessions, and total duration of intervention delivered), and timing of intervention contacts (time from ED discharge to the initial home visit, and subsequent telephone coaching calls), were recorded on the project database by the RESPOND clinicians following each intervention contact, and compared to the parameters set in the RESPOND RCT protocol (summarised in Fig. 1: planned activities).

**Participant focus groups and RESPOND clinician interviews** The opinions of and experiences with the implementation fidelity components detailed above, from the perspectives of those participating in, as well as those delivering RESPOND, were captured qualitatively. Intervention participants' perspectives were examined through focus groups at the completion of the intervention period. Following the intervention period, participants were contacted via telephone and invited to participate in a focus group, with a follow-up letter sent to individuals who agreed to participate. All focus groups were conducted by the lead researcher (RLM), using a discussion guide developed in consultation with the RESPOND investigator team. The guide included prompts to discuss opinions about program content, dose, delivery style, and delivery mode, as well as perceived benefits of and barriers and facilitators to participation.

The opinions and experiences of the RESPOND clinicians were identified through individual semi-structured audio-recorded interviews, following the intervention period. The interview discussion guide mirrored that of the focus groups to allow for comparison between the experiences of those delivering and receiving the program.

The lead researcher conducted the focus groups and interviews, and field notes were taken. All interviews and focus groups were audio-recorded and transcribed. Copies of the transcripts were sent to the participants to provide the opportunity to comment on accuracy.

### *Barriers and facilitators*

Barriers and facilitators to implementing RESPOND were identified through the participant focus groups and clinician interviews as detailed above. In addition, clinicians routinely asked participants to identify barriers and facilitators to achieving RESPOND goals as part of the intervention sessions. These were recorded in the project database via 'tick box' categorical options.

**Acceptability** Acceptability of RESPOND was determined using a purpose-designed questionnaire sent to all intervention participants on completion of the 6 month RESPOND program. The questionnaire comprised nine Likert-type five point scale questions (strongly agree to strongly disagree) exploring opinions related to key program components, and perceived benefits and satisfaction with participating in RESPOND. A further four questions explored participant opinions related to the mode of delivery (one face-to-face visit and telephone calls) and dose delivered, with categorical options to choose from.

### *Data analysis*

A random selection of 10% of all audio-recorded intervention sessions were used to analyse clinician adherence. The lead researcher analysed the audio-recordings, in accordance with the purpose-designed analysis guide, and the RPAD coding manual (obtained on request from C.G. Shields [30]). A second researcher analysed 20% of the selected audio-recordings to determine inter-rater consistency and ensure rigour. Discrepancies were

discussed until consensus was reached. An inter-rater discrepancy of <10% was considered acceptable. Descriptive statistics were used to summarise all quantitative data, using Stata version 14 [31].

Qualitative data were analysed by the lead researcher using deductive and inductive coding [32]. Coding was guided by the assumptions underlying the RESPOND program logic, and key components of the RESPOND program design: person-centredness, motivational interviewing, provision of education and community linkage, dose and timeliness of intervention delivery, perceived relevance and benefit of RESPOND, and barriers and facilitators to implementation. An inductive approach was used to code relevant features of the data beyond the pre-defined categories described above. Coding was validated by a second researcher who coded 10% of the transcripts selected at random to ensure rigour with difference being resolved by consensus. Coding was supported by NVivo version 11 [33]. Themes were identified from the codes and mapped to the Capability Opportunity Motivation – Behaviour (COM-B) model [34]. This model categorises behaviour (B) as the result of an individual's capability (C); opportunity (O); and motivation (M), to perform the behaviour. The behaviours of interest for this evaluation were: (i) participation in the RESPOND program (intervention participants); and (ii) delivery of RESPOND (RESPOND clinicians). The themes and their categorisation in the COM-B model were reviewed by a second researcher and refined following discussion and consensus.

For each evaluation component, quantitative and qualitative data were synthesised at the interpretation and reporting level. Data were integrated through narrative, using a weaving approach, with qualitative and quantitative findings reported together on a component-by-component basis [35].

As the trial was conducted in two Australian States, it was possible that State-specific contextual variations could have influenced implementation of the program. An inter-site comparison was made to determine fidelity across sites using chi square tests for categorical data and t-tests for continuous data, with a $p$ value of $< 0.05$ considered statistically significant.

## Results

Intervention participants were a mean (SD) age of 73 (8.4) years, with the majority (71%) of high socio-economic status. A large proportion (42%) of participants lived alone, and a further 36% were a high falls risk. Participant characteristics are presented in Table 1. A total of 224 (85%) of all participants randomised to the intervention participated in at least one intervention session. The seven RESPOND clinicians contributed various proportions of intervention delivery. Six clinicians participated in interviews, with one declining (clinician 6). Participant flow through the study is summarised in Fig. 2.

**Table 1** Participant characteristics

| RESPOND intervention participant characteristics | |
|---|---|
| Recruitment | $n = 263$ |
| Female, n (%) | 132 (50.2) |
| Age group, n (%) | |
| 60–69 | 107 (40.7) |
| 70–79 | 89 (33.8) |
| 80–90 | 67 (25.5) |
| Socio-economic status[a] | |
| 1st quartile | 4 (1.5) |
| 2nd quartile | 22 (8.4) |
| 3rd quartile | 51 (19.4) |
| 4th quartile | 186 (70.7) |
| Home visit | $n = 224$ |
| Lives alone, n (%) | 93 (41.5) |
| Number of falls[b], n (%) | |
| 1 fall | 135 (60.2) |
| 2 falls | 51 (22.8) |
| ≥ 3 falls | 38 (17.0) |
| Number of comorbidities[c], n (%) | |
| None | 53 (23.6) |
| 1 | 55 (24.6) |
| 2 | 53 (23.7) |
| ≥ 3 | 63 (28.1) |
| Falls risk[d] | |
| Mild, n (%) | 54 (24.1) |
| Moderate, n (%) | 90 (40.2) |
| High, n (%) | 80 (35.7) |

[a]Socio-economic status was approximated using the Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) [36]. The 1st quartile (25th percentile) represents those with the most disadvantage, with the 4th quartile (100th percentile) representing those with the most advantage

[b]Number of falls in the last 12 months (including the index fall) was reported by participants as part of the Falls Risk for Older People – Community setting (FROP-Com) risk assessment tool

[c] Number of comorbidities was reported by participants as part of the FROP-Com assessment. Defined as total number of diagnoses of: arthritis; any respiratory condition; Parkinson's Disease; diabetes; dementia; peripheral neuropathy; any cardiac condition; stroke; any other neurological condition; lower limb amputation; osteoporosis; vestibular disorder; or lower limb joint replacement

[d] Falls risk was determined from the FROP-Com total score (0–60): mild = 0–11; moderate = 12–18; high = 19–60 [25]

### Implementation fidelity

#### *Reach*

Over the study period, 9690 people aged 60–90 years presented to the two EDs with a fall, and had a planned discharge home within 72 h; of these, 4118 (43%) were

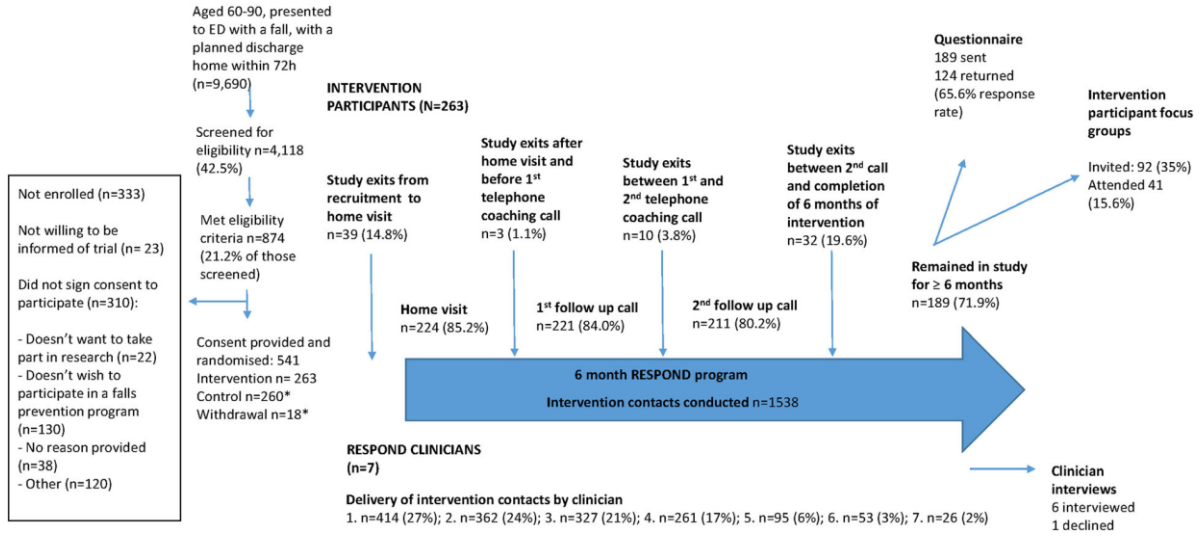


**Fig. 2** Participant flow. *Data from control participants, and those who withdrew from the study prior to completion, are not included in this process evaluation

screened for eligibility. The remainder either presented outside trial recruitment times or were discharged before recruitment could occur. Of those screened, 21% met all eligibility criteria. Of those eligible but not enrolled ($n$ = 333), 39% did not want to participate in a falls prevention program, and 7% did not wish to be part of a research project (Fig. 2).

### *Intervention participant adherence*

Better Strength and Balance was the most frequently selected module ($n$ = 204; 91% of participants who received the intervention), followed by Better Bones ($n$ = 148; 66%). Better Sleep and Better Eyesight were the least frequently chosen ($n$ = 81; 36% and $n$ = 72; 32% respectively). Participants chose a median (IQR) of 2 (2–3) modules over the intervention period. Five of the 224 participants who received at least one intervention session did not choose a module throughout their intervention period. Two of these five dropped out after their home visit, one dropped out after their first follow up coaching call, and one after their second call. The fifth participant was lost to follow up after six follow up coaching calls. Adherence to the program was defined as choosing at least one module, completing a minimum of three intervention sessions and setting at least one goal. A total of 195 of the 263 intervention participants (74%) met these three minimum requirements. Participants who chose Better Strength and Balance had the highest proportion of adherence 180 (88%); with similar proportions for Better Eyesight and Better Bones ($n$ = 55, 76% and $n$ = 111, 75% respectively). The lowest adherence was for those who chose Better Sleep ($n$ = 41, 51%).

### *RESPOND clinician adherence*

A total of 926 sessions (60% of all intervention contacts) were audio-recorded by the RESPOND clinicians. Ten percent ($n$ = 93) of recordings were randomly selected for inclusion in the analysis. Overall, the RESPOND clinicians delivered the program in a person-centred manner, as indicated by the RPAD scores (median RPAD score 7; IQR: 6.5–7.5) (Table 2). Some aspects of participatory decision-making were exemplary, with evidence of the clinicians matching their language to the participants' level of understanding in all of the analysed intervention contacts. The clinicians explained the issue, asked open ended questions, and checked their understanding of the participant's point of view in over 90% of analysed audio-recordings. However, there was little evidence (4%) of the clinicians asking the participants if they had any questions (Table 2).

Qualitative data demonstrated that a person-centred, participatory decision-making approach was favoured by clinicians and participants:

> "*When people set their own goals it's often a lot more empowering and they're often a lot more motivated to actually do them because they've come up with them themselves.*" (Clinician 1).

**Table 2** Implementation fidelity

| RESPOND program component | Median (IQR) | Protocol requirement | Protocol requirement met by those remaining in the study at the time point of interest, *n* (%) | % of total intervention cohort who met requirement (*n* = 263) |
|---|---|---|---|---|
| Intervention participants who received at least one intervention session (home visit) *n* = 224 | | | | |
| Number of intervention contacts (home visit plus telephone calls) | 7 (5, 8) | 1 home visit + 2 telephone calls | 211 (94.2) | 80.2 |
| Total duration of direct intervention provided per participant (hours) | 2.9 (2.1, 4) | ≥ 10 h | 0 (0) | 0 (0) |
| Total duration of intervention (days) | 171 (158, 178) | 6 months (> 182 days) | 38 (17.0) | 14.5 |
| Duration of home visit (minutes) | 45 (30, 50) | ≥ 45 mins | 114 (50.9) | 43.3 |
| Days from ED discharge to home visit (days) | 18 (12, 30) | ≤14 days | 85 (38.1) | 32.3 |
| Intervention participants who received at least 1 follow up coaching call *n* = 221 | | | | |
| Duration of each telephone contact (minutes) | 20 (15, 25) | ≥ 45 mins | 2 (0.9) | 0.8 |
| Days from the home visit to the first coaching call (days) | 14 (9, 17) | ≤ 14 days | 148 (67.0) | 56.3 |
| Intervention participants who received at least 2 follow up coaching calls *n* = 211 | | | | |
| Days from the first to the second coaching call (days) | 21 (14, 30) | ≤ 3 months (91 days) | 207 (98.1) | 78.7 |
| Audio-recordings of intervention sessions *n* = 93 | | | | |
| RPAD 1) Clinician explains the clinical issue or nature of the decision | 1 (1, 1) | Scored 1 | 92 (98.9) | |
| RPAD 2) Clinician discusses uncertainties associated with the situation | 0.5 (0, 1) | Scored 1 | 43 (46.2) | |
| RPAD 3) Clarification of agreement with the management plan | 1 (0.5, 1) | Scored 1 | 51 (54.8) | |
| RPAD 4) Examining barriers to follow-through with management plan | 1 (1, 1) | Scored 1 | 78 (83.9) | |
| RPAD 5) Participant asks questions | 0.5 (0.5, 0.5) | Scored 1 | 17 (18.3) | |
| RPAD 6) Clinician's medical language matches participant | 1 (1, 1) | Scored 1 | 93 (100) | |
| RPAD 7) Clinician asks, "any questions?" | 0 (0, 0) | Scored 1 | 4 (4.3) | |
| RPAD 8) Clinician asks open ended questions | 1 (1, 1) | Scored 1 | 87 (93.6) | |
| RPAD 9) Clinician checks their understanding | 1 (1, 1) | Scored 1 | 88 (94.6) | |
| RPAD total score | 7 (6.5, 7.5) | Scored 9 | 0 (0) | |
| Falls risk and management education provided | | Yes | 89 (95.7) | |
| Linkage to community falls prevention services provided | | Yes | 88 (94.6) | |
| Motivational interviewing: Open-ended questions | | Yes | 87 (93.6) | |
| Motivational interviewing: Affirmation | | Yes | 88 (94.6) | |
| Motivational interviewing: Reflection | | Yes | 80 (86.0) | |
| Motivational interviewing: Summary | | Yes | 79 (85.0) | |

> "[The RESPOND clinician] *encouraged you and sort of steered you in the right* [direction] *or gave you options… if someone tells me what to do I just ignore it.*" (Male participant, aged 68).

The clinicians implemented at least one motivational interviewing technique in the majority of intervention sessions (85–95%), with 71% (*n* = 66) of recorded contacts demonstrating evidence of all four OARS components (Table 2). The clinicians recognised that motivational interviewing techniques were a useful strategy for delivering behaviour change interventions:

> *"I think motivational interviewing is really appropriate*

*whenever you're dealing with any kind of health care."* (Clinician 1).

However, some clinicians found that this approach worked better with some participants than others:

*"Using* [motivational interviewing] *in the purer sense was difficult at times… There's a couple of male* [RESPOND participants] *that come to mind who don't want to have in-depth conversations. They really want a "yes/no". Some people are used to a very prescriptive style of care. "* (Clinician 5).

Falls prevention education was provided in most (96%) of the analysed intervention sessions (Table 2). The clinicians and participants recognised the benefits of providing education related to falls risk and associated management strategies:

*"I think bringing new ideas to them, new information, new education, that was also a key benefit, and a lot of people didn't have a lot of this knowledge, and they were really grateful for that".* (Clinician 7).

*"They* [RESPOND clinicians] *were informative… and explained them* [the RESPOND modules] *all very thoroughly".* (Female participant, aged 62).

The clinicians linked participants with appropriate community services in 95% of analysed audio-recordings. The participants appreciated having an allocated clinician to facilitate this community linkage:

*"Before I had the fall I did strength training with* [community health centre]. *After the RESPOND clinician came to me see me, I said I wanted to go back to the exercise program, but if I'd just rung the exercise program and said I'd like to go back, I would have been on the waiting list for six months. I said 'this is my goal, I'd like to go back to this exercise program'.* [My RESPOND clinician] *either phoned … they did something, which meant that I was able to get in much quicker, and that was very helpful. And I'm still involved in that, and I intend to continue it".* (Female participant, aged 67).

The unique role of the RESPOND clinician as the 'missing link' for providing coordinated falls prevention advice and support was recognised by clinicians at both sites:

*"When you actually look at it, I listen to that person for as long as they want to talk, and we make a plan of what to do next, and I encourage them. What other services do that? Very, very few".* (Clinician 1).

*"I think it* [RESPOND] *does fill a gap….When someone turns up at the ED it's unlikely that they're going to get anywhere near the kind of information that RESPOND's providing for them, and it's a bit hit and miss with their GP as well just because they're busy… the ongoing support* [provided by the RESPOND clinician] *over a period of time is really valuable for these people".* (Clinician 7).

The participants expanded on this idea of RESPOND meeting a clinical need and suggested that it has particular value to those who live alone and/or are socially isolated:

*"She* [RESPOND clinician] *put me on to the right exercise program, she encouraged me, she helped me to get bits and pieces of furniture, lifting up the mats. I found her invaluable, plus having that support. When you live on your own, it's a horrible experience".* (Female participant, aged 79).

*"There must be other people, like me, that really don't have anybody and you fill in a very important job".* (Male participant, aged 74).

#### *Dose and timeliness of intervention delivery*

The majority of participants (80% of the total intervention cohort) received the minimum requirement of one home visit plus two follow up coaching calls. However, overall, the intervention was delivered at a lower dose than planned. Less than 1% achieved a telephone call that lasted 45 min or more (median 20 mins, IQR: 15, 25). No participants received the planned 10 h of intervention contact time with their RESPOND clinician, with a median total intervention time of 2.9 h (IQR: 2.1, 4) (Table 2).

However, the clinicians highlighted the importance of quality over quantity in terms of the dose of program delivered:

*"I've got another man who very seldom went over eight minutes in a call, and he just loved having the calls, and he was in a totally different place…in a positive way…at the end of that six months than the beginning".* (Clinician 1).

The clinicians suggested that a higher dose was often associated with increased participant complexity:

*"Lower-functioning ones who needed more assistance and support, you could do a half-an-hour phone call with them".* (Clinician 5).

Of those who had a home visit, less than half (38%) received this within the intended 2 weeks of ED discharge

(median 18 days; IQR 12, 30) (Table 2). A further 85 (38%) received their first intervention session within 30 days, meaning that 76% of participants received their home visit within 1 month of ED discharge.

Clinicians cited complex health reasons as contributing to the delay in completing a home visit:

> *"Perhaps all of the health issues weren't immediately understood when they were seen in ED so sometimes that would mean re-presentations or it would mean later on they'd end up being admitted to rehab… or staying on in the hospital… or they'd gone to stay with family".* (Clinician 1).

Despite the challenges of delivering an early intervention, the participants perceived value in receiving the RESPOND program during the vulnerable post-fall period:

> "[RESPOND] *really helped in those first few weeks when you're at home and you're sort of thinking 'oh my god, what have I done here?' I just found that very reassuring. I was very impressed".* (Female participant, aged 62).

Nearly all participants (98%) received their second coaching call within 3 months of the first call (Table 2). The clinicians perceived the frequency of intervention sessions as important for maintaining progress towards RESPOND goals:

> *"In terms of frequency I think you need to stay in touch with them every two or three weeks otherwise they forget and it becomes strange to talk something that you have discussed at the last phone call".* (Clinician 5).

Inter-site consistency was high with no statistically significant differences between sites for program dose, timeliness, or delivery of key program components.

## Barriers and facilitators

### *Capability*

The main 'capability' barrier to participation in RESPOND was participants' complex health issues taking priority and/or limiting the participant's physical capacity to take part (Table 3). Complex health issues fell into the following main categories: recent surgery; an exacerbation of an existing condition; or new medical diagnosis and associated treatment. Conversely, medical clearance to exercise (physical capacity to participate in falls prevention exercises following fall-related musculoskeletal injury, as judged by the participant's GP or other medical professional) was stated as a facilitator for participants to engage in RESPOND activities. Increased awareness of falls risk factors and their associated management strategies, resulting from the educational component of RESPOND, was also reported as a key facilitator to participants' capability to engage in RESPOND.

> "[RESPOND is] *worth doing from the point of view that they make you aware of the reasons why you have a fall… I think the information was beneficial…it made me change my lifestyle".* (Female participant, aged 62).

For the clinicians, lack of prior knowledge or training for delivering certain RESPOND components was viewed as a barrier to delivering RESPOND. The clinicians considered prior relevant experience as a facilitator to their perceived capacity to deliver RESPOND, with a bias towards modules that correlated most closely with their professional background:

> *"I skew more to strength and balance and bones, because it's something I know a lot more about than, say, vision or sleep".* (Clinician 7).

### *Opportunity*

The external factor that was perceived as the greatest barrier to participating was complex social issues. This most frequently related to carer commitments (caring for a spouse, or grandchildren); breakdown of personal relationships; social engagements; or travel. Lack of time was an additional barrier for some, most commonly due to work commitments. Some participants also reported their primary healthcare provider sometimes posed a barrier to completing agreed actions in order to achieve RESPOND goals:

> *"My doctor wouldn't give me a referral to have the vitamin D checked. He said it was an overtreatment and unnecessary".* (Female participant, aged 71).

The participants' other health and social issues were also identified as key 'opportunity' challenges for the clinicians delivering RESPOND, because participants' priorities were elsewhere:

> *"A lot of comorbidities makes it essential but difficult".* (Clinician 7).

> *"She* [RESPOND intervention participant] *had all this other emotional stuff – family issues – going on that were a higher priority* [than RESPOND] *to deal with".* (Clinician 5).

In some instances, RESPOND appeared less relevant for participants and engaging them in the program posed a

**Table 3** Barriers and facilitators to participation in and delivery of RESPOND, mapped to the COM-B Framework

| | | Participant Behaviour = participation in RESPOND Theme | Clinician Behaviour = delivery of RESPOND Theme |
|---|---|---|---|
| Capability: physical and psychological capacity to engage in the behaviour | Barrier | • Complex health situation[CR] | • Lack of prior knowledge or training for delivery of specific RESPOND components[I] |
| | Facilitator | • Increased awareness of falls risk factors and their management strategies[FG]<br>• Medical clearance to commence exercise program[CR] | • Prior work experience or training in certain aspects of RESPOND[I] |
| Opportunity: external factors that make the behaviour possible | Barrier | • Complex social situations[CR]<br>• Insufficient time[CR]<br>• RESPOND recommendations not supported by participant's primary healthcare provider[CR, FG] | • Participants' competing priorities (health and social)[I]<br>• Participants' lack of perceived relevance[I] |
| | Facilitator | • Access to transport[CR]<br>• Adequate time[CR]<br>• Financially viable[CR]<br>• Services readily available[CR]<br>• Supportive primary healthcare provider[FG] | • RESPOND education pamphlets as basis for intervention sessions[I]<br>• Participants' perceived relevance[I] |
| Motivation: brain processes that direct behaviour, such as decision-making, habitual processes and emotional responses | Barrier | • Lack of perceived relevance[CR, FG] | • Clinical decision-making within the constraints of the RCT[I] |
| | Facilitator | • Support from RESPOND clinician[CR, FG]<br>• Perceived personal relevance[CR, FG]<br>• Positively-framed health messages[FG]<br>• Participatory decision-making[FG] | • Peer support[I]<br>• Person-centred approach[I]<br>• Rapport with participant[I]<br>• Positively-framed health messages[I] |

Data source: *CR* Clinician records, *FG* Focus group (participants), *I* Interview (clinicians). This table is based on the COM-B framework [34]

challenge for clinicians:

> *"Those who came through with a really severe health event, or an accident… and don't even classify it as a fall, it was harder to see a link between what we're offering and what's happening in their life. There was not so much relevance there."* (Clinician 7).

Key facilitators for participants included adequate access to transport, affordable and accessible services, and having sufficient time for the intervention sessions and to address RESPOND goals.

The clinicians identified the RESPOND pamphlets as facilitating the delivery of RESPOND by providing a prompt and focus for the intervention sessions:

> *"To leave them with people so that they could look at them and then ask them, 'Had they looked at them since you'd spoken?', 'Was there anything else that came up out of them?', and as a memory jogger. Sometimes they used them as a cue when they went to their GP to cover some element of whichever module was involved. So, yeah, I found them quite useful".* (Clinician 5).

The clinicians found that participants were more engaged in the program if they perceived RESPOND to be personally relevant:

> *"Some of those people* [RESPOND participants] *would definitely relate* [to the RESPOND modules] *if they were looking at their health and general wellbeing and going 'yeah, I notice that my balance has been getting a little bit worse in the last few weeks'. These are the words and the language that you could usually pick up from the conversation and go, great, I think there's going to be some perceived relevance and some acceptance here".* (Clinician 7).

#### *Motivation*

Lack of perceived relevance was a key motivational barrier to participation for some participants:

> *"I think it* [RESPOND] *is more for people that have a 'proper' fall".* (Male participant, aged 84).

Conversely, perceiving the RESPOND modules to be personally relevant, was a motivating factor for many:

> *"Once you have one fall the chances of you having another fall are high. So it* [RESPOND] *really made me aware of that…I was off to exercise".* (Female participant, aged 60).

For the clinicians who were used to having a broad repertoire of patient management options in real-world clinical situations, performing clinical decision-making and treatment within the constraints of an

RCT sometimes posed a challenge to delivering RESPOND.

> *"The thing is when you've got fixed strategies like we do in our modules, to let a person take their choices and be the one guiding their choices… is such a difficult thing to do".* (Clinician 7).

> *"Having the four specific modules that we were to stick to was really tricky".* (Clinician 1).

Participants considered decision-making support from the RESPOND clinicians to be a main motivational factor. This included problem-solving identified barriers to participation, practical suggestions for navigating the healthcare system, and adapting strategies to achieve RESPOND goals. Words used by the participants to describe their clinicians include: *"supportive"; "friendly"; "caring"; "approachable"; "encouraging"; "motivating"; "uplifting"*. In a similar theme, the clinicians identified their rapport with the participants as a factor that facilitated their delivery of the program.

Health messages delivered in a positively-framed manner were facilitating factors for both participants and clinicians. Specifically, participants and clinicians identified the RESPOND education pamphlets and their "Be Your Best" slogan as non-confrontational and motivating:

> *"There's nothing in here to say you had a fall…it's just 'be your best' …and happy, older person on the front… and it's health education. I think this is excellent."* (Male participant, aged 76).

> *"I think it's good – especially for those patients who are very fall-phobic."* (Clinician 1).

### Acceptability

Over half of the participants who received the intervention ($n$ = 124, 55%) completed the post-intervention questionnaire. The majority of respondents perceived the program to be acceptable and were satisfied with the program (87%) (Fig. 3). Half (51%) were satisfied with the mode of delivery (one face-to-face home visit with subsequent telephone calls) with 23% preferring to only talk over the phone, and 11% preferring to only have face-to-face meetings with their RESPOND clinician. A further 9% preferred other modes of communication, such as email, and the remaining 6% left this question blank. Mixed opinions regarding mode of delivery were also evident in the focus groups, however, the majority were happy with the RESPOND format:

> *"I think one visit's enough… I loved the phone calls much better."* (Female participant, aged 60).

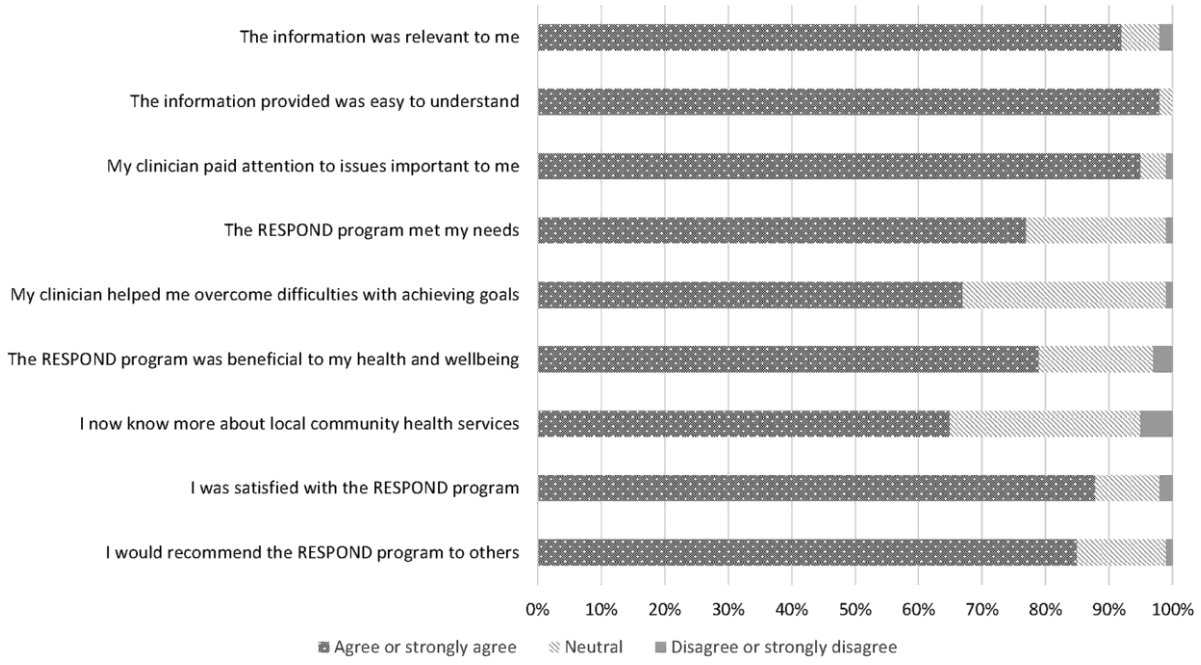


**Fig. 3** Participant acceptability and satisfaction from questionnaire results

The clinicians found the telephone calls to be flexible and convenient:

> *"Some of them would say 'here's my mobile number, call me on my mobile, I'll be out and about but I'll answer it'… so it was very convenient for them."* (Clinician 1).

However, the clinicians also valued the face-to-face session in terms of rapport building:

> *"I feel like when you've spent more time with them in the house they're more likely to relax and chat to you longer on the phone at the subsequent follow-ups because you've got a little rapport."* (Clinician 7).

A similar sentiment was expressed by the participants:

> *"I like the phone calls, but it was also nice to have the initial face-to-face and meet the person, that's just a nice way to communicate with somebody."* (Female participant, aged 62).

Of the participants who preferred the home visits over the phone calls, social interaction was commonly stated as the main reason:

> *"I personally like the visits… but that's probably because I am on my own so much."* (Male participant, aged 74).

The total number of telephone calls was considered acceptable, with 89% of participant questionnaire respondents stating that they had just the right amount of calls and 85% felt the program length of 6 months was just right.

## Discussion

This is the first comprehensive process evaluation to be performed in parallel with an RCT of a falls prevention program that significantly reduced the rate of falls and fractures for older people who have presented to an ED with a fall. Our evaluation showed that RESPOND was effective at a substantially lower dose than intended, and the program content and style was acceptable to participants and clinicians. This evaluation suggests that the critical success factors are: i) the delivery style - delivering positively framed health messages in a person-centred manner, using motivational interviewing techniques; ii) the program content - the provision of consistent support, targeted education, and coordination of community services; and iii) timely intervention - the first session being conducted within 1 month of ED discharge.

An important aspect of person-centred care is participatory or shared decision-making. This involves people making informed decisions based on facts as well as their personal values and preferences [37]. The RESPOND clinicians delivered the program in a person-centred manner, as evidenced by the overall RPAD scores. Importantly, this style of program delivery was preferred by RESPOND participants and clinicians.

In addition to participatory decision-making, motivational interviewing is a well-established method for accomplishing person-centred care [38]. However, motivational interviewing has only been used to a limited extent with older adults [27]. The current evaluation demonstrated that over 70% of analysed audio-recordings of RESPOND intervention sessions had evidence of the clinicians using all four key motivational interviewing 'OARS' skills; this may have contributed to the positive RCT results. Similarly, a recent study found that provision of motivational interviewing was associated with older adults' adherence to a falls prevention exercise program at 1 year [39].

RESPOND education and the accompanying module pamphlets emphasised maximising independence and functional capabilities to allow people to "Be Your Best", rather than focusing on reducing falls and the associated negative connotations [40]. This was well received by the RESPOND participants, and the clinicians found the positively-framed messages facilitated their delivery of the program. This finding is consistent with the literature. A meta-analysis found that 'gain-framed' messages appear to be more effective than 'loss-framed' messages in promoting prevention behaviours [41]. This is supported by a recent study that concluded that older adults prefer falls prevention information to be delivered in a positive tone [42]. In contrast, Haines et al. (2014) suggested that explicitly discussing falls and falls risks is required to overcome the "better for others than me" attitude to falls prevention activities [43]. However, only 36% of their study participants had experienced a fall in the last 12 months, compared with 100% of RESPOND participants, which may account for differences in the perceived relevance and benefit of engaging in falls prevention activities.

The importance of education in reducing falls has been previously demonstrated [44]. Importantly, RESPOND participants mostly found the information provided to be personally relevant, which has been found to be more motivational for engaging in fall prevention activity [45]. An additional finding from our study was the importance of the relationship built between the participant and the education provider - the clinician. The concept of preventive information being provided with empathy and time to listen has been shown to foster motivation and engagement in recommended activities [42]. The rapport established between the RESPOND clinicians and the participants emerged as a factor that

facilitated the delivery of the program, and motivated the participants. This support for the participants for the first 6 months following an ED presentation for a fall appears to address a clear gap in existing falls prevention services. This may be especially pertinent for those living alone or socially isolated. Prior studies highlight the importance of social support for maintaining health and function for older adults [46–48].

The RESPOND intervention was not as timely as planned (the initial home visit was intended to be conducted within 2 weeks of ED discharge). However, despite not achieving trial protocol, most participants were seen within 1 month of ED discharge. Delivery of the intervention within 1 month of the index fall appears to differentiate successful programs from others [7]. A Dutch RCT cited the time lag for intervention as a reason for the ineffectiveness of the program, with medical and occupational therapy assessments taking place five and 10 weeks after baseline, respectively [17]. In contrast, a successful UK trial delivered services within 1 month of ED discharge [16]. The main reasons identified for the delay in delivering the initial RESPOND intervention session were the participants' complex health and social issues acting as competing priorities. These factors should be considered when planning appropriate timing of intervention sessions.

RESPOND was effective at reducing falls and fractures at a lower dose than anticipated (median of 3 h, compared with the planned 10 h), thereby requiring fewer resources. The concept of 'quality over quantity' was cited as a reason for brief intervention sessions. Despite the relatively short contact duration, the median number of intervention sessions was seven per participant, exceeding the minimum of three contacts stated in the protocol. This suggests that frequency may be more beneficial than duration of intervention contacts. This was supported by the clinicians' perceptions that regular clinician contact maintained participant progress towards goals. However, the delivery of a substantially lower dose of intervention than planned may be a reason for the lack of impact on falls injuries or hospitalisations. Further information is required to better understand the program dose or other factors required to support reduction in fall injuries and hospitalisation outcomes.

Refining the clinician training program is recommended. RPAD item scores indicated a need for further training related to consistently asking the participant if they have any questions. Interview data showed that clinicians were more confident delivering aspects of RESPOND that they had prior knowledge or experience with. This suggests that RESPOND clinician training and resources may need to be tailored to account for individual expertise and professional backgrounds.

A further suggestion for future implementation is to allow increased flexibility with the mode of program delivery. The home visits were valued by clinicians and participants, particularly those who live alone or are socially isolated, and some participants may benefit from additional face-to-face sessions. Similarly, addition of alternative methods of communication, such as email or text messaging, may improve engagement for some.

This evaluation has a number of methodological strengths. The use of a mixed methods approach, with pre-specified data collected alongside the multi-centre RCT, allows for a rich understanding of the RESPOND trial results to be generated. Our evaluation of program fidelity through analysis of audio-recordings reduced the risk of bias associated with clinician- or participant-reported data alone.

We also acknowledge the study limitations. While program acceptability was high among participants who returned the participant questionnaire, the opinions of those who exited the intervention prior to 6 months or chose not to complete the questionnaire could not be captured. Similarly, those who chose to attend the focus groups are unlikely to be representative of those who declined to participate, or exited the study prior to completion. However, this was somewhat mitigated through the additional data related to barriers and facilitators recorded following each intervention session. A further limitation is that despite participant adherence being high, as per our definition, we do not have data related to whether participants acted on recommendations made by their clinicians, and whether their goals were met. A separate paper will augment this study by reporting: i) participation in falls prevention strategies, comparing the RESPOND RCT intervention and control groups; and 2) sub-group analyses of intervention participants to determine who RESPOND is most effective for, as described in the RESPOND program evaluation protocol [24].

## Conclusions

This process evaluation found that RESPOND was delivered in a timely and person-centred manner, with positively-framed, personally relevant health messages aiding participant engagement. These appear to be the critical success factors for the significant reduction in the rate of falls and fractures. Participants' complex health and social issues pose the greatest challenge to implementation fidelity. A lower than planned dose delivered may account for the lack effect on fall injuries or hospitalisation. The results of this process evaluation can provide guidance to researchers, clinicians, and policy makers on implementation of RESPOND, or similar programs, in other clinical settings.

**Abbreviations**
COM-B: Capability, opportunity, motivation – behaviour (behaviour change framework); ED: Emergency department; FROP-Com: Falls Risk for Older People – Community setting (falls risk assessment tool); GP: General practitioner; IQR: Interquartile range; MI: Motivational interviewing; OARS: Open-ended questions, affirmations, reflections, summaries (motivational interviewing skills); RCT: Randomised controlled trial; RPAD: Rochester Participatory Decision-Making Scale

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**Authors' contributions**
Concept and design: RLM, KDH, DA, GA, CB, PC, CEB, LF, AMH, PH, JAL, SRN, RM, JR, DS, ALB; data collection and analysis: RLM, KDH, INA, DA, CB, SRN, RM, ALB; manuscript writing: RLM, KDH, INA, DA, CB, SRN, RM, ALB. All authors approved the final version of the manuscript to be published.

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**Availability of data and materials**
The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

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## Publisher's Note

# 5 RESPOND IMPACT AND OUTCOME EVALUATION

## 5.1 INTRODUCTION

This chapter describes the impact and outcome evaluation of the RESPOND RCT, as outlined in the protocol paper[212] (Chapter 3). It augments the process evaluation,[213] which was reported in Chapter 4.

### 5.1.1 Impact evaluation

The intended impact of the RESPOND intervention was increased participation in falls prevention strategies. Based on prior literature,[6, 214] participation in falls prevention strategies was assumed to be the mechanism of impact linking implementation of the RESPOND program components to the main RCT outcomes: falls, fall-related injuries, and ED re-presentations, as per the RESPOND program logic (Chapter 3, Figure 3.1).[212] For this impact evaluation, 'participation in falls prevention activities' was operationalised as attendance at a range of healthcare appointments relevant to falls prevention. This impact evaluation aimed to compare participation in falls prevention strategies for the intervention group with participation for the usual care group, and identify factors associated with participation.

### 5.1.2 Outcome evaluation

In a healthcare system where financial and staffing resources are limited, it is important to determine which sub-groups of patients would benefit the most from an intervention program. The overall RESPOND RCT results provide us with an understanding of whether the program was effective for the intervention group as a whole.[1] The trial found that RESPOND reduced the rate of falls and fractures in the intervention group, compared with usual care. RESPOND did not, however, reduce the rate of fall-related injuries or hospitalisations, including ED re-presentations. This outcome evaluation aimed to analyse key participant and program factors, and their association with RESPOND RCT outcomes (falls, fall-related injuries, and ED re-presentations). This will allow for recommendations to be made regarding streamlining patient referrals to this or similar programs, in order to optimise efficiency and sustainability of future program delivery.

### 5.1.3 Objectives

1. Impact evaluation
    a. To identify whether RESPOND increased participation in falls prevention strategies, and identify factors influencing participation (intervention group, compared with the usual care group).

**To determine the degree to which participant characteristics and RESPOND program factors were associated with participation in falls prevention strategies (for the intervention group only).**

2. Outcome evaluation
    a. To determine the degree to which participant characteristics, participation factors, and RESPOND program factors influenced falls, fall injuries and ED re-presentations (for the intervention group only).

## 5.2 METHODS

### 5.2.1 Study design and participants

This impact and outcome evaluation was embedded within the design of the RESPOND RCT.[1, 2, 212] Evaluation participants were the participants randomised to the RESPOND RCT (intervention and control groups, as specified in the objectives above).

### 5.2.2 Data collection

#### *5.2.2.1 Participant characteristics*

Participant characteristics included in this evaluation are detailed in Table 5.1. Age and sex of the trial participants were collected at the time of recruitment in the ED and recorded by the recruiting member of the research team. The remaining participant characteristics data were collected at the baseline home visit assessment by the allocated RESPOND clinician. The participants and clinicians were blinded to group allocation at the time of collecting these baseline data. Group allocation was revealed following this initial assessment, with the home visit extended for those revealed to be in the intervention group, in order to provide their first RESPOND program intervention session.

Falls risk (total FROP-Com score ranging from 0 (lowest risk) to 60 (highest risk), falls history (number of falls in the last 12 months), and comorbidities were recorded as part of the Falls Risk for Older People – Community setting (FROP-Com) assessment.[96, 97] The FROP-Com was administered by the RESPOND clinician at the baseline assessment home visit, prior to randomisation and group allocation. Comorbidities refers to the participant having been diagnosed by a doctor as having a chronic medical condition that could potentially affect their balance and mobility. Specifically, as per the FROP-Com, comorbidities documented were: arthritis, respiratory conditions, Parkinson's disease, diabetes, dementia, peripheral neuropathy, a cardiac condition, stroke, other neurological condition, lower limb amputation, osteoporosis, vestibular disorder, other dizziness, back pain, or lower limb joint replacement.

Health literacy was measured using the Health Literacy Questionnaire (HLQ).[204] As with the FROP-Com, the tool was administered during the initial home visit assessment. The HLQ comprises nine independent scales of four to six items per scale, with each scale representing a different element of the overall health literacy construct. The HLQ provides a score for each scale based on an average of the items within each scale.

Score range is between 1 and 4 for Scales 1 to 5, and between 1 and 5 for Scales 6 to 9. There is no overall composite score for the HLQ but higher scale scores indicate higher health literacy ability.

**Table 5.1: RESPOND impact and outcome evaluation data collection**

| Evaluation component | Component description | Data source | Timing of data collection | Participants |
|---|---|---|---|---|
| **PARTICIPANT CHARACTERISTICS** | | | | |
| Participant characteristics (objectives 1b and 2) | Age; sex | Hospital ED admission records | Recruitment | Intervention group |
| | Lives alone | Face-to-face participant assessment at participant's home | Home visit following recruitment to trial and prior to group allocation | Intervention group |
| | Falls risk; falls history; comorbidities [c] | FROP-Com completed at participant's home | Home visit following recruitment to trial and prior to group allocation | Intervention group |
| | Health literacy: 1) sufficient information to manage own health; 2) actively managing own health; 3) ability to navigate the healthcare system | Self-administered Health Literacy Questionnaire (HLQ) | Home visit following recruitment to trial and prior to group allocation | Intervention group |
| **PARTICIPATION FACTORS** | | | | |
| Participation in falls prevention strategies as per primary definition (objectives 1a, b and 3) | Participation in falls prevention strategies (count data), defined as attendance at the following appointments: | | | |
| | General practitioner (GP); geriatrician; falls clinic; physiotherapist; occupational therapist; optometrist; ophthalmologist | Participant-completed calendars[a] | Completed daily and reported monthly for 12 months | Intervention and control group |
| Participation: exploratory analysis (objective 1a) | Participation in falls prevention strategies, (count data) defined as attendance at the following appointments: | | | |
| | Podiatrist; pharmacist | Participant-completed calendars[a] | Completed daily and reported monthly for 12 months | Intervention and control group |
| | Minutes of exercise conducted[b] | Participant-completed calendars[a] | Completed daily and reported monthly for 12 months | Intervention and control group |
| | Completion of the following strategies over the 12-month trial period (binary: Y/N) | | | |

| Evaluation component | Component description | Data source | Timing of data collection | Participants |
|---|---|---|---|---|
| | Serum vitamin D test; vitamin D supplementation; increased exposure to sunlight; home environment assessment; DXA scan | Participant questionnaire | At 12 months | Intervention and control group |
| **RESPOND PROGRAM FACTORS** | | | | |
| Dose | 1) number of intervention contacts; 2) total minutes of intervention received over the six-month intervention period | Clinician intervention records | Following each intervention session | Intervention participants |
| Timeliness | Days from ED discharge to first intervention session | Clinician intervention records | Following each intervention session | Intervention participants |
| Modules | Total number of modules chosen per participant (0-4) over the six-month intervention period | Clinician intervention records | Following each intervention session | Intervention participants |
| **RESPOND OUTCOMES** | | | | |
| | Falls; fall injuries; ED re-presentations (count data) | Participant-completed calendars[a] | Completed daily and reported monthly for 12 months | Intervention participants |
| | | Hospital administrative records | Routinely collected hospital data, extracted following 12 month follow up period[d] | Intervention participants |

[a] Verified by monthly telephone calls from a research team member blind to participant group allocation
[b] Exercise was defined as: formal or structured exercise, including organised activities such as fitness classes, gym sessions, swimming, team sports, DVD/TV-based exercise programs and it also included exercises prescribed by a physiotherapist or other health professional. Exercise was not deemed to include activities of daily living such as gardening, walking activities, or housework.
[c] Comorbidities as per the FROP-Com. Includes medical diagnosis of: arthritis; any respiratory condition; Parkinson's Disease; diabetes; dementia; peripheral neuropathy; any cardiac condition; stroke; any other neurological condition; lower limb amputation; osteoporosis; vestibular disorder; or lower limb joint replacement.
[d] Hospital data from the two participating hospitals only. Data were not collected if the participant presented to a different hospital.
DXA = Dual-energy X-ray absorptiometry

Three of the nine HLQ scales most closely aligned with the RESPOND program components were chosen as indicators of health literacy for this evaluation: HLQ scale 2 corresponds with the health education component of RESPOND; HLQ scale 3 relates to RESPOND's intended person-centred style, incorporating participatory decision-making and proactively engaging participants in goal setting and managing health issues; and HLQ scale 7 aligns with RESPOND's intention to link participants with appropriate community health services. (Table 5.2).

**Table 5.2: HLQ scales used in this evaluation**

| HLQ scale | Scoring | Items in scale |
|---|---|---|
| HLQ scale 2: Having sufficient information to manage my health | Score range 1–4 on a four-point scale of strongly disagree to strongly agree | • I feel I have good information about health<br>• I have enough information to help me deal with my health problems<br>• I am sure I have all the information I need to manage my health effectively<br>• I have all the information I need to look after my health |
| HLQ scale 3: Actively managing my health | Score range 1–4 on a four-point scale of strongly disagree to strongly agree | • I spend quite a lot of time actively managing my health<br>• I make plans for what I need to do to be healthy<br>• Despite other things in my life, I make time to be healthy<br>• I set my own goals about health and fitness<br>• There are things that I do regularly to make myself more healthy |
| HLQ scale 7: Navigating the healthcare system | Score range 1–5 on a five-point scale:<br>cannot do;<br>usually difficult;<br>sometimes difficult;<br>usually easy;<br>always easy | • Find the right health care<br>• Get to see the healthcare providers you need to<br>• Decide which healthcare provider you need to see<br>• Make sure you find the right place to get the health care you need<br>• Find out which healthcare services you are entitled to<br>• Work out what the best care is for you |

#### *5.2.2.2 Participation in falls prevention activities*

The collection of participation data is summarised in Table 5.1. All RESPOND participants (intervention and control) were asked to complete a daily calendar each time they attended a healthcare appointment, for the 12-month trial period. This information was verified with monthly phone calls from a blinded assessor. Participation in falls prevention activities over the 12-month follow up period was defined as the rate per person-year of attendance at appointments with the following healthcare professionals:

- general practitioner (GP);
- geriatrician;
- falls clinic specialist;
- physiotherapist;
- occupational therapist;
- optometrist;
- ophthalmologist.

These specific healthcare appointment types were chosen *a priori* as they were considered to align closely with the key falls risk management strategies recommended by the RESPOND clinicians during the intervention contacts (Figure 5.1).

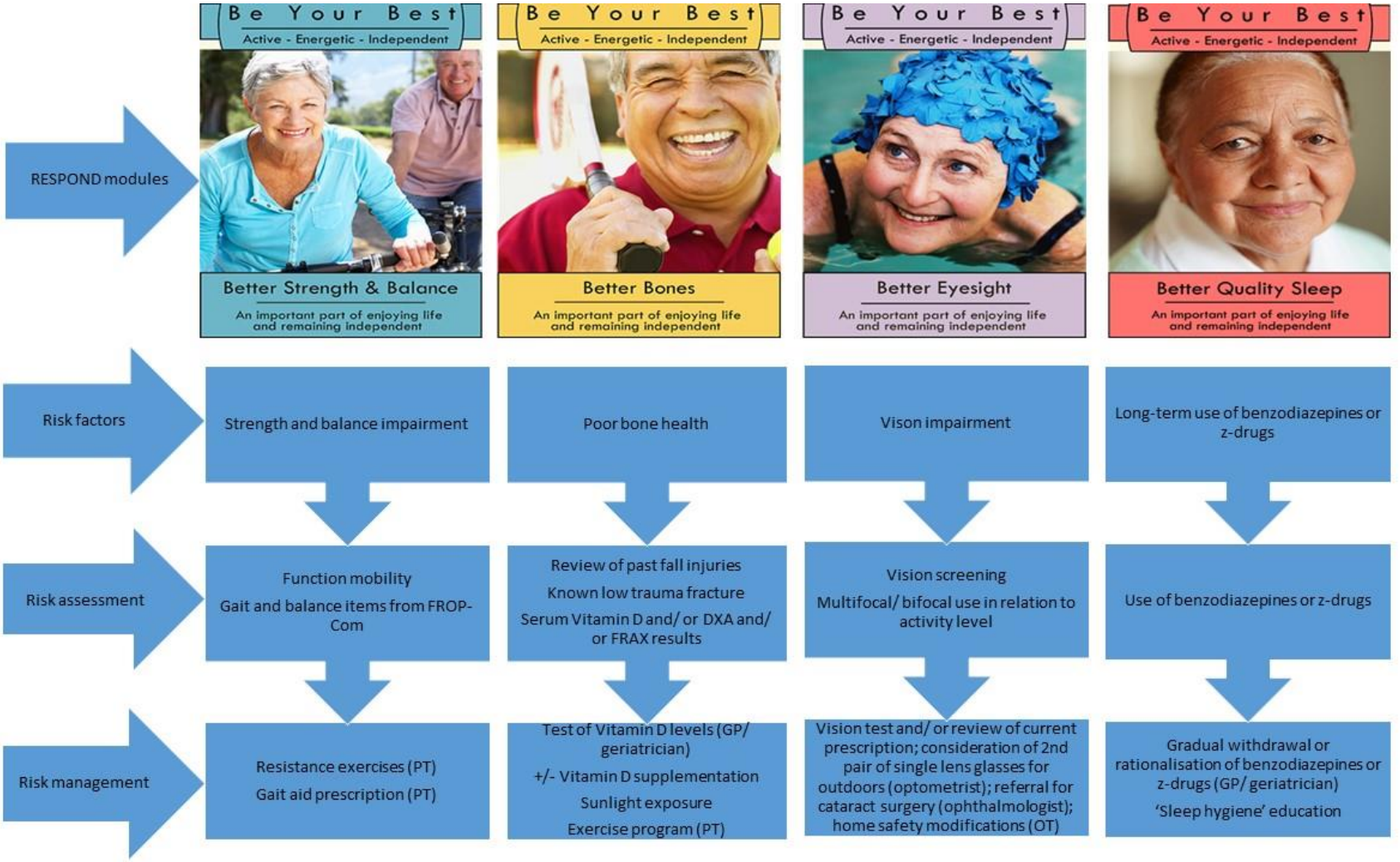


**Figure 5.1: RESPOND modules and risk management foci**

PT= physiotherapist; DXA= Dual-energy X-ray absorptiometry; FRAX= Fracture Risk Assessment Tool; GP = general practitioner; OT = occupational therapist
This figure is adapted from Figure 2 in the RESPOND RCT protocol.[2]

In addition to the specified healthcare appointments, further indicators of participation were collected to gain a deeper understanding of the extent of falls prevention management in standard care, and to make comparisons with the intervention group. These indicators included appointments with a pharmacist or podiatrist, and minutes of exercise, collected as part of the participant-completed calendars. Data related to having Dual-energy X-ray absorptiometry (DXA) bone density scans, vitamin D tests, vitamin D supplementation, increased exposure to sunlight, and home environment assessments, were collected using a purpose-designed questionnaire that the participants were asked to complete at 12 months. Collection of these data is summarised in Table 5.1.

#### *5.2.2.3 RESPOND program factors*

RESPOND program factors have been described in detail in the process evaluation chapter (Chapter 4).[213] This outcome and impact evaluation focused on the following specific program factors:

- Dose of the RESPOND program provided per participant, defined as:
  - i. Number of intervention contacts; and
  - ii. Total minutes of intervention provided.
- Timeliness of the program being commenced, defined as days from ED discharge to initial home visit.
- The total number of intervention modules chosen per participant (0-4) over the six-month intervention period.

These data were drawn from the RESPOND process evaluation (Chapter 4).[213]

#### *5.2.2.4 RESPOND outcomes*

Data related to RESPOND outcomes are detailed in Table 5.1. In line with WHO terminology, a fall was defined as "an event resulting in a person coming to rest inadvertently on the ground, floor or other lower level".[34] A fall injury was defined as any physical harm resulting from a fall (including fractures, dislocations, sprain, skin tears and bruising) that was reported by study participants.[215] Data on ED presentations to the two trial hospital EDs were for any cause and were not limited to falls-related presentations.

### 5.2.3 Statistical analysis

All impact and outcome evaluation analyses were undertaken on an intention-to-treat basis and analyses were undertaken using Stata v.14. All participants who completed a baseline assessment and provided at least one monthly calendar or telephone call were included in the impact and outcome evaluation. Consistent with contemporary efforts to minimise the use of p values indicating 'significant' or 'non-significant' findings,[216] where possible this evaluation reports variability around point estimates using 95% confidence intervals.

#### *5.2.3.1 Impact evaluation (Objective 1a)*

Participant demographic data were analysed using descriptive statistics. Participation rates per person-year were calculated for each appointment type, and as a sum of the seven appointment types comprising the

'participation' definition. A sensitivity analysis also examined the rate of participation excluding GP appointments, as reasons for seeing a GP were not available and it was considered that these visits could be for many other health conditions unrelated to falls. Rates per person-year were calculated for hours of exercise undertaken, which was a key recommended RESPOND strategy (Figure 5.1), as well as attendance at pharmacist and podiatry appointments, although these latter appointment types were not part of the targeted RESPOND module recommendations. All markers of participation were compared between groups using negative binomial regression models with results reported as incidence rate ratios (IRR) and 95% confidence intervals (CI). Between group differences in proportions were examined using chi square analyses.

#### *5.2.3.2 Impact evaluation (Objective 1b)*

Multivariate negative binomial regression models were used for the impact evaluation. Participation in falls prevention strategies (operationalised as the sum of the seven healthcare professional appointment types) was used as the dependent variable. Participant characteristics, including health literacy ability, and RESPOND program factors, were the independent variables.

The models adjusted for all independent variables as categorical variables. Participant characteristics categories were defined as follows - age group: 60-69 years (reference), 70-79 years, or 80-90 years; sex: male (reference) or female; lives alone: no (reference) or yes; comorbidities: no conditions (reference), one, two, or three or more conditions; falls history in the preceding 12 months: one (reference), two, or three or more falls. Falls risk was categorised as mild falls risk (FROP-Com score 0-11) (reference), moderate falls risk (12-18), or high falls risk (19-60) as per the tool guidelines.[97]

HLQ scale scores were split into tertiles of approximately equal numbers of participants with low (reference), moderate, or high health literacy for each of the three HLQ scales. The tertiles for each scale were defined by the following scale scores: *Having sufficient information to manage health* – low (≤2.75), moderate (2.76-3.24), and high (≥3.25); *Actively managing my health* – low (≤2.8), moderate (2.9-3.1), and high (≥3.2); and *Navigating the healthcare system* – low (≤3.8), moderate (3.9-4.2), and high (≥4.3). Similarly, program factors (number of intervention sessions, number of RESPOND modules chosen, and days from ED discharge to home visit) were categorised as low, moderate or high, based on their tertile distribution. The number of intervention sessions was categorised as low (≤6), moderate (7-8), and high (≥9); and minutes of intervention provided was categorised as low (≤164), moderate (165-177), and high (≥178); days from ED discharge to home visit – low (≤13), moderate (14-24), and high (≥25). The number of RESPOND modules chosen across the intervention period was categorised as 0, 1, 2, 3, or 4. The 'low' categories for health literacy and program factors were set as the reference categories. The only exception was for the number of modules chosen, where '1' was set as the reference category as only two participants did not choose a RESPOND module. Despite not choosing a module, these participants met the requirements for inclusion in the analysis (having completed a baseline assessment and provided at least one month of data). For each model, the exposure time was calculated for each participant (n=430) as the number of days from the date of recruitment to 365

days or to the last date of calendar data recorded if follow-up was incomplete. The exposure time was used in the calculation of rates per person-years.

#### *5.2.3.3 Outcome evaluation (Objective 2)*

For the outcome evaluation, multivariate negative binomial regression models were constructed for each of the three outcomes (falls, fall injuries, and ED re-presentations) in the same way as described above for objective 1b.

## 5.3 RESULTS

### 5.3.1 Participants

The participant flow through the study is summarised in Figure 5.2. A total of 541 participants were recruited to the study (289 in Victoria and 252 from Western Australia). Of those recruited, 430 (79.5%) provided at least one monthly calendar and were included in the analysis.

Participant characteristics are reported in Table 5.3. Reflecting effective randomisation, key participant characteristics were comparable between intervention and control groups, with a mean (SD) age of 73.0 (8.4) in the intervention group, and 73.0 (8.6) in the control, and a mean (SD) FROP-Com score of 16.4 (6.1) and 16.6 (5.6) respectively, indicating a moderate level of falls risk. A large proportion of all participants (intervention and control) lived alone (42%), and approximately one third of all participants were at high risk of falls (34%). Over 40% of participants had two or more falls in the preceding 12 months (including the index fall resulting in the ED presentation for this study), further highlighting the high and recurrent falls risk of this population.

Overall, HLQ scores for the sample were generally high. For the scale 'Feeling understood and supported', the mean (SD) score was 3.27 (0.29) out of a maximum possible score of four for the intervention group and 3.20 (0.27) for the control group. Similarly, participants' confidence in their 'ability to actively engage with healthcare providers' and 'understand health information well enough to know what to do' was high across both groups (intervention: 4.16 (0.30), control: 4.14 (0.32) out of five; and intervention: 4.15 (0.40), control 4.15 (0.37) out of five, respectively). 'Appraisal of health information' was scored lowest for both groups: 2.75 (0.43) in the intervention and 2.77 (0.43) in the control, out of four.

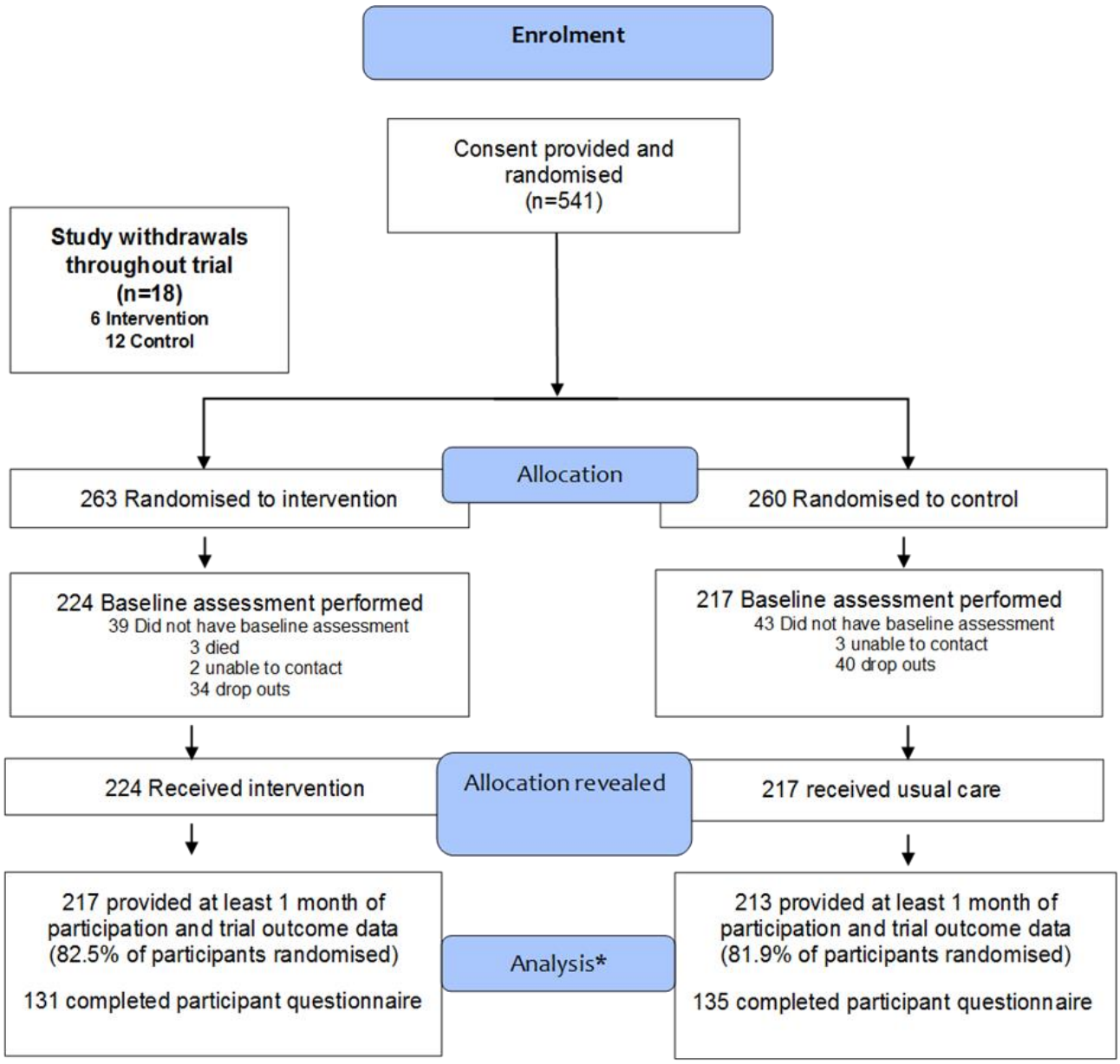


**Figure 5.2: Participant flow through the RESPOND RCT**

Adapted from Barker *et al* Figure 2: Participant flow through the RESPOND RCT[1]

* Participants included in the impact and outcome analysis

**Table 5.3: RESPOND participant characteristics**

| | | | Intervention | Control |
|---|---|---|---|---|
| **Recruitment** | | | *n=263* | *n=260* |
| Female, n (%) | | | 132 (50.2) | 156 (60.0) |
| Age group, n (%) | 60-69 | | 107 (40.7) | 111 (42.7) |
| | 70-79 | | 89 (33.8) | 83 (31.9) |
| | 80-90 | | 67 (25.5) | 66 (25.4) |
| **Baseline assessment** | | | *n=224* | *n=217* |
| Lives alone, n (%) | | | 93 (41.5) | 94 (43.3) |
| Number of falls in past 12 months*, n (%) | 1 fall | | 135 (60.2) | 124 (57.2) |
| | 2 falls | | 51 (22.8) | 43 (19.8) |
| | ≥ 3 falls | | 38 (17.0) | 50 (23.0) |
| Number of comorbidities, n (%) | None | | 53 (23.6) | 44 (20.3) |
| | 1 | | 55 (24.6) | 53 (24.4) |
| | 2 | | 53 (23.7) | 56 (25.8) |
| | ≥ 3 | | 63 (28.1) | 64 (29.5) |
| Falls risk | Mild | (FROP-Com score 0-11), n (%) | 54 (24.1) | 41 (18.9) |
| | Moderate | (FROP-Com score 12-18), n (%) | 90 (40.2) | 107 (49.3) |
| | High | (FROP-Com score 19-60), n (%) | 80 (35.7) | 69 (31.8) |
| **Health Literacy Questionnaire (HLQ)** | | | *n=218* | *n=216* |
| Health literacy, mean HLQ scale score (SD) | 1. Feeling understood and supported | (range 0-4) | 3.27 (0.29) | 3.20 (0.27) |
| | 2. Having sufficient information | (range 0-4) | 2.99 (0.53) | 3.01 (0.31) |
| | 3. Actively managing my health | (range 0-4) | 2.93 (0.33) | 2.99 (0.32) |
| | 4. Social support for health | (range 0-4) | 3.13 (0.40) | 3.07 (0.41) |
| | 5. Appraisal of health information | (range 0-4) | 2.75 (0.43) | 2.77 (0.43) |
| | 6. Ability to actively engage | (range 0-5) | 4.16 (0.30) | 4.14 (0.32) |
| | 7. Navigating the healthcare system | (range 0-5) | 4.03 (0.41) | 3.99 (0.38) |
| | 8. Ability to find health information | (range 0-5) | 3.91 (0.45) | 3.91 (0.42) |
| | 9. Understanding health information | (range 0-5) | 4.15 (0.40) | 4.15 (0.37) |

* This includes the fall resulting in ED presentation for inclusion in this study

### 5.3.2 Impact evaluation: participation in falls prevention strategies

Table 5.4 reports participation data, including the rate of attendance at key healthcare appointments, for the intervention and control groups. There was greater participation among the intervention group, compared with the control, for optometry appointments (incidence rate ratio (IRR): 1.72, 95% confidence interval (CI): 1.20-2.47). For most other appointment types (falls clinic, physiotherapy, occupational therapy, and ophthalmology), there was a consistent trend towards increased participation in the intervention group, compared with the control. A trend towards more exercise for the intervention group was also evident (average of 65.4 hours per person-year versus 53.9 hours for the control group) (Table 5.4). Similar rates of general practitioner (GP) visits were found between the two groups with 8.6 visits per person-year for those in the intervention, compared with 9.9 in the control (IRR: 0.86; 95% CI: 0.73-1.01). For the composite

outcome of participation, there was a trend towards greater total participation for the intervention group, which remained after excluding GP appointments from the analysis.

**Table 5.4: Participation in falls prevention strategies**

| | Rate per person year | | Rate ratio (95% CI) |
|---|---|---|---|
| **Appointment type** | **Intervention** | **Control** | |
| General practitioner | 8.60 | 9.90 | 0.86 (0.73-1.01) |
| Falls clinic | 0.40 | 0.30 | 1.53 (0.63-3.70) |
| Physiotherapist | 5.80 | 4.70 | 1.23 (0.84-1.80) |
| Occupational Therapist | 0.40 | 0.30 | 1.73 (0.65-4.57) |
| Geriatrician | 0.10 | 0.10 | 1.18 (0.26-5.34) |
| Optometrist | 0.50 | 0.30 | 1.72 (1.20-2.47) |
| Ophthalmologist | 0.50 | 0.40 | 1.33 (0.81-2.21) |
| Total participation* | 16.30 | 15.90 | 1.02 (0.86-1.20) |
| **Further exploratory analysis** | | | |
| Total participation** | 7.70 | 6.10 | 1.29 (0.94-1.76) |
| Hours of exercise | 65.40 | 53.90 | 1.16 (0.91-1.48) |
| Pharmacist | 0.24 | 0.31 | 0.71 (0.40-1.24) |
| Podiatry | 0.09 | 0.11 | 0.78 (0.41-1.48) |

* Sum of 7 appointment types above
** Sum of 6 appointment types, excluding GP
A rate ratio of <1 indicates that rate of attendance at the appointment type was lower in the intervention group compared with the control group; rate ratio of >1 indicates that rate of attendance at the appointment type was higher in the intervention group compared with the control group; rate ratio=1 indicates no difference in rates between groups

Table 5.5 reports participant completion of specific falls prevention activities related to the RESPOND modules for each group, as reported by participants in their 12-month follow-up questionnaire. A total of 266 participants (62% of those included in these analyses) completed the questionnaire (n=131 from the intervention group and n=135 from the control group). The RESPOND process evaluation identified that Better Strength and Balance was the most frequently selected module, chosen by 91% of participants who received the intervention, followed by Better Bones (66%). Better Sleep and Better Vision were the least frequently chosen (by 36% and 32% of participants, respectively).[213] Participants chose a median (IQR) of 2 (2-3) modules over the intervention period.[213] Five intervention participants did not choose any modules throughout their intervention period.[213] Two of these five met the requirements for inclusion in the analyses for this impact and outcome evaluation.

Use of vitamin D testing and facilitating optimal exposure to sunlight were key strategies for the Better Bones module. As shown in Table 5.5, these activities were undertaken more frequently in the intervention group, compared with usual care (15% and 10% more frequently, respectively). There was a trend towards increased use of vitamin D supplementation and dual-energy X-ray absorptiometry (DXA) scans (both recommended in the Better Bones module) and completion of home environment assessments (Better Eyesight) in the intervention group compared with the control group, although chi-square tests did not identify significant between-group differences.

**Table 5.5: Completion of falls prevention activities recommended in RESPOND modules**

| **Falls prevention strategies** | **Intervention** (n=131) **n (% of respondents)** | **Control** (n=135) **n (% of respondents)** | **p value** |
|---|---|---|---|
| DXA scan | 27 (20.6%) | 23 (17.0%) | 0.456 |
| Vitamin D test | 48 (36.6%) | 31 (22.0%) | 0.015 |
| Vitamin D supplement | 58 (44.3%) | 49 (36.3%) | 0.185 |
| Increased exposure to sunlight | 31 (23.7%) | 19 (14.1%) | 0.045 |
| Home environment assessment | 32 (24.4%) | 24 (17.8%) | 0.184 |

DXA= Dual-energy X-ray absorptiometry

### 5.3.3 Impact evaluation: factors associated with participation rates

Participation in falls prevention strategies was shown to increase substantially as falls risk status increased, with a 43% increase (on average) for those at moderate risk of falls, and a 92% increase for those at high risk, compared with those at low risk of falls (Table 5.6). The high falls risk group attended on average 10 more appointments per person-year than the low risk group. No other associations between participant characteristics and participation rates were identified.

Examining health literacy factors, there was a trend towards lower participation with increased health literacy ability for the HLQ subscale 'having sufficient information to manage health'. Participation decreased from an average of 19.1 appointments attended per person-year to 14.5 from low to high health literacy ability for this HLQ scale (Table 5.7).

### Table 5.6: Association between participant characteristics and participation rates

| | | | Multivariate model | |
|---|---|---|---|---|
| **Participant characteristic (n=217)** | **Participants (n)** | **Participation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Age group** | | | | |
| 60-69 years (reference) | 93 | 16.5 | | |
| 70-79 years | 72 | 15.9 | 0.97 | 0.75-1.26 |
| 80-90 years | 52 | 16.7 | 0.91 | 0.69-1.18 |
| **Sex** | | | | |
| Male (reference) | 108 | 14.5 | | |
| Female | 109 | 18.2 | 1.19 | 0.95-1.50 |
| **Lives alone** | | | | |
| No (reference) | 129 | 15.5 | | |
| Yes | 88 | 17.6 | 0.92 | 0.75-1.13 |
| **Falls risk** | | | | |
| Mild (reference) | 53 | 11.7 | | |
| Moderate | 86 | 15.4 | 1.43 | 1.09-1.87 |
| High | 78 | 21.5 | 1.92 | 1.38-2.68 |
| **Falls history (preceding 12 months)** | | | | |
| 1 fall (reference) | 134 | 15.9 | | |
| 2 falls | 48 | 15.0 | 0.91 | 0.72-1.16 |
| ≥ 3 falls | 35 | 20.3 | 0.96 | 0.69-1.33 |
| **Comorbidities** | | | | |
| No conditions (reference) | 51 | 12.4 | | |
| 1 condition | 55 | 16.1 | 1.16 | 0.83-1.61 |
| 2 conditions | 52 | 20.3 | 0.91 | 0.67-1.24 |
| ≥3 conditions | 59 | 21.3 | 1.03 | 0.73-1.47 |

This multivariate model was adjusted for all included participant characteristics and program factors

### Table 5.7: Association between health literacy and participation rates

| | | | Multivariate model | |
|---|---|---|---|---|
| **Health literacy ability (n=213)** | **Participants (n)** | **Participation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Sufficient information to manage health** | | | | |
| Low HLQ score (≤2.75) (reference) | 73 | 19.1 | | |
| Moderate HLQ score (2.76-3.24) | 72 | 15.9 | 0.83 | 0.61-1.13 |
| High HLQ score (≥3.25) | 68 | 14.5 | 0.82 | 0.60-1.10 |
| **Actively managing health** | | | | |
| Low HLQ score (≤2.8) (reference) | 88 | 15.3 | | |
| Moderate HLQ score (2.9-3.1) | 72 | 17.7 | 1.19 | 0.90-1.57 |
| High HLQ score (≥3.2) | 53 | 17.0 | 1.07 | 0.84-1.36 |
| **Navigating the healthcare system** | | | | |
| Low HLQ score (≤3.8) (ref) | 71 | 19.9 | | |
| Moderate HLQ score (3.9-4.2) | 80 | 15.1 | 0.99 | 0.75-1.32 |
| High HLQ score (≥4.3) | 62 | 14.9 | 1.05 | 0.79-1.39 |

This multivariate model was adjusted for all included participant characteristics and program factors

Participation in falls prevention strategies was associated with the number of modules chosen, with the highest rate of participation (18.8 appointments per person-year) found for those who chose two modules (IRR: 1.42; 95% CI: 1.07-1.88), (Table 5.8). Participation increased with increased dose of RESPOND, operationalised as the total minutes of intervention delivered. Participants receiving a moderate dose of RESPOND attended more appointments (17 per person-year) and those receiving a high dose of RESPOND attended double the appointments (20 per person-year), compared with those receiving a low dose of intervention (10 per person-year). In other words, an increased dose of RESPOND was associated with a greater uptake of falls prevention strategies, after adjustment for other RESPOND program factors and participant characteristics.

**Table 5.8: Association between RESPOND program factors and participation rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **RESPOND program factors (n=217)** | **Participants (n)** | **Participation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Number of modules chosen (0-4)** | | | | |
| 0* | 2 | | | |
| 1 (reference) | 40 | 12.5 | | |
| 2 | 84 | 18.8 | 1.42 | 1.07-1.88 |
| 3 | 75 | 14.7 | 0.96 | 0.71-1.30 |
| 4 | 16 | 15.4 | 1.28 | 0.83-2.00 |
| **Number of intervention sessions** | | | | |
| Low (2-6) (reference) | 85 | 12.4 | | |
| Moderate (7-8) | 79 | 16.1 | 0.99 | 0.76-1.28 |
| High (9-20) | 53 | 21.6 | 1.33 | 0.94-1.90 |
| **Minutes of intervention provided** | | | | |
| Low (19-164) (reference) | 73 | 10.2 | | |
| Moderate (165-177) | 73 | 17.1 | 1.43 | 1.07-1.92 |
| High (178-226) | 71 | 20.4 | 1.47 | 1.00-2.17 |
| **Days from ED discharge to home visit** | | | | |
| Low (3-13) (reference) | 79 | 16.7 | | |
| Moderate (14-24) | 66 | 15.8 | 0.85 | 0.67-1.07 |
| High (25-120) | 72 | 16.5 | 0.96 | 0.75-1.23 |

This multivariate model was adjusted for all included participant characteristics and program factors
***** Analysis for those who did not choose a RESPOND module was not performed due to the small number in this group (n=2)

### 5.3.4 Outcome evaluation: factors associated with falls rates

The rate of falls per person-year was clearly associated with age (Table 5.9). Those aged 70-79, and 80-90 years experienced more falls than younger participants, with a falls rate of 1.47 per person-year for those in their 70's and 1.53 per person-year for those in their 80's, compared with 0.72 per person-year for those aged 60-69 years.

A modest difference in falls rates was found between those who live alone or with others. Participants who lived alone experienced fewer falls than those who lived with others, with 1.01 falls per person-year compared with 1.25 falls per person-year (IRR: 0.67, 95% CI: 0.48-0.95) (Table 5.9).

There was also an association between falls risk and falls rates. Those at moderate risk of falls (based on the baseline FROP-Com assessment) demonstrated an increased falls rate in the subsequent 12 months (IRR 1.88, 95% CI: 1.07-3.31), while a trend towards an increased falls rate for those at high risk of falls was also seen (IRR 1.94, 95%CI 0.96-3.90). Falls history was strongly associated with the rate of falls during the RESPOND RCT follow-up period. Participants who had experienced multiple falls over the previous 12 months (including the fall resulting in the ED presentation for inclusion in this study) were more likely to fall again during the subsequent 12 months, with a rate of 3.08 per person-year for those with three or more falls, compared with 0.56 for those who experienced only the index fall. This resulted in a more than four-fold increase in incidence rate ratio (IRR: 4.57, 95% CI: 2.78-7.52) after adjustment for other factors.

**Table 5.9: Association between participant characteristics and falls rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **Participant characteristic (n=217)** | **Participants (n)** | **Falls rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Age group** | | | | |
| 60-69 years (reference) | 93 | 0.72 | | |
| 70-79 years | 72 | 1.47 | 1.76 | 1.12-2.78 |
| 80-90 years | 52 | 1.53 | 1.76 | 1.08-2.88 |
| **Sex** | | | | |
| Male (reference) | 108 | 1.08 | | |
| Female | 109 | 1.22 | 0.94 | 0.62-1.43 |
| **Lives alone** | | | | |
| No (reference) | 129 | 1.25 | | |
| Yes | 88 | 1.01 | 0.67 | 0.48-0.95 |
| **Falls risk** | | | | |
| Mild (reference) | 53 | 0.45 | | |
| Moderate | 86 | 0.93 | 1.88 | 1.07-3.31 |
| High | 78 | 2.03 | 1.94 | 0.96-3.90 |
| **Falls history (preceding 12 months)** | | | | |
| 1 falls (reference) | 134 | 0.56 | | |
| 2 falls | 48 | 1.58 | 2.84 | 1.82-4.42 |
| ≥ 3 falls | 35 | 3.08 | 4.57 | 2.78-7.52 |
| **Comorbidities** | | | | |
| No conditions (reference) | 51 | 0.55 | | |
| 1 condition | 55 | 1.27 | 1.11 | 0.65-1.91 |
| 2 conditions | 52 | 1.16 | 0.93 | 0.47-1.83 |
| ≥3 conditions | 59 | 1.63 | 0.67 | 0.36-1.28 |

This multivariate model was adjusted for all included participant characteristics and program factors

The relationship between health literacy and falls rate was examined (Table 5.10). Trends towards reduced falls rates for participants with higher health literacy scores for the 'Sufficient information to manage their health' and 'Navigating the healthcare system' scales were seen; however, there was considerable variability around the IRR point estimates.

**Table 5.10: Association between health literacy and falls rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **Health literacy ability (n=213)** | **Participants (n)** | **Falls rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Sufficient information to manage health** | | | | |
| Low HLQ score (≤2.75) (reference) | 73 | 1.88 | | |
| Moderate HLQ score (2.76-3.24) | 72 | 0.80 | 0.70 | 0.40-1.21 |
| High HLQ score (≥3.25) | 68 | 0.76 | 0.77 | 0.45-1.31 |
| **Actively managing health** | | | | |
| Low HLQ score (≤2.8) (reference) | 88 | 0.59 | | |
| Moderate HLQ score (2.9-3.1) | 72 | 0.90 | 0.73 | 0.46-1.16 |
| High HLQ score (≥3.2) | 53 | 0.87 | 0.65 | 0.42-1.00 |
| **Navigating the healthcare system** | | | | |
| Low HLQ score (≤3.8) (reference) | 71 | 1.62 | | |
| Moderate HLQ score (3.9-4.2) | 80 | 1.22 | 0.97 | 0.62-1.51 |
| High HLQ score (≥4.3) | 62 | 0.64 | 0.66 | 0.39-1.13 |

This multivariate model was adjusted for all included participant characteristics and program factors

There was a trend towards an increased rate of falls for patients with increasing dose of RESPOND (minutes of intervention delivered), although the confidence intervals indicate considerable variability around the point estimates (Table 5.11).

### 5.3.5 Outcome evaluation: factors associated with fall injury rates

Similar to the falls rate findings, age appeared to be associated with fall injuries (Table 5.12). The 70-79 year old age group had a higher rate of fall injuries, with 1.32 falls per person-year, compared with 0.77 per person-year for those aged 60-69 years (IRR: 2.41; 95% CI: 1.27-4.57). This pattern was not observed for those aged 80-90, however, with the injury rate the same as for those in their 70's and the 95%CI indicating no association (IRR: 1.81, 95% CI: 0.86-3.80).

As noted with participation and falls rates, there was a trend towards more falls injuries with higher falls risk, with falls rates rising from 0.41 to 1.85 injuries per person-year from the mild to high risk groups. As seen for falls rates, falls history was strongly associated with fall injuries in the multivariate model. Those who experienced two or more falls in the previous 12 months had a higher rate of fall injuries, with 1.46 fall injuries per person-year for those with two previous falls and 2.69 fall injuries per person-year for those with three or more falls, compared with 0.58 fall injuries per person-year for those who experienced only the index fall.

### Table 5.11: Association between RESPOND program factors and falls rates

| | | | Multivariate model | |
|---|---|---|---|---|
| **RESPOND program factors (n=217)** | **Participants (n)** | **Falls rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Number of modules chosen (0-4)** | | | | |
| 0* | 2 | | | |
| 1 (reference) | 40 | 0.95 | | |
| 2 | 84 | 1.30 | 1.08 | 0.62-1.89 |
| 3 | 75 | 1.02 | 0.84 | 0.45-1.57 |
| 4 | 16 | 1.43 | 1.30 | 0.54-3.14 |
| **Number of intervention sessions** | | | | |
| Low (≤6) (reference) | 85 | 0.83 | | |
| Moderate (7-8) | 79 | 1.11 | 0.77 | 0.45-1.32 |
| High (≥9) | 53 | 1.59 | 1.16 | 0.59-2.29 |
| **Minutes of intervention provided** | | | | |
| Low (≤164) (reference) | 73 | 0.57 | | |
| Moderate (165-177) | 73 | 1.22 | 1.35 | 0.76-2.37 |
| High (≥178) | 71 | 1.53 | 1.72 | 0.83-3.56 |
| **Time from ED discharge to home visit (days)** | | | | |
| Low (≤13) (reference) | 79 | 1.09 | | |
| Moderate (14-24) | 66 | 1.23 | 0.89 | 0.57-1.39 |
| High (≥25) | 72 | 1.15 | 0.86 | 0.55-1.34 |
| **Participation in falls prevention activities (number of appointments attended)** | | | | |
| Low (≤6) | 75 | 0.64 | | |
| Moderate (7-16) | 74 | 1.01 | 1.07 | 0.63-1.82 |
| High (≥17) | 68 | 1.72 | 1.58 | 0.93-2.68 |

This multivariate model was adjusted for all included participant characteristics and program factors
***** Analysis for those who did not choose a RESPOND module was not performed due to the small number in this group (n=2)

This resulted in a more than five-fold increase in falls injuries for those with three or more falls, after adjustment for other factors (Table 5.12).

There was a trend towards fewer falls injuries with increasing health literacy ability for 'Navigating the health system' (Table 5.13), although no other clear patterns were evident for the other HLQ scales.

### Table 5.12: Association between participant characteristics and fall injury rates

| | | | Multivariable model | |
|---|---|---|---|---|
| **Participant characteristic (n=217)** | **Participants (n)** | **Fall injury rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Age group** | | | | |
| 60-69 years (reference) | 93 | 0.77 | | |
| 70-79 years | 72 | 1.32 | 2.41 | 1.27-4.57 |
| 80-90 years | 52 | 1.32 | 1.81 | 0.86-3.80 |
| **Sex** | | | | |
| Male (reference) | 108 | 0.90 | | |
| Female | 109 | 1.25 | 1.76 | 0.97-3.19 |
| **Lives alone** | | | | |
| No (ref) | 129 | 1.27 | | |
| Yes | 88 | 0.80 | 0.54 | 0.29-1.01 |
| **Falls risk** | | | | |
| Mild (reference) | 53 | 0.41 | | |
| Moderate | 86 | 0.92 | 2.39 | 0.99-5.78 |
| High | 78 | 1.85 | 2.12 | 0.79-5.64 |
| **Falls history (preceding 12 months)** | | | | |
| 1 fall (reference) | 134 | 0.58 | | |
| 2 falls | 48 | 1.46 | 2.84 | 1.44-5.58 |
| ≥ 3 falls | 35 | 2.69 | 5.94 | 2.95-11.96 |
| **Comorbidities** | | | | |
| No conditions (reference) | 51 | 0.59 | | |
| 1 condition | 55 | 1.47 | 0.82 | 0.35-1.90 |
| 2 conditions | 52 | 0.76 | 0.28 | 0.11-0.74 |
| 3 conditions | 59 | 1.46 | 0.47 | 0.19-1.15 |

This multivariate model was adjusted for all included participant characteristics and program factors

### Table 5.13: Association between health literacy and fall injury rates

| | | | Multivariate model | |
|---|---|---|---|---|
| **Health literacy ability (n=213)** | **Participants (n)** | **Fall injury rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Sufficient information to manage health** | | | | |
| Low HLQ score (≤2.75) (reference) | 73 | 1.71 | | |
| Moderate HLQ score (2.76-3.24) | 72 | 0.57 | 0.59 | 0.26-1.30 |
| High HLQ score (≥3.25) | 68 | 0.94 | 0.85 | 0.37-1.94 |
| **Actively managing health** | | | | |
| Low HLQ score (≤2.8) (reference) | 88 | 1.53 | | |
| Moderate HLQ score (2.9-3.1) | 72 | 0.57 | 0.56 | 0.28-1.10 |
| High HLQ score (≥3.2) | 53 | 1.11 | 0.78 | 0.38-1.59 |
| **Navigating the healthcare system** | | | | |
| Low HLQ score (≤3.8) (reference) | 71 | 1.52 | | |
| Moderate HLQ score (3.9-4.2) | 80 | 1.06 | 0.86 | 0.42-1.78 |
| High HLQ score (≥4.3) | 62 | 0.71 | 0.63 | 0.28-1.41 |

This multivariate model was adjusted for all included participant characteristics and program factors

Table 5.14 shows a trend towards increased rates of falls injuries with increasing number of RESPOND intervention sessions (from 0.64 to 1.65 fall injuries per person-year from low to high number of sessions), increased minutes of RESPOND intervention provided (from 0.54 to 1.50 injuries per person-year from low to high minutes of intervention provided) and increased participation (from 0.60 to 1.63 injuries per person-year from low to high participation in falls prevention strategies).

**Table 5.14: Association between RESPOND program factors and fall injury rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **RESPOND program factors (n=217)** | **Participants (n)** | **Fall injury rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Number of modules chosen (0-4)** | | | | |
| 0* | 2 | | | |
| 1 (reference) | 40 | 0.54 | | |
| 2 | 84 | 1.29 | 1.24 | 0.41-3.72 |
| 3 | 75 | 1.02 | 0.71 | 0.21-2.42 |
| 4 | 16 | 1.30 | 1.37 | 0.30-6.38 |
| **Number of intervention sessions** | | | | |
| Low (≤6) (reference) | 85 | 0.64 | | |
| Moderate (7-8) | 79 | 1.05 | 0.83 | 0.38-1.83 |
| High (≥9) | 53 | 1.65 | 1.71 | 0.68-4.31 |
| **Minutes of intervention provided** | | | | |
| Low (≤164) (reference) | 73 | 0.54 | | |
| Moderate (165-177) | 73 | 1.08 | 1.06 | 0.46-2.45 |
| High (≥178) | 71 | 1.50 | 1.44 | 0.52-4.00 |
| **Time from ED discharge to home visit (days)** | | | | |
| Low (≤13) (reference) | 79 | 1.05 | | |
| Moderate (14-24) | 66 | 1.28 | 0.81 | 0.42-1.56 |
| High (≥25) | 72 | 0.92 | 0.90 | 0.41-1.97 |
| **Participation in falls prevention activities (number of appointments attended)** | | | | |
| Low (≤6) | 75 | 0.60 | | |
| Moderate (7-16) | 74 | 0.92 | 1.18 | 0.56-2.48 |
| High (≥17) | 68 | 1.63 | 1.52 | 0.72-3.23 |

This multivariate model was adjusted for all included participant characteristics and program factors
***** Analysis for those who did not choose a RESPOND module was not performed due to the small number in this group (n=2)

### 5.3.6 Outcome evaluation: factors associated with ED re-presentation rates

Table 5.15 shows the factors associated with re-presentation to one of the two participating hospital EDs. Similar to analyses of other outcomes in this evaluation, increased falls risk was also associated with increased rate of ED re-presentation, with a rate of 1.24 re-presentations for those at high risk of falls compared with 0.19 for those at low risk (IRR: 4.12; 95% CI: 1.73-9.77). However, the wide confidence interval indicates low precision for this association.

As with falls rates and fall injury rates, a history of more falls in the preceding 12 months was also associated with an increase in rate of ED re-presentation. Those who experienced three or more falls in the year prior to being recruited into the RESPOND trial presented to ED at a rate of 1.15 times per person-year compared with 0.52 times per person-year for those with only one fall at baseline assessment (IRR: 2.06; 95% CI: 1.02-4.19).

**Table 5.15: Association between participant characteristics and ED re-presentation rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **Participant characteristic (n=217)** | **Participants (n)** | **ED re-presentation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Age group** | | | | |
| 60-69 years (reference) | 93 | 0.59 | | |
| 70-79 years | 72 | 0.79 | 1.30 | 0.71-2.37 |
| 80-90 years | 52 | 0.95 | 1.29 | 0.62-2.66 |
| **Sex** | | | | |
| Male (reference) | 108 | 0.75 | | |
| Female | 109 | 0.72 | 0.75 | 0.46-1.24 |
| **Lives alone** | | | 0.80 | 0.48-1.36 |
| No (reference) | 129 | 0.77 | | |
| Yes | 88 | 0.69 | | |
| **Falls risk** | | | | |
| Mild (reference) | 53 | 0.19 | | |
| Moderate | 86 | 0.71 | 3.42 | 1.63-7.18 |
| High | 78 | 1.24 | 4.12 | 1.73-9.77 |
| **Falls history (preceding 12 months)** | | | | |
| 1 fall (reference) | 134 | 0.52 | | |
| 2 falls | 48 | 1.10 | 1.91 | 1.06-3.42 |
| ≥ 3 falls | 35 | 1.15 | 2.06 | 1.02-4.19 |
| **Comorbidities** | | | | |
| No conditions (reference) | 51 | 0.33 | | |
| 1 condition | 55 | 0.72 | 1.29 | 0.61-2.74 |
| 2 conditions | 52 | 0.71 | 0.95 | 0.42-2.15 |
| 3 conditions | 59 | 1.20 | 1.03 | 0.44-2.44 |

This multivariate model was adjusted for all included participant characteristics and program factors

As seen for falls rates and falls injury rates, a trend towards a lower rate of ED re-presentation was found for those with a moderate or high level of ability to navigate the healthcare system (Table 5.16)

### Table 5.16: Association between health literacy and ED re-presentation rates

| | | | Multivariate model | |
|---|---|---|---|---|
| **Health literacy ability (n=213)** | **Participants (n)** | **ED re-presentation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Sufficient information to manage health** | | | | |
| Low HLQ score (≤2.75) (ref) | 73 | 0.79 | | |
| Moderate HLQ score (2.76-3.24) | 72 | 0.80 | 1.46 | 0.70-3.07 |
| High HLQ score (≥3.25) | 68 | 0.62 | 1.02 | 0.47-2.22 |
| **Actively managing health** | | | | |
| Low HLQ score (≤2.8) (ref) | 88 | 0.72 | | |
| Moderate HLQ score (2.9-3.1) | 72 | 0.84 | 1.21 | 0.66-2.23 |
| High HLQ score (≥3.2) | 53 | 0.67 | 1.03 | 0.56-1.92 |
| **Navigating the healthcare system** | | | | |
| Low HLQ score (≤3.8) (ref) | 71 | 0.90 | | |
| Moderate HLQ score (3.9-4.2) | 80 | 0.72 | 0.75 | 0.37-1.51 |
| High HLQ score (≥4.3) | 62 | 0.61 | 0.75 | 0.36-1.58 |

This multivariate model was adjusted for all included participant characteristics and program factors

Examining RESPOND program factors, there was a trend towards an increased rate of ED re-presentation with a greater number of RESPOND modules chosen (Table 5.17). A trend towards increased ED re-presentation rates with increased time from index ED discharge to RESPOND home visit was also observed. The ED re-presentation rate was 0.98 for those who experienced a delay of 25 days or more in receiving the home visit, compared to 0.51 per person-year for those who had their home visit within two weeks after discharge. Finally, a trend towards a higher rate of ED re-presentations was seen for participants who had a higher rate of participation in falls prevention strategies (0.99 ED re-presentations per person-year), compared with those who had low participation (0.44 ED re-presentations per person-year).

**Table 5.17: Association between RESPOND program factors and ED re-presentation rates**

| | | | Multivariate model | |
|---|---|---|---|---|
| **RESPOND program factors (n=217)** | **Participants (n)** | **ED re-presentation rate (per person-year)** | **Rate ratio** | **95% CI** |
| **Number of modules chosen (0-4)** | | | | |
| 0* | 2 | | | |
| 1 (reference) | 40 | 0.60 | | |
| 2 | 84 | 0.66 | 1.08 | 0.51-2.30 |
| 3 | 75 | 0.80 | 1.30 | 0.61-2.78 |
| 4 | 16 | 1.11 | 1.74 | 0.64-4.73 |
| **Number of intervention sessions** | | | | |
| Low (≤6) | 85 | 0.76 | | |
| Moderate (7-8) | 79 | 0.67 | 1.00 | 0.47-2.11 |
| High (≥9) | 53 | 0.81 | 1.22 | 0.47-3.16 |
| **Minutes of intervention provided** | | | | |
| Low (≤19) | 73 | 0.74 | | |
| Moderate (165-177) | 73 | 0.65 | 0.61 | 0.30-1.25 |
| High (≥178) | 71 | 0.82 | 0.74 | 0.30-1.86 |
| **Time from ED discharge to home visit (days)** | | | | |
| Low (≤13) | 79 | 0.51 | | |
| Moderate (14-24) | 66 | 0.75 | 1.24 | 0.70-2.22 |
| High (≥25) | 72 | 0.98 | 1.59 | 0.86-2.91 |
| **Participation in falls prevention activities (number of appointments attended)** | | | | |
| Low (≤6) | 75 | 0.44 | | |
| Moderate (7-16) | 74 | 0.72 | 1.50 | 0.76-2.96 |
| High (≥17) | 68 | 0.99 | 1.76 | 0.85-3.62 |

This multivariate model was adjusted for all included participant characteristics and program factors

## 5.4 DISCUSSION

A high level of participation in recommended falls prevention strategies is considered to be a critical success factor for positive outcomes from falls prevention interventions.[2, 11] However, clinical trials demonstrate that at 12 months only half of community-dwelling older people are still adhering to falls prevention interventions.[119] Furthermore, it is unclear which factors influence the outcomes of falls prevention programs for older people who present at ED after a fall. This is the first detailed impact and outcome evaluation of a successful falls prevention program for older fallers presenting to the ED. The impact evaluation focused on participation in falls prevention strategies, while the outcome evaluation focused on factors associated with falls rates, falls injury rates and ED re-presentation rates.

Despite small absolute differences for individual elements, the mostly consistent pattern of increased participation in falls prevention strategies in the intervention group, compared with the control, is likely to be clinically important. The most significant finding from the outcome evaluation was that a history of multiple falls was associated with an increase in falls, fall injuries, and ED re-presentations during the 12-month follow-up period, after adjusting for other participant characteristics and RESPOND program factors.

A trend was also seen with moderate and high falls risk (compared to low falls risk), and an increase in rates for each of the evaluated trial outcomes. This information builds on the findings of the RESPOND process evaluation[213] (Chapter 4) and provides useful information to guide future implementation of falls prevention programs.

### 5.4.1 Impact evaluation: participation in falls prevention strategies

The modest increase in participation in falls prevention strategies, operationalised as attendance at all healthcare appointments, was observed for most appointment types except GP visits. Given the broad range of reasons for which older people may consult a GP, this finding was not unexpected. A similar result was found in the landmark 'PROFET' study by Close *et al*.[75] They conducted a multi-disciplinary RCT of a falls prevention program, including referral to community services where appropriate, and found a significant decrease in the risk of further falls compared with usual care. They did, however, report 668 GP visits among the control group, and 487 with the intervention group (p=0.33). This may be because visits to the GP are not specific to falls prevention.

It is noteworthy that 92% of the intervention sessions were delivered by RESPOND clinicians who were either registered physiotherapists (PTs) or occupational therapists (OTs) (RESPOND process evaluation,[213] Chapter 4). The intervention group may have received PT or OT services from their allocated RESPOND clinician, such as discipline-specific advice and education, thus reducing the need for ongoing community referral for these health disciplines. These results may, therefore, represent a conservative estimate of the difference in participation between groups.

RESPOND comprised of only four modules, targeting selected falls risk factors and evidence-based management strategies (Figure 5.1). Greater uptake of strategies recommended as part of the Better Bones module was demonstrated in the intervention group, compared with the control group. Specifically, there was a significant increase in exposure to sunlight, and increased use of Vitamin D testing, and a non-significant increase in use of DXA scans and Vitamin D supplementation. These findings may in part explain why the RESPOND RCT primary analysis demonstrated significantly fewer falls and fractures than the control group.[1] A recent systematic review and meta-analysis of vitamin D supplementation,[104] concluded that there is little justification to use vitamin D supplements to maintain or improve musculoskeletal health. This review has been criticised for excluding significant high quality studies which have shown vitamin D supplementation to be of benefit to subgroups of older people, including those with vitamin D deficiency and those living in residential care.[105, 217] The results from this evaluation strengthen the case for appropriate use of Vitamin D testing and supplementation if levels are found to be low.

Building on the trend towards an increase in participation in falls prevention activities, this evaluation identified a trend towards a higher rate of exercise for the intervention group compared with the control. Exercise was a key recommended strategy in both the Better Strength and Balance and the Better Bones

RESPOND modules. A recent systematic review with meta-analysis provided strong evidence that exercise prevents falls among community-dwelling in older people.[99, 100]

The challenges of ensuring adequate participation in falls prevention programs that refer participants into existing community-based services have been highlighted previously by Russell *et al*.[6] They conducted an Australian-based RCT, with a referral-based multifactorial intervention for older people discharged directly home from ED after presenting with a fall, and found no effect on falls or injuries for the intervention group.[6] They concluded that compared to direct-service models, there is no control over the nature, intensity, or scope of service provided with referral to community services. This point is reinforced by a Dutch RCT of an ineffective falls prevention program for those who presented at ED with a fall.[112] The researchers found that one quarter of intervention participants did not receive the intended falls prevention-related referrals and recommendations from their GP and therefore did not receive the intended interventions.

The present evaluation was likely underpowered to detect statistically significant differences in participation between subgroups, as *a priori* sample size calculations were tailored to the primary RCT outcomes of falls injuries. However, a mostly consistent pattern towards increased participation across a wide range of evidence-based falls prevention strategies still provides clinically useful information and helps us to better understand factors that may have contributed to the positive RCT outcomes. This evaluation supports the assumption that participation in falls prevention strategies is a critical success factor for reducing the rate of falls and fractures in RESPOND. It is possible that the participation rates were not sufficient to elicit a significant reduction in fall injuries or hospitalisations. However, further research would be required to determine whether a change in participation rate is associated with a change in clinical outcomes. There remains scope for interventions that can build on the RESPOND approach and further increase participation in key fall prevention recommendations for this high falls risk population.

### 5.4.2 Outcome evaluation: sub-group analyses

#### *5.4.2.1 Participant characteristics*

Increase in age was, perhaps unsurprisingly, associated with an increase in rate of falls. A history of falls in the preceding 12 months was strongly associated with all three RESPOND RCT outcomes, and a consistent trend was seen between increased falls risk and increased adverse outcomes. Falls history remained an independent predictor of falls, fall injuries and ED presentations, even after accounting for all other participant characteristics and program factors.

Those who had experienced only one fall in the preceding year (the index fall leading to their recruitment in RESPOND), had the lowest rate of falls, injuries, and ED presentations during the 12-month follow up period. This fits with previous literature, with a systematic review and meta-analysis reporting a history of falls to be a strong predictor of future falls for community-dwelling older people (OR = 2.8 for all fallers; OR = 3.5 for recurrent fallers).[80] In a comparable cohort to RESPOND, Close *et al* analysed the control group of the

successful British PROFET trial, to identify risk factors associated with future falls, and found a history of previous falls to be a strong predictor (OR: 1.5, 95% CI: 1.1-1.9).[218] This finding strengthens the case for the intervention being delivered following the index fall, rather than when people have already experienced multiple falls. This finding aligns closely with the rationale behind the RESPOND program tagline: *"RESPOND to the first fall to prevent the second"*.

A moderate to high falls risk, as determined at baseline, was associated with an increase in falls, fall injury, and ED re-presentations rates (compared with those at low risk of falls). This highlights the importance of programs such as RESPOND that focus on identifying individual falls risk factors in order to improve outcomes through targeted intervention. Increased falls risk was also associated with increased participation rates. This may reflect the strong encouragement from health professionals for those classified as moderate to high falls risk to engage in falls prevention strategies.

These findings highlight that for older people with recurrent ED fall presentations, clinicians need to recognise the high likelihood of future falls and related ED re-presentations, and initiate strategies to support optimal long-term falls prevention, even though the main focus of these will be in the community (not the ED). In this way the ED can be a point of triage for high falls risk identification and intervention initiation. Both falls history and falls risk can be identified using validated screening tools such as the FROP-Com screen, or detailed falls risk assessment tools such as the FROP-Com. Routine use of falls risk identification tools for appropriate patients in ED may facilitate this process. This would, however, likely require staff upskilling and new protocols to be developed.[219]

#### 5.4.2.1.1 Health literacy

The ability and confidence to navigate the healthcare system is a key component of health literacy. This outcome evaluation identified trends towards reduced falls rates, reduced falls injury rates, and reduced ED re-presentations for people who had greater baseline ability to navigate the healthcare system. Mindful of the variability around the point estimates, these findings suggest that assessing health literacy among this patient group prior to commencing RESPOND, particularly use of HLQ scale 7, may be of value when allocating program resources. Information related to participants' baseline health literacy ability may help distinguish between those who have sufficient health literacy ability to engage in components of RESPOND that require navigation of the health system, such as community linkage, and those who may require additional support and education from their RESPOND clinician.

Similarly, a US study found that for males, the number of falls and injuries decreased with higher health literacy ability.[191] However, health literacy was measured using a version of the Brief Health Literacy Screen which comprises of three questions related to understanding medical materials. The health literacy constructs measured are different to those included from the HLQ in this evaluation and therefore the results are not directly comparable.

Jaffee *et al* conducted an observational study of adult hospital patients that found low health literacy (using the Brief Health Literacy Screen) to be associated with greater hospital readmission rates for older people, but that health literacy was not significantly associated with falls risk.[220] The mixed results related to health literacy and falls-related outcomes may reflect the heterogeneity of the health literacy constructs measured in various health literacy measurement tools, as well as the multiple and complex interactions of falls risk factors. The HLQ was found to have good measurement properties for the RESPOND cohort.[221] One of the advantages of the HLQ over other health literacy measurement tools is the breadth of the health literacy construct it encompasses. The nine distinct components, each represented by an individual scale, can be applied individually or the tool can be administered in its entirety, depending on the clinical situation. Individual HLQ scales are short (four to six items each) and therefore quick to administer. Given the time pressures, and often demanding caseloads for ED staff, the flexibility of the HLQ makes it an appropriate tool to quickly determine health literacy ability of older community-dwelling adults who have experienced a fall and presented at the ED.

A large body of prior literature has consistently shown that low health literacy is a barrier to healthcare access, clinician-patient communication, adherence, and effective healthcare use for a range of chronic health conditions, such as cardio-vascular disease, diabetes, and asthma.[20, 158, 222, 223] Few studies have examined the concept of health literacy for older people who have experienced a fall. This evaluation contributes new evidence of the relationship between health literacy and falls prevention for older people.

#### *5.4.2.2 RESPOND program factors*

An association was found between the delivered dose of RESPOND and falls outcomes. Those at higher risk of fall injuries received more RESPOND sessions. It is likely that clinical judgment prompted the RESPOND clinicians to call these participants more frequently as they had identified a higher falls risk; additionally, falls injuries may have triggered more follow up calls by the clinicians. It is also possible that interventions that encourage participants to 'Be Your Best' through maximising functional capacity may increase the opportunity for falls and associated injuries through increased physical activity.[48, 110, 113] There is always a risk of increased exposure to falls when undertaking interventions that improve mobility and physical function. For example, if someone who is usually housebound is able to walk to the local shops following participation in a strength and exercise program, they may be exposed to a number of new environmental falls risks. This potential explanation, however, needs to be considered in the context that RESPOND reduced the rate of falls and fractures overall.

Those with greater total intervention contact time had higher rates of participation in falls prevention strategies. This may be because people who received a higher dose of RESPOND were more complex, from health and social perspectives, thus requiring longer, more frequent coaching sessions with their clinician. This would allow for increased opportunity for the clinicians to provide education and recommendations for community linkage, as well as discussion related to overcoming barriers to participation and reinforcing

facilitators, compared with those receiving a lower dose. One study investigating attitudes to falls and injury prevention for those who presented to a hospital ED after a fall, found that up to 72% of respondents were reluctant to undertake a falls prevention strategy.[214] The authors argued that participation in falls prevention activities requires the individual to move through the stages of behaviour change, which involves self-efficacy, decisional balance, and cognitive processes. Movement through these stages, through the use of motivational interviewing techniques, requires time. A meta-analysis of motivational interviewing studies found a significant relationship between an increased dose delivered and positive effects on a range of outcomes.[224] This may explain why a greater dose of intervention resulted in the intended behaviour change of greater participation in recommended strategies.

A further program factor that was associated with falls outcomes was the timeliness of commencing the RESPOND program. A trend towards a higher rate of ED re-presentations was observed for participants who experienced delays from the time of initial ED discharge to the initial home visit intervention session. This finding supports prior literature that a timely service is important for the success of falls prevention programs, particularly in this high falls risk population.[12] In another Australian RCT, there was a median of 28 days (IQR 18-43) between ED presentation and baseline home assessment.[6] Similar delays were found in a Dutch RCT.[112] Both of these studies were found to be ineffective for preventing falls compared with usual care. In contrast, the first RESPOND intervention session (home visit) was delivered a median (IQR) of 18 days (12 to 30) from ED discharge. This highlights the need for falls prevention services to be implemented as soon as feasible after ED presentation for this high falls risk group.

### 5.4.3 Strengths and limitations

This impact and outcome evaluation, in combination with the RESPOND process evaluation, provides a deeper understanding of the RESPOND RCT results and in particular, factors that may have contributed to the program's effectiveness. Key strengths of the evaluation include the collection of data from multiple sources, including hospital administration records, clinician records, participant calendars, and validated falls risk and health literacy tools. The evaluation occurred alongside a multi-centre RCT, and rigorous methods were used for the trial and program evaluation, including blinding of participants and clinicians during collection of baseline data, triangulation of data sources, and the use of an intention-to-treat analysis.

However, the methodological limitations should also be acknowledged. Firstly, the definition of "participation in falls prevention strategies" used in this study may not be sensitive and specific enough to the underlying construct it was intended to measure. However, similar definitions of participation have been used in previous studies,[6] and many falls prevention recommendations result from attendance at these key healthcare appointments. For example, seeing an ophthalmologist because of difficulty with vision for driving is likely to be relevant for the ability to safely negotiate an uneven environment when walking. In this regard, "participation" can be considered a useful overall indicator of whether behaviour change was achieved.

It is also important to acknowledge that only three key aspects of health literacy (of a total 9) were selected to be included in the analysis. These constructs were carefully chosen as they represented the HLQ scales most closely aligned with the RESPOND program components. It is possible that other aspects of health literacy may also influence outcomes, and these could be investigated in future studies.

It is also noted that ED re-presentations were for any cause and were not falls specific. The primary RCT analysis showed that four out of five re-hospitalisations were for reasons other than a fall.[1] A limitation of the parent trial inclusion criteria was the exclusion of those over the age of 90. The 85 and older age group is the fastest growing proportion of the Australian population, and is projected to constitute 4-5% of the population around 2050. Given that this evaluation found an increase in age was associated with an increase in rate of falls, it is important that those over 90 years of age be included in any future studies of RESPOND or similar falls prevention programs.

Recall and reporting bias may affect the accuracy of data collected in the participant calendars, and the process of keeping a calendar may result in a Hawthorne effect in the control group. This is possible in all falls prevention RCTs because control participants may reduce their falls risk as a result of being observed. It is also possible that falls are underreported as this can have consequences for maintaining independence.

### 5.4.4 Clinical implications

This is the first comprehensive impact and outcome evaluation of a multi-centre falls prevention program targeting older adults who present to ED with a fall. A trend towards increased participation in falls prevention strategies was found for the intervention group and this may in part explain the decrease in falls and fractures rates for RESPOND intervention participants compared with control participants. This suggests that clinicians should focus on overcoming barriers and emphasising facilitators to engagement with and uptake of recommended falls prevention strategies.

Furthermore, the intervention should be delivered as soon as practical after discharge home from the ED in order to optimise outcomes. RESPOND appears to be most effective for those who have only experienced one fall, and are of lower falls risk, prior to commencing the program. These groups should be targeted in future implementation of RESPOND. The FROP-Com is recommended to identify key falls risk factors such as falls risk status and falls history. Ability to navigate the health system effectively may also impact on falls outcomes and it is recommended that individual health literacy ability is measured using the HLQ prior to commencing a falls prevention initiative, in order to tailor the program accordingly. Use of the HLQ, particularly scale 7, may assist with differentiating between those who are better able to engage in key RESPOND components, and those who may require additional support and education from their RESPOND clinician.

## 5.5 Conclusion

In the context of a health system with limited resources, the information generated from this impact and outcome evaluation, in conjunction with the results from the RESPOND process evaluation, can be used to guide clinicians, researchers and policy makers to maximise the effectiveness and efficiency of future falls prevention programs. The study findings indicate that RESPOND should be initiated as soon as practical after the first fall, targeting participants at lower falls risk who have presented to ED with their first fall. Where possible, barriers to participation in falls prevention strategies should be identified and mitigated.

# 6 MEASUREMENT PROPERTIES OF THE HLQ

Chapter 6 is the published paper detailing the methods and results of study three addressing objective three. The study corresponds with the secondary aims of this thesis and describes the health literacy level of the RESPOND cohort, using the Health Literacy Questionnaire (HLQ). It also reports an analysis of the measurement properties of the HLQ, using Rasch methods.[221]

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# Measurement properties of the Health Literacy Questionnaire (HLQ) among older adults who present to the emergency department after a fall: a Rasch analysis

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## Abstract

**Background:** Health literacy is an important concept associated with participation in preventive health initiatives, such as falls prevention programs. A comprehensive health literacy measurement tool, appropriate for this population, is required. The aim of this study was to evaluate the measurement properties of the Health Literacy Questionnaire (HLQ) in a cohort of older adults who presented to a hospital emergency department (ED) after a fall.

**Methods:** Older adults who presented to an ED after a fall had their health literacy assessed using the HLQ ($n$ = 433). Data were collected as part of a multi-centre randomised controlled trial of a falls prevention program. Measurement properties of the HLQ were assessed using Rasch analysis.

**Results:** All nine scales of the HLQ were unidimensional, with good internal consistency reliability. No item bias was found for most items (43 of 44). A degree of overall misfit to the Rasch model was evident for six of the nine HLQ scales. The majority of misfit indicated content overlap between some items and does not compromise measurement. A measurement gap was identified for this cohort at mid to high HLQ score.

**Conclusions:** The HLQ demonstrated good measurement properties in a cohort of older adults who presented to an ED after a fall. The summation of the HLQ items within each scale, providing unbiased information on nine separate areas of health literacy, is supported. Clinicians, researchers and policy makers may have confidence using the HLQ scale scores to gain information about health literacy in older people presenting to the ED after a fall.

**Trial registration:** This study was registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12614000336684 (27 March 2014).

**Keywords:** Older adults, Falls prevention, Health literacy, Measurement properties, Rasch analysis

## Background

Falls represent the main cause of emergency department (ED) presentations for older adults [1]. However, participation in falls prevention activities following presentation to the ED with a fall is suboptimal [2]. Health literacy is an important concept associated with participation in preventive health initiatives [3]. Health literacy is defined as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" [4].

Adults with sub-optimal health literacy are less likely to participate in preventive health programs, such as falls prevention programs, possibly due to lack of understanding of health information and education provided [5]. Accurate measurement of health literacy prior to commencing a falls prevention program may guide clinicians to adapt provider-patient communication, such as provision of information related to falls risks and their management strategies, to match the patient's level of

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health literacy. This may lead to increased participation in falls prevention activities, potentially resulting in improved outcomes for these individuals.

A range of health literacy measurement tools are available. However, most tools do not reflect the multidimensional definition of health literacy, and predominantly focus on reading comprehension, pronunciation and numeracy [6, 7]. The Health Literacy Questionnaire (HLQ) was developed to address the shortcomings of previous tools [8]. The HLQ comprises nine independent scales related to the understanding of, engagement with, and use of health services, from both an individual and organisational perspective.

The measurement properties of the HLQ have been explored in depth using predominantly classical test theory (CTT) approaches [8–11] and qualitative approaches [8, 12]. The HLQ was originally validated using a sample from clinical, home and community care settings in Australia [8]. A highly restrictive 9-factor confirmatory factor analysis (CFA) model fitted satisfactory, with each of the HLQ scales representing nine conceptually distinct areas of health literacy. Subsequent studies evaluating the psychometric properties of the HLQ, including German, Danish, and Slovakian versions, support these findings, with the HLQ demonstrating good model fit and reliability, as well as homogeneity of items within each of the HLQ scales [9–11, 13]. Diverse cohorts were used in these studies representing people with a range of health conditions, receiving a variety of health services. A recent study evaluated the measurement properties of the initial version of the HLQ among people at risk of cardiovascular disease, using Rasch methods [14]. Similar to previous studies, each of the nine HLQ scales were found to measure nine separate constructs of health literacy with good internal consistency. Unclear distinction between some response categories in some HLQ scales was reported and the scales were deemed to be suboptimally targeted in relation to the particular cardiovascular cohort [14]. With the HLQ version used in this study, some disordered thresholds among items in scales 6 to 9 were observed. Kolarcik et al. observed this effect as well and subsequently improved the response options which resulted in lower scores (better targeting), and improved model fit, with no disordered thresholds [13].

Rasch analysis is a modern and unique form of item response theory (IRT) [15]. It involves testing an outcome scale against a mathematical model that operationalises the key principles of good measurement [15–17]. Rasch analysis allows for a unified approach to evaluating several measurement issues, such as unidimensionality, local dependency, response category ordering, item bias and targeting, producing rich data that complements and adds to CTT approaches [15–18]. Rasch analysis is widely accepted as the standard for modern psychometric evaluations of outcome scales [15, 19]. As such, this methodology was deemed to be the most appropriate for this study.

Previous studies provide robust evidence to guide the practical use of the HLQ among a variety of international community and clinical populations. However, the measurement properties of the HLQ have not previously been determined for older adults who have presented to an ED after a fall. The appropriateness of a tool may vary across settings, therefore it is imperative to analyse the HLQ in specific populations prior to applying the tool and interpreting scores [8, 12]. The aim of this study was to use Rasch methods to evaluate the measurement properties of the HLQ in a cohort of older adults who presented to a hospital ED after a fall.

## Methods

### Design

This study was embedded within a multi-centre randomised controlled trial (RCT) of a patient-centred falls prevention program: RESPOND. RESPOND incorporates (1) a home-based assessment; (2) education, goal setting and telephone coaching for management of selected falls risk factors; and (3) healthcare provider communication and community linkage, delivered over 6 months [20]. Ethical approval was obtained from Alfred Health (HREC 439/13) and Royal Perth Hospital (REG 13–128), Monash University Human Research Ethics Committee (HREC) (MUHREC CF13/3869–2013001975) and Curtin University HREC (HR 43/ 2014).

### Participants and setting

Adults aged between 60 and 90 years who presented at two Australian EDs with a fall, and had a planned discharge home within 72 h, were eligible to participate in the RESPOND trial [20]. Exclusion criteria were: current palliative care or terminal illness, requiring hands-on assistance to walk, needing an interpreter, a history of psychoses or social aggression, and cognitive impairment (Mini Mental State Examination (MMSE) <23) [21]. A total of 438 patients were recruited to the RESPOND RCT and completed the HLQ. Of these participants, five withdrew prior to completion of the trial. Data from the remaining 433 participants were used for this study.

### Data collection

Demographic data were collected by members of the research team at the screening and recruitment phase at the participating hospitals, and the initial face-to-face assessment conducted at the participant's home. The home visit was planned to occur within two weeks of discharge from hospital [20]. The HLQ was self-

administered by the participant either prior to or during the home visit.

### The health literacy questionnaire (HLQ)

The HLQ comprises 44 items over nine independent scales, each representing a different element of the overall health literacy construct: (1) Feeling understood and supported by healthcare providers; (2) Having sufficient information to manage my health; (3) Actively managing my health; (4) Social support for health; (5) Appraisal of health information; (6) Ability to actively engage with healthcare providers; (7) Navigating the healthcare system; (8) Ability to find good health information; and (9) Understanding health information well enough to know what to do. There are four to six items in each scale. Depending upon the purpose of inquiry, the full instrument or selected scales can be used. The first five scales comprise items that ask the respondents to indicate their level of agreement on one of four response options (strongly disagree to strongly agree). The remaining scales (6–9) represent scales of self-reported capability and items within these scales are scored on one of five response options (cannot do; very difficult; quite difficult; quite easy; very easy). The full HLQ provides nine individual scores based on an average of the items within each of the nine scales. There is no overall total score for the HLQ as that could potentially mask individual needs in specific health literacy domains [22].

### Other measures

Socio-economic status (SES) was measured using The Index of Relative Socio-economic Advantage and Disadvantage (IRSAD) [23], a reliable and robust approach to assessing socio-economic status [24]. Data are based on participant postcodes and take into consideration socio-economic factors such as income, education, employment, occupation and housing [23]. The 20% most advantaged, according to their IRSAD score, were considered to be a relatively high socio-economic group for the purpose of this study. The remaining participants were combined into a second group representing lower socio-economic status.

Whether or not participants have private health insurance or live alone were self-report questions answered yes/no at the time of the initial face-to-face assessment. Falls risk status was measured at the face-to-face interview using a reliable assessment tool: the Falls Risk for Older People – Community setting (FROP-Com) [25]. A FROP-Com score > 18 represented high falls risk [25].

### Analyses

Descriptive statistics were used to profile the cohort using SPSS v22.0 (IBM Corporation, Armonk, New York). Rasch analysis was conducted using the partial credit model, as this allows the thresholds to vary for each of the individual items [26], using RUMM2030 software (RUMM Laboratory Pty Ltd., Perth, Australia). In order to determine whether the HLQ scales fit the Rasch model, response patterns to HLQ items were evaluated against the model's expectations [15]. Three statistics were considered to determine the degree of fit for each HLQ scale: overall fit; individual person fit; and individual item fit [15]. Adequate overall fit of the HLQ to the Rasch model was indicated by a non-significant Bonferroni adjusted Chi-square probability value [27] ($p \geq 0.0125$ for four item scales (1 and 2); $p \geq 0.01$ for five item scales (3, 4, 5, 6, 8 and 9); $p \geq 0.0083$ for the six item scale (7)). Satisfactory overall item and individual fit for each scale was determined by a fit residual standard deviation (SD) value of ≤1.5 [27].

Individual items were further analysed to determine whether or not each of the four to six items comprising the nine HLQ scales fit the Rasch model requirements. Individual item fit was indicated by two statistics: fit residual values; and Chi-square probability values [16]. Item fit residual values −2.5 to 2.5 indicated adequate fit [28]. Above this range (underfit) suggests deviation from the model, below (overfit) suggests that some items in the scale are similar to each other [26]. Consistent with overall fit, a non-significant Bonferroni adjusted Chi-square probability value ($p > 0.0125$ for scales 1 and 2; $p > 0.01$ for scales 3, 4, 5, 6, 8, and 9; and $p > 0.0083$ for scale 7) indicated adequate item fit [28].

In addition to model fit the following measurement properties were analysed: unidimensionality; internal consistency reliability; response format; item bias; and targeting. Measurement properties analysed, their definitions, statistical tests used and criteria for assessment are summarised in Table 1.

## Results

### Participant characteristics

The mean age of participants was 73 years, 55% were female, and 42% of participants lived alone. Most had private health insurance (61%), and most were of high SES (62%). Approximately one third (34%) were classified as being at high risk of falls. Participant characteristics and HLQ scores are presented in Table 2.

### Rasch analysis

Three of the nine scales: (5) Appraisal of health information; (8) Ability to find good health information; and (9) Understanding health information well enough to know what to do -demonstrated adequate overall fit to the Rasch model as indicated by a non-significant Bonferroni adjusted Chi-square probability value ($p = 0.33$; $p = 0.02$; $p = 0.05$ respectively) (Table 3). The remaining scales demonstrated some degree of misfit between the data and the Rasch model (scales 1 and 2 $p < 0.0125$;

**Table 1** Measurement properties analysed and criteria for assessment

| Measurement property | Definition | Statistical test and ideal values |
|---|---|---|
| Unidimensionality | Whether or not each of the nine HLQ scales measures a single health literacy construct [18]. | % of significant t-tests from the Principal Components Analysis (PCA) of the standardised residuals <5% indicates unidimensionality. Where >5% significant t-tests, if lower bounds of CI < 0.05, unidimensionality is supported [16, 33]. |
| | Local independence is an element of unidimensionality. This occurs where the response to one item is not dependent on the response to another item [18, 26]. | Person-item residual correlation value <0.2 indicates local independence [34]. |
| Internal consistency reliability | The degree to which items in each scale measure the same construct [16]. | Person Separation Index (PSI) > 0.7 indicates good internal consistency reliability [15, 28, 34]. |
| Response format | Whether or not participants are able to consistently choose a response category appropriate for their level of health literacy. The point between two response categories (such as strongly agree and agree) where either response is equally probable is known as a 'threshold' [28]. | The absence of disordered thresholds on the category probability curve graphs indicates appropriate response format [34]. |
| Item bias | Whether or not different subgroups within the sample respond differently to an item, despite having equal levels of health literacy [16, 18]. This is measured using differential item functioning (DIF). Item bias for gender (male or female) and age group (60–75 and 76–90) were analysed. | A Bonferroni adjusted $p$ value for significance was used for the DIF analysis [16]: $p > 0.006$ for 4 item scales (1 and 2); $p > 0.005$ for five item scales (3, 4, 5, 6, 8 and 9); and $p > 0.004$ for the six item scale (7) indicating no item bias. |
| Targeting | The degree to which the HLQ was appropriately targeted to the RESPOND cohort [16]. | Targeting was evaluated through analysis of person-item distribution graphs [35]. The mean person location should approximate zero for a well targeted tool [16]. A positive person mean suggests that on the whole respondents found the scales easy to endorse. A negative person mean suggests that respondents found the scales difficult to endorse. A well targeted scale should see items spanning across the full range of individual person scores. |

scales 3, 4 and 6 $p < 0.01$; scale 7 $p < 0.0083$). The majority of item misfit, as determined by a negative item fit residual value below −2.5 (17 items), suggested overfit (Table 4). A further seven items (one item from each of scales 1, 2, 3, 4, 6, 7, and 8) demonstrated underfit with a Chi-square probability below the adjusted alpha value (scale 1 and 2 $p < 0.0125$; scales 3, 4, 6, and 8 $p < 0.01$; and scale 7 $p < 0.0083$) (Table 4).

Good person fit was demonstrated for the majority of the scales (1, 2, 6, 7, 8, and 9) with a person fit residual SD < 1.5 indicating that overall people responded to items as expected. Minor person misfit was shown across three of the nine scales: (3) Actively managing my health; (4) Social support for health; and (5) Appraisal of health information, with a person fit residual SD >1.5 (Table 3). This suggest that some people responded in an unusual way to some items in these scales.

Unidimensionality is a critical property of good measurement and a prerequisite to the summation of items within a scale [15, 29]. Unidimensionality was demonstrated for all nine scales (Table 3) as determined by <5% significant $t$-tests (scales 1, 2, 4, 6, 7, and 8) or a 95% confidence interval (CI) including 5% where >5% significant $t$-tests were evident: scale (3) CI:0.04–0.09; scale (5) CI:0.04–0.08; and scale (9) CI:0.03–0.07. Local independence further supports the concept of unidimensionality [29]. All nine scales demonstrated local independence with between-item residual correlations matrix values <0.2. The Person Separation Index (PSI) for all scales was >0.7 indicating good internal consistency reliability.

No item bias was evident for the majority of the HLQ items (43 out of 44), demonstrating that people with the same level of health literacy consistently responded to items in the same way, regardless of their gender or age group. Only one item: 'Get health information by yourself' from scale (8) Ability to find good health information, demonstrated item bias for gender as indicated by a probability value below the Bonferroni adjusted probability value ($p < 0.005$). This means that males and females responded differently to each other despite having the same level of health literacy (non-uniform DIF) [16] (Fig. 1).

Overall, the response format was found to be satisfactory for the 'strongly disagree to strongly agree' scales (scale 1 to 5) as indicated by the absence of disordered thresholds. Mild disordering was evident in scale (4) Social support for health, for the following item: 'I have at least one person who can come to medical appointments with me'. Disordered thresholds predominantly occurred among the capability response categories (cannot do to very easy) for the following items: 'discuss

**Table 2** Participant characteristics

| | |
|---|---|
| Gender | |
| Female, *n* (%) | 237 (54.7%) |
| Age | |
| Mean age (yrs) | 72.5 |
| 60–75, *n* (%) | 271 (62.6%) |
| 76–90, *n* (%) | 162 (37.4%) |
| Private health insurance | |
| Yes, *n* (%) | 264 (61%) |
| Lives alone | |
| Yes, *n* (%) | 180 (41.6%) |
| High falls risk | |
| Yes, *n* (%) | 148 (34.2%) |
| Socio-economic status (IRSAD) | |
| High socio-economic status, *n* (%) | 267 (61.7%) |
| HLQ score, mean (SD) | |
| *Section one: scales of agreement. Range 1 (lowest) to 4 (highest)* | |
| 1) Feeling understood and supported by healthcare providers | 3.24 (0.28) |
| 2) Having sufficient information to manage my health | 3.00 (0.34) |
| 3) Actively managing my health | 2.96 (0.33) |
| 4) Social support for health | 3.10 (0.41) |
| 5) Appraisal of health information | 2.76 (0.44) |
| *Section two: scales of capabilities. Range 1 (lowest) to 5 (highest)* | |
| 6) Ability to actively engage with healthcare providers | 4.15 (0.31) |
| 7) Navigating the healthcare system | 4.01 (0.40) |
| 8) Ability to find good health information | 3.91 (0.43) |
| 9) Understanding health information well enough to know what to do | 4.15 (0.38) |

things with healthcare providers…' and 'Ask healthcare providers questions to get…' from scale (6) Ability to actively engage with healthcare providers; 'Find out what healthcare services you are…' from scale (7) Navigating the healthcare system; 'Find health information from several…', Get information about health so you are…', and 'Get health information by yourself' from scale (8) Ability to find good health information; and all items in scale (9) Understanding health information well enough to know what to do. On inspection of the category probability curves, the main issue participants had was choosing between 'very difficult' and 'quite difficult'. The HLQ authors, however, recently changed the capability response options (scales 6–9) to include elements of frequency as well as difficulty, and this was found to be better than the original options [13].

In terms of targeting, a positive mean person location for all nine scales (0.89–2.99) suggested that participants found some of the items easy to endorse. Person-item distribution graphs plot item difficulty and the person's level of health literacy along a common measure: logits. A logit is the unit of measurement that results when the Rasch model is used to transform raw scores from ordinal data to log odds ratios on a common scale [26]. The value of zero is allocated to the mean of the item difficulty [16, 26]. There should be an even spread of HLQ items across the range of participants' health literacy levels. On inspection of these graphs there were no items matching participants' level of health literacy at approximately the one to two logit point (mid to high HLQ score) despite a number of participants at this ability level for each scale (Fig. 2).

## Discussion

This is the first study to assess the measurement properties of the HLQ among a cohort of older people who have presented to an ED after a fall. Health literacy is an important factor associated with participation in preventive health programs, such as falls prevention initiatives. Overall, the HLQ demonstrated good measurement properties. The summation of the HLQ items within each scale to provide scale summary scores, with each scale representing one distinct component of health literacy, is supported. This finding is consistent with previous validation studies of the HLQ [8–11, 14]. This indicates that each HLQ scale measures what it purports to measure, and nothing more, providing detailed information on nine separate areas of health literacy.

Absence of item bias is considered a fundamental principle of good measurement [15, 18]. It is important that items work consistently for individuals across different sub-groups, particularly if different demographic groups are to be compared [18]. Almost all the items (43 of 44) did not demonstrate item bias for the covariates assessed, with minor bias demonstrated for only one item. This suggests that un-biased estimates of health literacy across gender and age groups can be obtained from the HLQ. This finding further supports previous studies that found both the English and Slovakian versions of the HLQ to be invariant across a number of key demographic groups [9, 13].

In this study, the majority of misfit suggests that the set of items within some scales may have overlapping content (overfit). Overfit does not compromise good measurement [26]. A strong rationale for including the items is provided in the development of the tool. Multiple structured processes were undertaken to develop the HLQ items, guided by the revised Bloom's taxonomy, to generate items of various difficulty. Detailed psychometric analyses were used to test and refine the

**Table 3** Model fit statistics for HLQ scales

| Rasch component | Overall model fit | Item fit Mean (SD) | Person fit Mean (SD) | Internal consistency reliability (PSI) | Unidimensionality (% of significant t tests). CI shown where % of significant t tests >5% |
|---|---|---|---|---|---|
| *Section one: scales of agreement (four response categories)* | | | | | |
| 1) Feeling understood and supported by healthcare providers | $\chi^2$ = 27.80 | −2.26 | −0.92 | 0.78 | 2.31% |
| | **$p$ < 0.0125** | (0.94) | (1.16) | | |
| 2) Having sufficient information to manage my health | $\chi^2$ = 58.10 | −2.20 | −0.81 | 0.75 | 3.70% |
| | **$p$ < 0.0125** | **(2.51)** | (1.13) | | |
| 3) Actively managing my health | $\chi^2$ = 43.21 | −2.28 | −1.235 | 0.73 | 6.47% |
| | **$p$ < 0.01** | **(1.99)** | **(1.81)** | | CI:0.04–0.09 |
| 4) Social support for health | $\chi^2$ = 55.62 | −0.77 | −0.86 | 0.72 | 4.85% |
| | **$p$ < 0.01** | **(2.51)** | **(1.69)** | | |
| 5) Appraisal of health information | $\chi^2$ = 22.16 | −0.80 | −0.81 | 0.79 | 6.00% |
| | $p$ = 0.33 | **(1.55)** | **(1.60)** | | CI:0.04–0.08 |
| *Section two: scales of capabilities (five response categories)* | | | | | |
| 6) Ability to actively engage with healthcare providers | $\chi^2$ = 27.77 | −2.20 | −1.00 | 0.74 | 3.46% |
| | **$p$ < 0.01** | (1.17) | (1.42) | | |
| 7) Navigating the healthcare system | $\chi^2$ = 46.64 | −2.00 | −0.86 | 0.82 | 4.16% |
| | **$p$ < 0.0083** | **(2.43)** | (1.34) | | |
| 8) Ability to find good health information | $\chi^2$ = 28.65 | −1.36 | −0.95 | 0.77 | 4.39% |
| | $p$ = 0.02 | (0.80) | (1.42) | | |
| 9) Understanding health information well enough to know what to do | $\chi^2$ = 18.58 | −2.03 | −0.94 | 0.72 | 5.31% |
| | $p$ = 0.05 | (1.26) | (1.40) | | CI:0.03–0.07 |

*SD* standard deviation, *PSI* person separation index, *CI* confidence interval
Statistics beyond the pre-specified ideal values are noted in bold

items, leading to removal or re-wording of poorly performing items [8]. Given the rigorous development process of the HLQ, deletion of misfitting items is not recommended. Doing so may compromise construct coverage and result in loss of some of the tool's important items [26]. Overall misfit to the Rasch model should be treated with caution. While Chi-square probability values are recommended to determine fit, these values are sensitive to sample size [30]. Given a sufficiently large sample size ($n$ = 433 in this study), even small deviations from model fit will be statistically significant [30].

All nine HLQ scales were found to be inadequately targeted for this sample, which is consistent with findings from Richtering et al. [14]. It is important to note that the RESPOND cohort were not representative of the general population in several ways. Firstly, the cohort consisted of participants who were taking part in a clinical trial. Those who volunteer to participate in research projects may have levels of education, motivation and engagement that differ from those who decline to participate. Secondly, due to the exclusion criteria necessary for the purpose of the RCT, the sample was underrepresented for certain subgroups known to have lower levels of health literacy. For example, those born overseas or who speak languages other than English at home, those with lower education, no private health insurance, multiple chronic conditions, and women have been found to have lower health literacy on some HLQ scales [31]. The RESPOND cohort had higher HLQ scores in seven of the nine HLQ scales (scales 1, 2, 4, 6, 7, 8, and 9), and similar levels of health literacy in two scales (3 and 5), when compared to a sample representing a diverse range of socio-economic and geographical characteristics [31]. This may explain why the RESPOND cohort appeared to find some HLQ items easy to endorse. The measurement gap identified has implications for measurement precision, which decreases at the level corresponding with this gap [32]. This means that a large change in health literacy is necessary in order to elicit a change in mid to high HLQ score for the RESPOND cohort.

The main strength of this study is that the sample was from a multi-centre trial, encompassing two geographically diverse areas of Australia. In terms of limitations, the sample size may have contributed to the significant Chi-square probability values [30]. A further limitation was that the sample was under representative of a number of socio-economic groups, limiting generalisability of the results to the broader population of older adults who present to an ED after a fall.

**Table 4** Individual item fit statistics

| HLQ scale | HLQ item | Location | SE | Item fit residual | Chi-square | Bonferroni adjusted Chi-square probability |
|---|---|---|---|---|---|---|
| *Section one: scales of agreement (four response categories)* | | | | | | |
| 1) Feeling understood and supported by healthcare providers | I have at least one healthcare provider who … | 0.20 | 0.10 | **−2.73** | 3.60 | 0.17 |
| | I have at least one healthcare provider I can … | 0.04 | 0.11 | **−2.85** | 2.46 | 0.29 |
| | I have the healthcare providers I need … | 0.40 | 0.12 | −0.87 | 21.21 | **<0.0125** |
| | I can rely on at least one … | −0.63 | 0.12 | **−2.61** | 0.53 | 0.76 |
| 2) Having sufficient information to manage my health | I feel I have good information about health … | −0.56 | 0.10 | 1.50 | 35.02 | **<0.0125** |
| | I have enough information to help me deal … | −0.14 | 0.10 | **−3.98** | 6.67 | 0.08 |
| | I am sure I have all the information I need to … | 0.42 | 0.10 | **−3.45** | 8.55 | 0.04 |
| | I have all the information I need to … | 0.28 | 0.09 | **−2.86** | 7.86 | 0.05 |
| 3) Actively managing my health | I spend quite a lot of time actively managing … | 0.48 | 0.09 | 0.461 | 20.54 | **<0.01** |
| | I make plans for what I need to do to be … | 0.19 | 0.10 | −1.384 | 3.63 | 0.30 |
| | Despite other things in my life, I make time … | 0.08 | 0.10 | **−4.56** | 5.44 | 0.14 |
| | I sent my own goals about health and fitness | −0.29 | 0.11 | −2.09 | 3.57 | 0.31 |
| | There are things that I do regularly … | −0.46 | 0.10 | **−3.80** | 10.03 | 0.02 |
| 4) Social support for health | I can get access to several people who … | −0.25 | 0.09 | 0.70 | 7.08 | 0.13 |
| | When I feel ill, the people around me really … | 0.27 | 0.09 | 0.22 | 7.42 | 0.12 |
| | If I need help, I have plenty of people I … | −0.09 | 0.09 | **−2.91** | 11.27 | 0.02 |
| | I have at least one person … | 0.60 | 0.08 | 2.02 | 10.69 | 0.03 |
| | I have strong support from … | −0.52 | 0.09 | **−3.87** | 19.17 | **<0.01** |
| 5) Appraisal of health information | I compare health information from different … | −0.02 | 0.09 | −0.15 | 0.84 | 0.93 |
| | When I see new information about health, I … | 0.50 | 0.09 | −1.864 | 2.49 | 0.65 |
| | I always compare health information from … | 0.36 | 0.09 | **−2.88** | 8.58 | 0.07 |
| | I know how to find out if the health … | −0.56 | 0.10 | −0.09 | 3.86 | 0.42 |
| | I ask healthcare providers about the quality … | −0.28 | 0.09 | 0.98 | 6.38 | 0.17 |
| *Section two: scales of capabilities (five response categories)* | | | | | | |
| 6) Ability to actively engage with healthcare providers | Make sure that healthcare providers understand … | −0.73 | 0.11 | −1.75 | 6.19 | 0.05 |
| | Feel able to discuss your health concerns with a … | −0.33 | 0.11 | −1.28 | 10.84 | **<0.01** |
| | Have good discussion about your health … | 0.01 | 0.10 | **−3.61** | 5.09 | 0.08 |

**Table 4** Individual item fit statistics *(Continued)*

| | | | | | | |
|---|---|---|---|---|---|---|
| | Discuss things with healthcare providers … | 0.37 | 0.10 | **−3.27** | 1.94 | 0.38 |
| | Ask healthcare providers questions to get … | 0.68 | 0.10 | −1.06 | 3.71 | 0.16 |
| 7) Navigating the healthcare system | Find the right healthcare | −0.03 | 0.09 | −1.44 | 1.58 | 0.45 |
| | Get to see the healthcare providers I need to | −0.29 | 0.09 | −1.06 | 8.55 | 0.01 |
| | Decide which healthcare provider you need … | −0.43 | 0.09 | **−3.27** | 7.35 | 0.03 |
| | Make sure you find the right place to get … | −0.34 | 0.09 | **−6.19** | 4.98 | 0.08 |
| | Find out what healthcare services you are … | 0.68 | 0.08 | 0.82 | 8.53 | 0.01 |
| | Work out what is the best care for you | 0.41 | 0.09 | −0.87 | 15.66 | **<0.0083** |
| 8) Ability to find good health information | Find information about your health problems | −0.25 | 0.09 | −1.70 | 1.91 | 0.59 |
| | Find health information from several … | 0.48 | 0.07 | −1.26 | 3.72 | 0.29 |
| | Get information about health so you are … | 0.15 | 0.08 | **−2.51** | 4.62 | 0.20 |
| | Get health information in words you … | −0.86 | 0.09 | −0.44 | 12.92 | **<0.01** |
| | Get health information by yourself | 0.48 | 0.07 | −0.87 | 5.49 | 0.14 |
| 9) Understanding health information well enough to know what to do | Confidently fill medical forms in the correct … | 0.25 | 0.07 | −1.70 | 3.84 | 0.15 |
| | Accurately follow the instructions from … | −0.35 | 0.09 | −0.37 | 2.33 | 0.31 |
| | Read and understand written health … | 0.23 | 0.08 | **−3.87** | 7.06 | 0.03 |
| | Read and understand all the information on … | 0.15 | 0.08 | −2.35 | 3.45 | 0.18 |
| | Understand what healthcare providers are … | −0.28 | 0.10 | −1.87 | 1.90 | 0.39 |

*SE* standard error
Statistics beyond the pre-specified range are noted in bold
Items are truncated. Full items are available from the tool developers

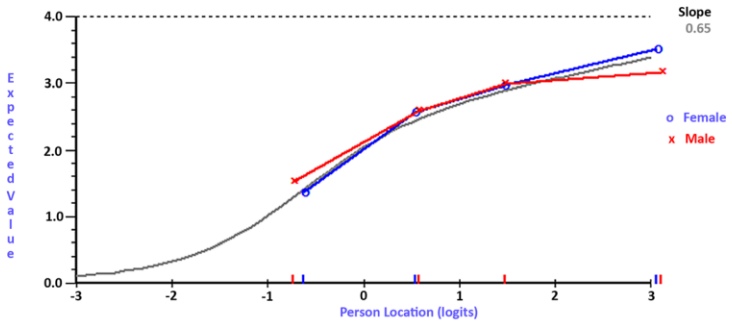


**Fig. 1** Item characteristic curve depicting DIF. Item characteristic curve for 'Get health information by yourself' from scale (8) Ability to find good health information, indicating item bias between males and females

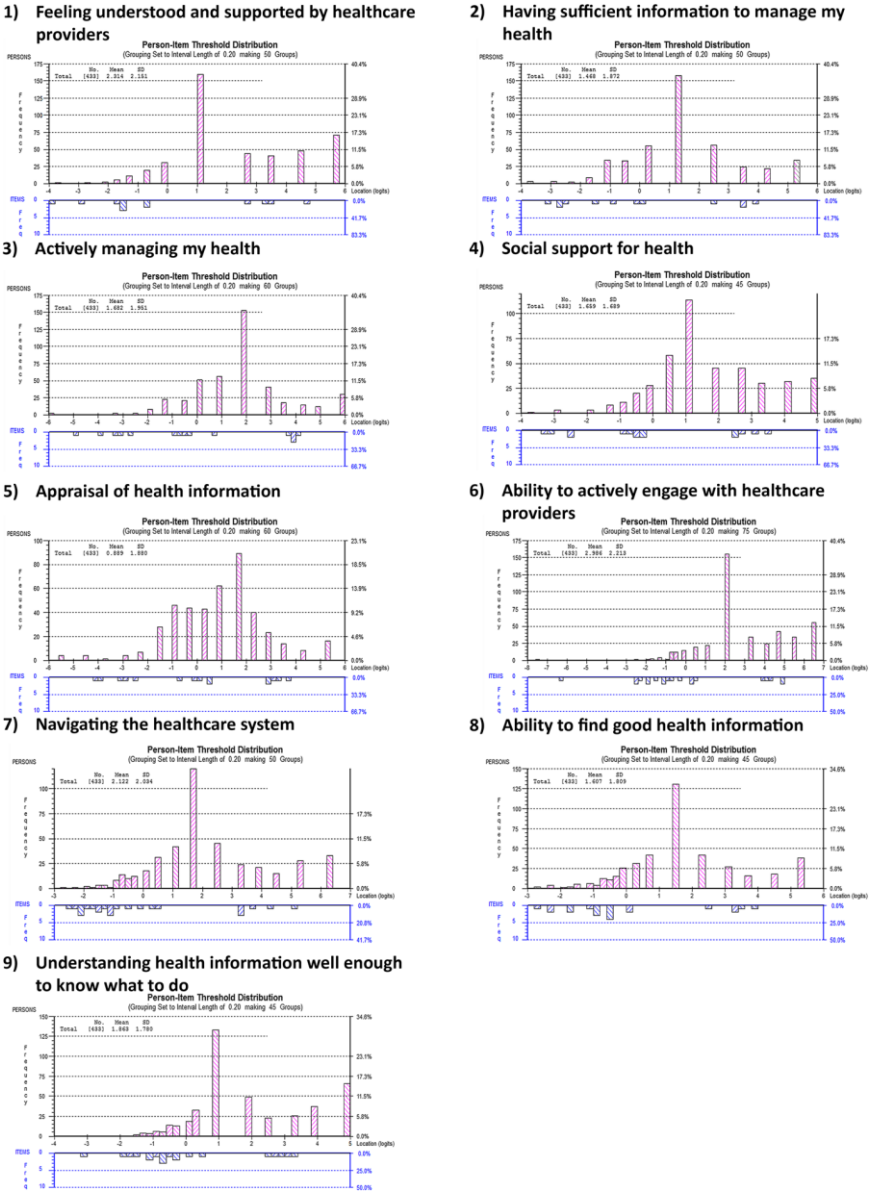


**Fig. 2** Person-item threshold distribution graphs depicting targeting for the nine HLQ scales. A positive mean person location for all nine scales (0.89–2.99) suggests that participants found some of the items easy to endorse. A measurement gap is evident for all nine HLQ scales - no items match participants' health literacy level at approximately the one to two logit point (mid to high HLQ score) despite a number of participants at this ability level for each scale

## Conclusions

The current study builds on previously established strong measurement properties of the HLQ and adds new knowledge specific to a population of older people who have presented to an ED after a fall. Overall, the HLQ was found to have good measurement properties among this cohort. The HLQ may be used to tailor falls prevention initiatives to allow for program components, such as provision of education, support and community linkage, to be delivered in a manner appropriate for individual health literacy ability. This may increase participation in falls prevention activities, potentially resulting in better health outcomes for these patients.

### Abbreviations

CFA: Confirmatory factor analysis; CI: Confidence interval; CTT: Classical test theory; ED: Emergency department; FROP-Com: Falls Risk for Older People – Community setting; HLQ: Health Literacy Questionnaire; IRSAD: Index of Relative Socio-economic Advantage and Disadvantage; IRT: Item response

theory; MMSE: Mini Mental State Examination; PCA: Principal Components Analysis; PSI: Person Separation Index; RCT: Randomised controlled trial; SD: Standard deviation; SE: Standard error; SES: Socio-economic status

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**Availability of data and materials**
The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

**Authors' contributions**
RLM led the data analysis and drafting of all sections of the article in consultation with the co-authors. ALB led the application for funding for this work. All authors provided substantial contribution to design and analysis of the study, interpretation of findings, drafting the paper and revising it critically for important intellectual content and approved the final version of the manuscript to be published.

**Ethics approval and consent to participate**
Ethical approval was obtained from Alfred Health (HREC 439/13) and Royal Perth Hospital (REG 13–128), Monash University Human Research Ethics Committee (HREC) (MUHREC CF13/3869–2013001975) and Curtin University HREC (HR 43/ 2014). Written informed consent was obtained from all study participants.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

## Publisher's Note



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# 7 DISCUSSION AND CONCLUSION

Falls are a major cause of ED (Emergency Department) presentations for older people. In Australia, rates of ED presentations for falls, and fall injury hospitalisations are increasing. Falls cause substantial negative impacts for the individual affected, their loved ones and communities, as well as the healthcare system and society as a whole. In the context of an ageing population, in Australia and worldwide, it is imperative that this issue is addressed.

Current evidence regarding the effectiveness of falls prevention interventions targeted to older people who present to ED after a fall is conflicting and the critical success factors for reducing falls among this group are unclear. In addition, there is a growing body of evidence linking health literacy to health outcomes for a number of health conditions. However, the relationship between health literacy and falls prevention has not been established.

RESPOND is a falls prevention program for community-dwelling older people who present to ED after a fall and who were discharged home within 72 hours. An RCT of RESPOND found that the program reduced rates of falls and fractures, compared with usual care. The trial found no significant difference for rates of fall injuries, ED presentations or hospitalisations between groups.

The aim of this thesis was to identify the critical success factors for the RESPOND RCT by conducting a comprehensive program evaluation. A secondary aim was to describe the baseline health literacy of the RESPOND cohort, evaluate the Health Literacy Questionnaire (HLQ) for use with this patient group, and explore associations between key aspects of health literacy and falls outcomes. This PhD thesis addressed these aims through three studies, each mapped to one of three thesis objectives.

This thesis represents the first comprehensive program evaluation (comprising process, impact and outcome evaluations) of an RCT of a falls prevention program targeting older people who presented to an ED with a fall. The two program evaluation studies in this thesis add value to the RESPOND RCT by explaining the 'how', 'why', and 'for whom' for the trial results, allowing for more detailed conclusions to be drawn and for recommendations to be made regarding the implementation of RESPOND and similar programs. The validation study of a health literacy measurement tool – the HLQ – is the first to provide detailed information related to the measurement properties of a health literacy measurement tool for use in this particular patient population.

## 7.1 SUMMARY OF KEY FINDINGS MAPPED TO THE THESIS OBJECTIVES

A summary of the objectives, studies undertaken, and the key results for each study are summarised in Table 7.1. The studies presented in this thesis have generated new knowledge that is intended to assist policy makers, researchers and clinicians who aim to provide effective falls prevention programs for older

community-dwelling people who have experienced a fall. Most importantly, the information presented in this thesis has the potential to improve the quality of health service provision for older people - the segment of the community that is most at risk of falls.

**Table 7.1: Summary of thesis objectives, studies, and key results**

| Objective | Study undertaken | Key results |
|---|---|---|
| 1) To conduct a process evaluation of the RESPOND RCT (implementation fidelity and barriers and facilitators to implementation). | Mixed methods process evaluation of the RESPOND RCT. | • RESPOND was implemented at a lower dose than planned.<br>• The majority of participants commenced the intervention within one month of ED discharge.<br>• Adherence to the modules was moderate to high, and highest for Better Strength and Balance, lowest for Better Sleep.<br>• Clinicians delivered the program in a participatory decision-making manner, consistent with the spirit of motivational interviewing.<br>• The main barriers to implementation were complex health or social issues.<br>• The person-centred, gain-framed approach was seen by participants and clinicians as facilitating implementation. |
| 2) To conduct an impact evaluation (factors associated with participation in falls prevention strategies) and outcome evaluation (sub-group analyses of key RESPOND RCT outcomes) of the RESPOND RCT. | Impact and outcome evaluation of the RESPOND RCT using negative binomial regression models. | • There was a trend towards increased participation in falls prevention activities in the intervention group, compared with the control group.<br>• A history of multiple falls was associated with an increase in falls, fall injuries, and ED re-presentations during the 12-month follow-up period, after adjusting for other factors.<br>• There was a trend towards higher rates of falls, falls injuries and ED re-presentation for those with higher falls risk.<br>• A trend towards reduced rates of falls, falls injuries, and ED re-presentations was also seen with increasing ability to navigate the healthcare system - a key element of health literacy. |
| 3) To analyse the measurement properties of the HLQ using the RESPOND RCT cohort. | Descriptive statistics on health literacy ability among the RESPOND cohort, using the HLQ. Measurement properties of the HLQ determined through Rasch analysis methods. | • The RESPOND cohort had a high level of health literacy at baseline, as measured using the HLQ.<br>• Overall, the HLQ demonstrated good measurement properties among the RESPOND cohort.<br>• All nine HLQ scales were unidimensional with good internal consistency reliability.<br>• No item bias was found for most (43 of 44) items for age or sex, with minimal item bias for one item.<br>• A degree of overall misfit was evident for 6 of the 9 HLQ scales, but usually represented item overlap (some items were measuring the same aspect of the scale construct), therefore not compromising measurement.<br>• A measurement gap was identified for the RESPOND cohort at mid to high HLQ scores for all nine scales (i.e. there were no items addressing mid to high health literacy ability). |

## 7.2 CRITICAL SUCCESS FACTORS FOR RESPOND

### 7.2.1 Person-centred approach

The interaction between the healthcare provider and the patient, and its influence on health outcomes has been extensively researched.[225, 226] There is a major global trend towards delivering healthcare in a person-centred manner.[227] In its 2001 report, "Crossing the Quality Chasm: A New Health System for the 21st Century," the Institute of Medicine (US) identified person-centred care as one of the six pillars of quality health care.[228] There is, however, currently no consensus on the definition of person-centred care.[229] A recent systematic review of person-centred care for older adults identified 15 definitions, addressing 17 core principles or values.[230] The most prominent components were: holistic care, respect and value, choice, dignity, self-determination, and purposeful living.[230] Broadly, the spirit of person-centred care is that healthcare initiatives are designed with respect for the individual's preferences, values and needs.[227]

Motivational interviewing and participatory decision-making are both well-described methods of accomplishing person-centred care in contexts where behaviour change is necessary in order to achieve individual health outcomes.[231] In programs such as RESPOND, both approaches are indicated: motivational interviewing to address ambivalence to behaviour modification, and participatory decision-making to support individuals in making appropriate healthcare decisions where there is more than one reasonable action to take.[231] RESPOND incorporated both these techniques, and the process evaluation found that both were implemented by the RESPOND clinicians to a satisfactory degree. Not only was person-centred care evident (from recordings of participant-clinician interactions), but qualitative data showed that it was perceived by RESPOND participants and clinicians as a facilitator to successful program delivery. This is consistent with findings from a systematic review that found that most patients prefer to be actively involved in decision-making, and that preferences for shared decisions have increased over time.[232]

The ability to participate in decision-making necessitates an adequate level of knowledge and understanding about one's health status and the available options, in order to make informed decisions.[229] A major component of RESPOND was the provision of falls risk education and associated management strategies. The process evaluation found that the RESPOND clinicians provided falls risk and management education in nearly all (96%) analysed RESPOND intervention sessions, which likely contributed to participants choosing appropriate RESPOND modules and setting goals that were relevant to their own circumstances.

The telephone-based delivery mode may have overcome barriers to uptake for some participants. For example, those who were not able to attend centre-based therapy, or those who were not in favour of home visits, may have found the telephone coaching calls to be the most appropriate mode of communication. A recent RCT found that a telephone-based motivational interviewing program resulted in clinically meaningful improvements in physical activity and psychosocial outcomes for people recovering from hip fracture.[233] Relative to usual care, the motivational interviewing group demonstrated improved self-efficacy, as

evidenced by increased confidence about not falling.[233] The results from the RESPOND RCT and this program evaluation also indicate that telephone-based motivational interviewing is an effective form of delivering and sustaining therapy for older community-dwelling people who have experienced a fall.

A further principle of person-centred care is concerned with continuity of care and smooth transitions.[234] The ED is a particularly challenging environment, with pressure on staff to maintain patient flow and meet time targets.[235] A recent study, conducted at one of the RESPOND RCT recruiting hospitals, found that ED staff could not always address the needs of older people, and did not have time for transitional care planning for older patients with often complex needs.[235] RESPOND appears to have contributed to filling some of these service gaps, as expressed qualitatively by the RESPOND clinicians. RESPOND assisted participants transitioning from ED back to home by providing a single point of health professional contact in a complex health system during the early post-fall period when many feel vulnerable and frightened. Lack of integration of complex health services has been identified by British health professionals as a barrier to falls prevention.[236] Conversely, coordinated care, delivered by a clinician who maintained an ongoing knowledge and relationship with the older person was found to be a facilitator.[237] The benefits of having a clinician that an individual knows and trusts is supported by the findings of a qualitative study that examined the views and preferences of community-dwelling older adults regarding falls prevention information.[238] The rapport built between the RESPOND clinicians and participants was considered a key facilitator to program implementation by RESPOND participants, who described their allocated clinician as 'knowledgeable' and 'caring'. Good interpersonal communication (including attributes such as respect and connectedness) has been found to be consistent with motivational strategies.[238]

Many of the prior falls prevention RCTs targeting those who have presented to ED after a fall can be considered person-centred in terms of comprising individualised multi-factorial interventions.[11] However, the degree to which the program implemented person-centred principles, and participant opinions regarding the person-centred approach, have not previously been evaluated in prior studies targeting this patient group. This thesis provides evidence for an effective application of participatory decision-making for falls and fracture prevention, demonstrating that this planned aspect of RESPOND was delivered as intended, and that the person-centred approach was favoured by those delivering and receiving the program.

#### *7.2.1.1 Health literacy and a person-centred approach*

As healthcare interactions move away from outdated models of health communication (which were traditionally based on the notion of clinicians as experts who make decisions on their patients' behalf), there is increasing emphasis on concepts such as health literacy, the association between health literacy and self-management, and shared decision-making.[239] Given an increasing recognition of the importance of health literacy it is useful to consider this concept in relation to priority health issues. While chronic diseases have been examined in detail with regard to health literacy and participatory decision-making,[176, 177, 179] the increasing personal and economic burden of falls is also a growing health priority.[240] Preventive health

interventions and resources designed to support people and optimise access to relevant services must be appropriate to the health literacy ability of the consumer if they are to be effective.[190] This thesis is the first to investigate the relationship between health literacy and person-centred falls prevention for those who present to ED with a fall.

At baseline, RESPOND RCT participants had a higher level of health literacy compared to a study that included a more diverse Australian sample of older people,[239] and a more recent sample of older French people,[205] when measured using the HLQ. Individuals with low health literacy report less understanding of their health condition and the process of care than those with adequate health literacy.[176] Furthermore, patients with low health literacy ask fewer questions and may be less able than those with adequate health literacy to respond to clinicians' use of person-centred communication strategies.[177] They may also have a tendency towards being more passive in healthcare interactions, thus limiting two-way communication and participatory decision-making.[20] Effective clinician–patient interactions have therefore been suggested to be a key pathway between health literacy ability and more favourable health outcomes.[20] In the context of this existing knowledge, it is possible that the participatory decision-making observed in the RESPOND clinicians delivering the program in the RESPOND cohort being particularly receptive to this approach through an above-average baseline health literacy ability. The relative contribution of person-centred techniques, and participant health literacy ability, to the RESPOND RCT outcomes, however, remains unknown.

### 7.2.2 Participation in falls prevention strategies

It is known that participation in falls prevention activities is suboptimal for older individuals in community settings.[241] In clinical trials, only half of community-dwelling older people are likely to be adhering to falls prevention interventions at 12 months.[241] Unsuccessful RCTs of falls prevention programs appear to be characterised by a low uptake of recommendations or poor adherence to key strategies.[2] This program evaluation of the successful RESPOND RCT builds on prior studies and provides evidence to suggest that a higher rate of participation in falls prevention strategies is associated with more favourable outcomes.

The concept of patient participation remains somewhat ill-defined.[242] There is no consensus on the definition of 'participation' in preventive health programs, such as falls prevention initiatives.[242] Compounding this, the term 'participation' has been used interchangeably with terms such as engagement, adherence, and uptake. The challenge of adopting a standard definition for participation is further complicated by the heterogeneity of falls prevention program designs. The intended impact of RESPOND was to increase participation in falls prevention strategies. The definition of 'participation' was tailored to be relevant to the select suite of evidence-based interventions related to the targeted risk factors comprising the four RESPOND modules. This approach is consistent with prior studies that have used attendance at key healthcare appointments as a marker of participation in falls prevention strategies.[6]

The RESPOND impact evaluation found that overall, those in the intervention group demonstrated a consistent trend towards increased participation, compared with those receiving usual care. The absolute difference in participation between the groups is likely to be clinically important. The process evaluation found that adherence, as defined by engagement in the minimum requirements for the intervention, was high for most modules. At least three quarters of participants who chose the Better Strength and Balance, the Better Bones, and the Better Eyesight intervention modules completed their home visit intervention session, set at least one goal, and engaged in at least two follow up telephone coaching calls (75-88%). Of those who chose the Better Sleep module, approximately half adhered (51%).

It is important to consider participant adherence to key RESPOND components (as examined in the process evaluation) alongside participation in existing community health services (as examined in the impact evaluation) in order to gain a more complete view of the potential impact of RESPOND on participation in falls prevention activities. Not all RESPOND intervention sessions would have resulted in community linkage to healthcare services. For example, RESPOND clinicians may have discussed the importance of removing loose fitting rugs, or ensuring adequate lighting at home, for the participant to action. This may have reduced the risk of falling through adhering to the minimal program requirements without ongoing referral to an occupational therapist to conduct a home visit.

In order to maximise reproducibility of the results and inform future implementation efforts, it is necessary to understand not only what the critical success factors to RESPOND were, but also to identify factors that moderated the findings. To use the program evaluation terminology used by Moore *et al*. in the UK Medical Research Council guidelines:[98] what were the mechanisms of impact? Which contextual factors led to participation in RESPOND components and attendance at recommended community healthcare appointments? The way information is presented (gain-framed versus loss-framed), the degree of perceived personal relevance, and whether the program design and content is suited to the participant's level of health literacy, may be factors that influenced participation in RESPOND. These concepts are discussed below.

Health messages are commonly classified as gain-framed (or positively framed message) that emphasise the benefits of adhering to a health initiative or conversely, as loss-framed messages that highlight the negative consequences of not adhering to the health message.[243] RESPOND was designed to be delivered in a gain-framed manner. The information pamphlets that accompanied the four RESPOND modules all had the slogan 'Be Your Best'. Qualitatively, this was appreciated by the RESPOND participants, and the RESPOND clinicians found this approach facilitated their delivery of the program. The preference among the RESPOND cohort for gain-framed messages is consistent with prior falls prevention literature.[127, 238, 244] A study of older people's views on falls prevention, across six European countries, found that people were motivated to participate in strength and balance training by a wide range of perceived benefits, not necessarily associated with reducing falls risk. This includes interest and enjoyment, improved health, mood, and independence.[245] A focus on these positive benefits is consistent with delivery of RESPOND.

Investigating the role of potential moderators of framing effects is important to increase our knowledge of the way message framing can influence perceptions, attitudes and behaviour. Perceived relevance has been identified as a factor that moderates the persuasive effects of gain- and loss-framed messages.[126] Those who perceive the message to be personally relevant may be more likely to respond positively to gain-framed messages. The reason for this may be that loss-framed messages are perceived as threatening, particularly where the messages hold a high degree of personal relevance, resulting in defensive reactions.[246] For the majority of the RESPOND cohort, perceived relevance was high with over 90% of intervention participants who completed the participant experience questionnaire reporting that the information was relevant to them, and they believed their allocated RESPOND clinician paid attention to issues important to them. It is not surprising that perceived relevance was high, as all RESPOND participants had recently experienced a fall that led to an ED presentation.

Given evidence showing that gain-framed messages are favoured by those who have experienced a fall, this approach may have contributed to the high levels of adherence to RESPOND modules, and the trend towards greater participation in community-based falls prevention strategies, reflecting the uptake of recommended services. It is possible that the success of this type of message framing, was moderated by a high proportion of perceived relevance among the RESPOND cohort.

#### *7.2.2.1 Health literacy and participation*

The association between lower health literacy and poor health has been supported by numerous studies.[16, 20, 168] Adequate health literacy may be the first step in a chain of events that contribute to improved health outcomes, however, the mechanisms by which health literacy impacts health remain unknown.[16]

There is evidence to suggest that health literacy ability influences health knowledge for those with chronic disease, such as heart failure and diabetes.[247, 248] Participation in RESPOND may increase individual health literacy, specifically 'falls literacy', potentially enabling participants to better self-manage their falls risk factors. The RESPOND clinicians matched their language to the participants' level of understanding in all analysed audio-recordings of intervention sessions (RPAD item 6). This is akin to the clinicians' communication matching the participants' level of health literacy. Additionally, over 95% of participant questionnaire respondents stated that they found the RESPOND information easy to understand. While this was not directly measured in this evaluation, it is possible that the RESPOND program increased participant knowledge.

The RESPOND impact evaluation found that those who scored highly for having sufficient information to manage their health tended to attend fewer healthcare appointments. Although participation in falls prevention strategies (attendance at healthcare appointments) was the desired impact for the RESPOND program, it is possible that the telephone coaching calls improved falls risk and management knowledge and confidence, reducing the need for ongoing linkage to community health services for some participants. This

thesis presents the first research linking health literacy to participation in falls prevention initiatives for those who present to ED after a fall, although the exact mechanism of action remains unclear.

### 7.2.3 How much and how soon? Optimal falls prevention program parameters

There is evidence to suggest that an adequate dose of intervention, delivered in a timely manner, results in better outcomes for those participating in falls prevention programs.[11, 12, 154] The optimal parameters of dose and timeliness will likely vary depending on the program design, and contextual or mediating factors influencing the program at the time of implementation.[98] This thesis provides new evidence which builds on the existing literature in order to draw clinically useful conclusions.

A systematic review of barriers and facilitators to participatory decision-making found that patients often feel that the time allocated for healthcare consultations is insufficient, limiting time available for provision and receipt of information, asking questions, or actively engaging in decision-making processes.[237] Similarly, a systematic review exploring this concept from the clinicians' perspective found that time constraints were the main barrier to effective participatory decision-making across many different cultural and organizational contexts.[249] With RESPOND, it was planned for the clinician to allocate at least 45 minutes for each intervention contact, as per the RCT protocol. However, each telephone coaching session was a median (IQR) of only 20 (15-25) minutes duration. Despite this being below the planned dose, clinicians considered that the sessions were not rushed and concluded naturally according to the needs of the individual participant. This may have contributed to the effective implementation of motivational interviewing and participatory decision-making.

The impact evaluation found that those with greater total intervention contact time (dose) also had higher rates of participation. Those who received a higher dose of RESPOND may be more complex, from a health and social perspective, thus requiring longer, more frequent coaching sessions with their clinician. This is consistent with qualitative data from the RESPOND clinicians who believed that the more complex participants were more time-intensive.

There is evidence that a shorter time from the index fall, to commencement of a falls prevention program, ideally within one month, is associated with better outcomes.[2] Overall, RESPOND was delivered in a timely manner, with a median (IQR) of 18 (12, 30) days from ED discharge to program start date. This is consistent with a qualitative study that found that health professionals viewed lengthy wait times as a key barrier to effective falls prevention services.[236] This emphasises the advantage of direct telephone-based intervention, as opposed to reliance on existing clinics or other face-to-face services with often complex referral pathways and high caseloads leading to initiation delays. The RESPOND outcome evaluation identified a trend towards a higher rate of ED re-presentations for participants with a longer time from ED discharge to the initial home visit intervention session, compared with those who had a shorter time to their home visit. This may be related to functional decline following a fall, and a high proportion of recurrent fallers, which is particularly

pertinent for those whose fall resulted in an ED presentation.[250] This would likely impede an individual's ability to participate in a falls prevention program, implying that intervention prior to secondary falls or functional decline is preferable.

## 7.3 STRENGTHS AND LIMITATIONS OF THIS RESEARCH

This research has a number of methodological strengths. The data were collected alongside a multi-centre RCT from patients and clinicians in two Australian states. This approach increases the generalisability of the results. Rigorous mixed methods were used for the process evaluation, allowing for increased depth of understanding of the mechanisms of impact and contextual factors of RESPOND, compared with either qualitative or quantitative methods alone. The mixed methods approach also allowed for triangulation of data from multiple sources. Researcher triangulation also occurred, integrating the author's clinical and research experience and education with the expertise and perspectives of the PhD supervisors and wider RESPOND project team.

The methods used for the program evaluation incorporated the measurement of contemporary components of patient-centred care such as participatory decision-making and health literacy. The views of intervention participants and RESPOND clinicians delivering the intervention were specifically sought (the former using a two-pronged approach encompassing both patient experience questionnaires and focus groups). The process evaluation used audio-recordings of intervention sessions that reduced potential bias associated with clinician-reported or participant-reported data. The HLQ was validated using a modern form of item response theory (IRT): Rasch analysis. This type of analysis provides a unified approach to evaluating several measurement characteristics that allow for rounded conclusions related to the practical application of psychometric tools.

This research is, however, not without its limitations. The data produced in the studies described in this thesis represent a snapshot in time. The identified active ingredients and relative contribution of moderating factors are undoubtedly influenced by contextual factors. This means that the same program may have different results if implemented in a different setting or at a different time, due to varying contextual barriers and facilitators. Despite providing useful clinical suggestions, this may in theory limit the reproducibility of the results. A further limitation is the lack of data on participants who chose to exit the trial prematurely. For example, the acceptability data pertains to questionnaire respondents who remained in the intervention for the full six months – similarly with focus group data. Understanding the perspectives of those who dropped out during the intervention period would be useful for maximising reach and retention in future programs.

The sample size for the RCT was determined according to the primary outcome of the RCT, not the program evaluation. This means that some of the analyses in this thesis may not have been sufficiently powered to detect between-group differences and this is most relevant to the multivariate models presented in Chapter

5. Nevertheless, they provide useful information on between-group trends and decisions regarding 'clinical significance' rather than 'statistical significance' can still be made.

All three studies reported in this thesis used data from the same cohort of participants. The RESPOND cohort was cognitively intact, of higher socio-economic status, and had higher health literacy ability than the general Australian population. Furthermore, the age cut-off for the RESPOND RCT was 90 years. This may limit generalisability of the findings to the broader population of community-dwelling older Australians. It is also important to note that RESPOND only aimed to address falls prevention for community-dwelling older people presenting to ED with a fall. A moderate proportion present to ED with a fall from residential care, and this group generally have even higher levels of falls risk. The outcomes of falls prevention programs for older people from residential care who present to ED with a fall represent an important area for future research.

## 7.4 CLINICAL IMPLICATIONS

The results from this thesis allow for a number of clinically useful implications and recommendations to be considered. The key results from the program evaluation of RESPOND are presented in Figure 7.1.

The RESPOND RCT was conducted in two Australian states (Victoria and Western Australia). RESPOND reduced the rate of falls and fractures, compared with usual care, through selection of up to four targeted RESPOND modules, using motivational interviewing and participatory decision-making techniques. The participant's allocated clinician (a physiotherapist, occupational therapist, nurse or dietician) provided the first intervention session, a 45-minute home visit on average, within an average of 18 days. An average of six follow up telephone coaching calls, each lasting an average of 20 minutes, were then conducted over a six-month period. During these calls, barriers and facilitators to achieving goals were discussed, further falls risk management education was provided, new goals were set, linkage to community services was made, and modules were added or completed. The inclusion of these elements, and the extent to which they were discussed in the telephone calls was dependent on the individual's needs, preferences and progress. The average participant chose two modules to implement over the six months, with Better Strength and Balance and Better Bones being the most commonly chosen, and adhered to, RESPOND modules.

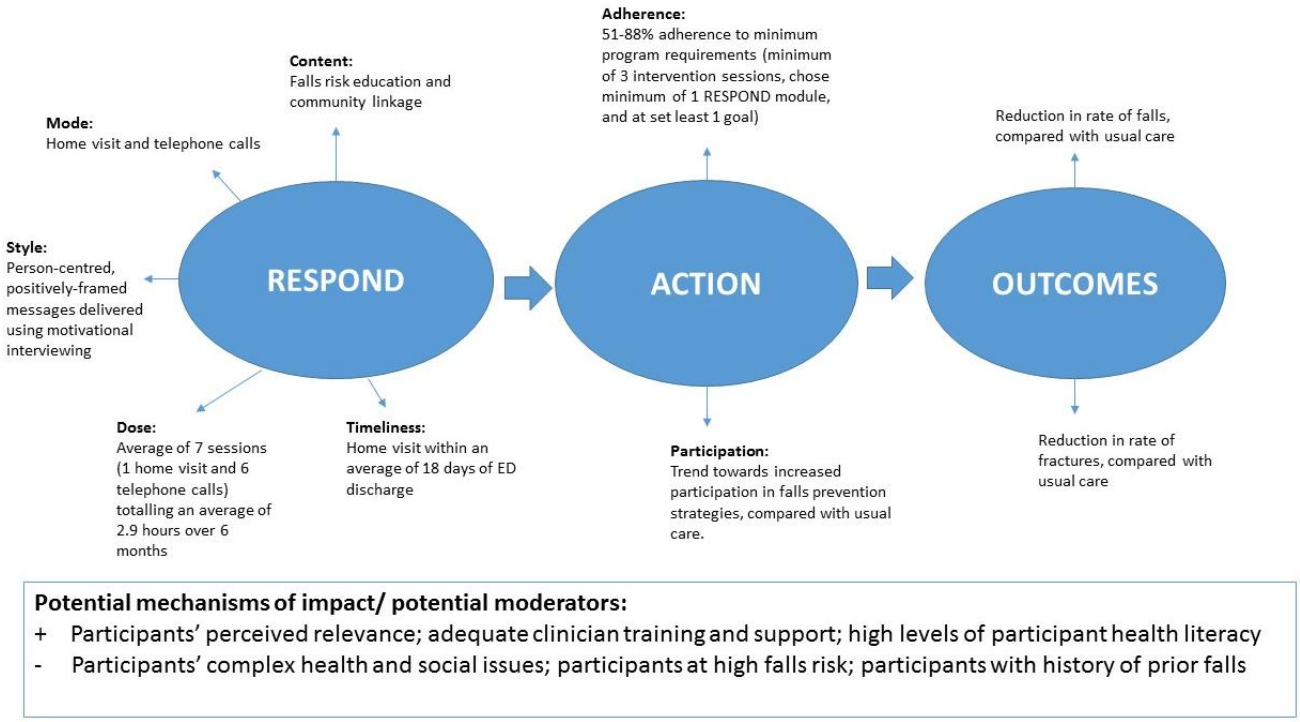


**Figure 7.1: Framework for RESPOND: Results from a comprehensive program evaluation**

The key potential mechanisms of impact, or moderators of the trial outcomes include the participants perceiving the messages to be personally relevant and having a high level of baseline health literacy, particularly the perceived ability to navigate the healthcare system. Participants who had complex health and/or social issues found these competing priorities impeded their ability to participate in RESPOND. Those with a high baseline risk of falling or a greater history of falls prior to the fall that led to them being enrolled in RESPOND experienced poorer outcomes, even after adjusting for other demographic and RESPOND program factors. Consistent with existing literature, the results from this thesis support the rationale behind the RCT tag line: "*RESPOND to the first fall to prevent the second*". This suggests that despite the high need for effective falls prevention services for frequent fallers, RESPOND was more effective for those whose presenting fall was their first.

A further clinically useful finding is that the telephone-based delivery mode was highly effective. It is flexible, convenient, and means there is no travel required for the participant or clinician. This can be of benefit to those with work or social commitments, those who are too unwell to attend a clinic, or those who prefer not to have a home visit. Telephone-based preventive health delivery is not resource intensive and has the potential to be cost effective. An economic evaluation of RESPOND is being conducted as a separate study to this thesis (Appendix 4).[251] It is important to consider, however, that there are some participants who would have preferred more than one home visit. In the spirit of person-centred care, a degree of flexibility related to the mode of delivery is recommended, with perhaps the addition of extra home visits if required.

It is acknowledged that the framework for RESPOND relates to what worked at the time the program was implemented, in specific settings, with a certain cohort of participants. In contrast to drug trials, for example, the relative contribution of each 'ingredient' to the RCT results is unknown and the effect of implementing the program at a different time, with different participants and clinicians, in a different place, will vary. This is the nature of complex preventive health interventions where there are multiple influencing, or mediating, factors at play. This again emphasises the need for flexibility in implementation, such as the dose delivered, accounting for personal and contextual variations.

It is important to consider that the framework above (Figure 7.1) describes the factors that led to a reduction in the rate of falls and fractures compared with usual care in the RESPOND RCT. There was no significant difference between groups for falls injuries, ED re-presentations, or hospitalisations. It is noteworthy that the capture of ED presentations was likely not complete as data were only collected from the two participating EDs and people may have presented to a different hospital ED during the trial period. This means that the true rate of ED re-presentations may have been higher than the rates reported, but this was not expected to differ systematically for the intervention or control groups.

Health literacy and its association with older people whose fall results in an ED presentation has not previously been evaluated. The HLQ is the first health literacy measurement tool to be validated among a cohort of older people who present to ED with a fall. This tool demonstrated good measurement properties, with each of the nine scales representing a distinct construct of health literacy.

In summary, the following five key clinical recommendations for implementation of RESPOND are derived from the research presented in this thesis:

1) **Person-centred program implementation**. This includes a flexible approach, incorporating motivational interviewing and participatory decision-making techniques that match the individual's level of health literacy. The use of a comprehensive and validated falls risk assessment tool, such as the FROP-Com, can help in guide personalisation of falls risk and management information.

2) **The HLQ is recommended to be used**, either in part (using individual scales) or in entirety (all nine scales) in order to tailor falls prevention education and service provision for older community-dwelling people who present to ED with a fall.

3) Identify and overcome (where possible) barriers in order to **maximise participation in falls prevention strategies**. Similarly, encourage and strengthen individual facilitating factors.

4) **Implement key program components in a timely manner, delivered at a sufficient dose**. The intervention should be delivered as soon as practical after discharge home from the ED in order to optimise outcomes.

5) **Target those who have only experienced one fall for best outcomes**. Those who have experienced multiple previous falls may require a different approach.

These recommendations may facilitate refinement of future applications of RESPOND, allowing for implementation to maximise effect and target those who are most likely to benefit. In a health system with limited resources this information is important, and useful not just for clinicians, but also for health funders and policy makers.

## 7.5 FUTURE RESEARCH DIRECTIONS

There are a number of recommendations for future research arising from this thesis. Further analysis of the relative contribution of the identified critical success factors is warranted. For example, further investigation of the dose-response relationship for RESPOND may determine whether the dose influences falls outcomes. A systematic review of health initiatives that use motivational interviewing techniques concluded that a total dose of five hours is optimal for desired behaviour change in primary care settings.[120] Further research is warranted to determine if a greater dose of RESPOND would result in more favourable results, such as a reduction in falls injuries, ED re-presentations and hospitalisations, particularly for people who have had multiple falls.

In recognition that the RESPOND cohort was from a relatively high socioeconomic status, with a high level of health literacy, and by nature of the exclusion criteria within the RCT design, the cohort cannot be considered representative of the broader general population of older community-dwelling adults. There is a substantial proportion of people with limited English language skills, low health literacy ability, or mild cognitive deficits that are at risk of falls but were excluded from this RCT. It would be of value to include more diverse populations in future research, in order to draw conclusions related to the generalisability of the program for these often under-represented groups who present to public hospital EDs. At a minimum, this would likely necessitate the cultural and linguistic translation of RESPOND resources and the use of interpreters or family members to facilitate program delivery.

The RESPOND outcome evaluation showed that those who had experienced only one fall, rather than multiple falls, had better health outcomes. The prevalence of falls among middle-aged people, particularly among middle-aged women, has increased over time.[252] This supports a new way of thinking: that falls are not just a problem of old age, and that middle-age may be a critical life stage for implementing preventive interventions. Perhaps intervening at a younger age, using the RESPOND model, may be of benefit to a middle-aged population of people who experience a fall. With this in mind, and in the spirit of the gain-framed RESPOND message: 'Be Your Best', it may be worthwhile to explore primary prevention, rather than secondary prevention. The anticipated challenge with this may be the lack of perceived relevance and subsequent lack of engagement in 'falls prevention' services. This may, however, be mitigated using gain-framed positive health messages. Further research is indicated to determine if RESPOND is effective for

middle-aged people who experience a fall, or for those who have never experienced a fall but are at greater risk.

At the other end of the age spectrum, a limitation of the RESPOND RCT was that the maximum age to participate in the RESPOND RCT was 90 years as per the trial eligibility criteria. The 85 and older age group is the fastest growing proportion of Australia's population and this older age group should be included in future studies like RESPOND.

In the modern world, people of all ages are increasingly turning to technology for health information, advice and treatment. More than ever, older adults are accessing preventive health information from digital sources, such as the Internet.[156, 253] This leads to dual recommendations for future research: exploring technology as a means of delivering RESPOND; and the use of an e-health literacy measurement tool. Firstly, RESPOND module information, motivational reminders, progress trackers, and appointment reminders could be delivered using web-based platforms, email, or short message service (SMS) to mobile phones. Secondly, in recognition of the increasing reliance on internet-based health information, the developers of the HLQ have recently created the eHLQ.[254] This is a multidimensional tool designed to understand and evaluate people's interaction with digital services. It has been found to have construct validity and reliable measurement across Danish and English-speaking groups of adults.[254] Alternatively, the eHEALS[255] is a commonly used measure of health literacy. It has been validated in a number of populations and languages,[256-260] including a cohort of Australians at risk of cardiovascular disease (Appendix 5).[261]

An e-health literacy tool has not previously been validated specifically for a population of older community-dwelling people who present to ED with a fall. This information would help support the targeted use of electronic delivery of components of RESPOND, for those who would most likely benefit. This could also allow for a flexible approach to future implementation of RESPOND, as other evidence-based approaches emerge, allowing for program adaptations including the addition of further modules.

## 7.6 CONCLUSION

Falls among older community-dwelling people who experience a fall that results in a hospital ED presentation are a growing public health issue. The detrimental consequences on the individual, their families, the health system and society, are substantial. The critical success factors for a falls prevention program targeting this population, and the role of health literacy in falls outcomes have not previously been investigated. This thesis has presented innovative research to better understand these issues. Together, the process, impact, and outcome evaluations represent a comprehensive program evaluation that adds to the body of existing falls prevention literature.

This research has identified three key factors for the successful implementation of the RESPOND falls prevention program:

1) a person-centred approach;
2) adequate participation in falls prevention strategies; and
3) sufficient dose and implementation as soon after ED discharge as practical.

In addition, the HLQ is the first health literacy measurement tool to be validated for use with older people who have experienced a fall. It was shown to have good measurement properties when used with this patient group and enabled key health literacy constructs to be examined in the impact and outcome evaluation. The results from this thesis have the potential to make meaningful positive change to falls prevention services for older people presenting to ED after a fall, and provide useful information to guide clinicians, researchers, and policy makers in future implementations.

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# 9 APPENDICES

Appendix 1: Patient focus group interview guide

Appendix 2: Healthcare provider interview guide

Appendix 3: Participant experience survey (6 month)

Appendix 4: Protocol for an economic evaluation of RESPOND

Appendix 5: Rasch analyses of the HLQ and eHEALS

## 9.1 Appendix 1: Patient focus group interview guide

**RESPOND Intervention Participant Focus Group/Phone Interview Discussion Guide**

Each focus group will involve 8-10 participants being asked to respond to questions asked by a member of the research team relating to their experiences of participating in the RESPOND program. The one-on-one phone interview will be initiated by a member of the research team, and will be based on the same semi-structured questions as the focus group.

| QUESTION | PROMPTS |
|---|---|
| Tell us about your experience of participating in the RESPOND program | What went well (and why)<br>What did not go so well (and why)<br><br>Opinions about:<br>• Content (modules, education leaflets)<br>• Dosage (number, frequency and duration of phone calls, total duration of program)<br>• Delivery style (education, patient-centred goal setting, motivational interviewing, community linkage)<br>• Delivery mode (initial home visit and telephone follow up)<br>• Social supports to participate in RESPOND e.g. of family, friends, health professionals |
| In what ways has RESPOND impacted on your health and wellbeing? | • Perceived benefits eg:<br>• Knowledge of risk factors and management, local community services<br>• Physical and mental wellbeing |
| How could we improve the RESPOND program in the future? | • Improvement/ change to content, dosage, delivery<br>• Recruitment and delivery location (hospital v community-based, individual v group)<br>• Who is RESPOND best and for?<br>• Would you take part again?<br>• Would you recommend it to others? |

## 9.2 Appendix 2: Healthcare provider interview guide

RESPOND
Respond to the first fall to prevent the second

**Health Care Provider Interview Discussion Guide**

This study will include a detailed program evaluation to assess the effectiveness of implementation, and barriers and enablers to patient participation and sustained uptake of effective interventions. The program evaluation will include assessment of acceptability of the RESPOND program to participants and to health care providers. To gain information about on this, health care providers (RESPOND clinicians) will be invited to participate in a one-on-one interview with a member of the research team. Interview sessions will be conducted by a member of the RESPOND research team and will be recorded and transcribed. Thematic analysis will be used to summarise the obtained data.

Interviews will be conducted with each RESPOND clinician individually. They will be asked to respond to questions asked by a member of the research team relating to their experiences as RESPOND clinicians.

Clinician's specialist background: _____

| QUESTION | PROMPTS |
|---|---|
| What was your experience of delivering the RESPOND program? | Barriers and facilitators to delivery, and reasons why they are considered barriers or enablers<br><br>Opinions about:<br>• Content (modules, education leaflets)<br>• Dosage (number, frequency and duration of phone calls, total duration of program)<br>• Delivery style (education, patient-centred goal setting, motivational interviewing, community linkage)<br>• Delivery mode (initial home visit and telephone follow up)<br>• Training/ support/ resources received<br>• RESPOND program fit with existing community-based services (standard care) |
| What do you perceive are the main benefits for participants of the RESPOND program? | Specific aspects of the program:<br>• Content<br>• Dosage<br>• Delivery<br>• Physical and mental wellbeing |
| How do you see RESPOND being implemented in the future? | • Content, dosage, delivery<br>• Recruitment and delivery location (e.g. hospital v community-based)<br>• Who is RESPOND best and for/ not so good for?<br>• Transferability of program beyond falls prevention (i.e. other preventive health initiatives) |

## 9.3 Appendix 3: Participant experience survey (6 month)

RESPOND
Respond to the first fall to prevent the second

Participant ID:

**Participant Experience Survey**

<date>

Dear <participant>,

Thank you for your involvement in the RESPOND study so far. As you are aware, by agreeing to participate in this study you have the option to complete a 'participant experience' survey after your participation in the RESPOND program. The survey is only a brief set of questions with tick-boxes, and will involve questions regarding your experience of participating in the RESPOND program. It should take you less than 10 minutes to complete.

By completing the survey you will be assisting us in gathering information to further understand the strengths and weaknesses of the RESPOND program and factors that need to be addressed to improve delivery of services.

If you agree to participate please complete and return the attached survey to: rebecca.morris@monash.edu

If you have any further questions about the study or your participation please contact Rebecca Morris on (03) 9903 0620 or by email at rebecca.morris@monash.edu

RESPOND
Respond to the first fall to prevent the second

Participant ID:

| RESPOND Participant Experience Survey | Date survey completed: |
|---|---|

Thank you for your participation in the RESPOND Program. We seek your assistance in obtaining feedback about the program so we can improve it in the future. All responses are strictly confidential.

**1. Why did you choose to participate in the RESPOND program?**

_____
_____
_____
_____
_____
_____

**2. The information provided to me by the RESPOND clinician home visit and phone calls was relevant to me**

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

**3. The information provided was easy to understand**

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

**4. My RESPOND clinician paid attention to issues that are important to me**

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

**5. I felt that the RESPOND program met my needs**

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

RESPOND
Respond to the first fall to prevent the second

Participant ID:

**6. My RESPOND clinician helped me overcome any difficulties I had with achieving my goals**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

**7. The RESPOND program was beneficial to my health and wellbeing**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

**8. As a result of participation in RESPOND I know more about local community health services available to me**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

RESPOND
Respond to the first fall to prevent the second

Participant ID:

**9. Please tick the statement that you most agree with**

☐ I would prefer to only meet with my RESPOND clinician face-to-face

☐ I would prefer to only talk to my RESPOND clinician over the phone

☐ I would prefer to both meet my RESPOND clinician face-to-face and talk over the phone

☐ I would prefer to communicate with my RESPOND clinician in another way (e.g. email, SMS)

Please specify:

_____

_____

_____

**10. The number of telephone calls from my RESPOND clinician was**

☐ Just right

☐ Too many

☐ Not enough

**11. The RESPOND program length was**

☐ Just right

☐ Too long

☐ Too short

**12. Overall, I was satisfied with the RESPOND program**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

**13. I would recommend the RESPOND program to others**

| ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|
| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

RESPOND
Respond to the first fall to prevent the second

Participant ID:

**14. What aspect of the RESPOND program did you find most useful and why?**

_____
_____
_____
_____
_____
_____

**15. What aspect of the RESPOND program did you find least useful and why?**

_____
_____
_____
_____
_____
_____

**16. Are there any ways in which you think the RESPOND program can be improved?**

_____
_____
_____
_____
_____
_____

Please return the completed survey to rebecca.morris@monash.edu

**THANK YOU FOR COMPLETING THIS SURVEY**

## 9.4 Appendix 4: Protocol for an economic evaluation of RESPOND


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# RESPOND: a programme to prevent secondary falls in older people presenting to the emergency department with a fall: protocol for an economic evaluation

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**ABSTRACT**

**Background** Falls remain common for community-dwelling older people and impose a substantial economic burden to the healthcare system. RESPOND is a novel falls prevention programme that aims to reduce secondary falls and fall injuries among older people who present to a hospital emergency department (ED) with a fall. The present protocol describes a prospective economic evaluation examining the incremental cost-effectiveness of the RESPOND programme, compared with usual care practice, from the Australian health system perspective.

**Methods and design** This economic evaluation will recruit 528 participants from two major tertiary hospital EDs in Australia and will be undertaken alongside a multisite randomised controlled trial. Outcome and costing data will be collected for all participants over the 12-month trial. It will compare the RESPOND falls prevention programme with usual care practice (current community-based falls prevention practices) to determine its incremental cost-effectiveness according to three intermediate clinical outcomes: (1) falls prevented, (2) fall injuries prevented and (3) injurious falls prevented. In addition, utilities will be derived from a generic quality-of-life measure (EQ-5D-5L) and used to calculate the 'incremental cost per quality-adjusted life years gained'.

**Discussion** The results of this study will provide healthcare decision makers with evidence to assist with setting spending thresholds for preventive health programmes and inform selection of emergency and community service models of care.

**Trial registration number** The protocol for this study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000336684); Pre-results.

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## BACKGROUND

One-third of people aged 65 years and over fall annually and half of this cohort fall recurrently,[1] increasing their risk for functional impairment, health service utilisation, residential aged care admission and death.[2 3] Falls are the leading contributor to the economic burden of injury among the older population and the second largest contributor to lifetime costs in the USA and Australia.[4] In Australia, the total annual health costs from fall injuries have been predicted to triple between 2001 and 2051.[5] A US study concluded that the annual direct medical costs for non-fatal fall injuries in 2000 totalled US$19 billion.[6] Of these, 63% of the costs were for hospitalisations, 21% for emergency department (ED) visits and 16% for treatment in outpatient settings.

The ED is a major point of access to healthcare for older people. Twenty per cent of ED presentations by older people are fall related.[7] Of those, up to 52% will experience subsequent falls in the 6 months following an index fall presentation[8] and 49% will be rehospitalised.[9] Effective fall prevention programmes have the potential to result in substantial cost savings to the healthcare system.[10]

Evidence to support the effectiveness of programmes aimed to reduce secondary falls in older people presenting to the ED is limited,[8 11–20] with only one study examining the cost-effectiveness of such a programme.[16] This randomised controlled trial (RCT) (n=217) targeted people aged over 65 years who consulted their general practitioners (GP) or ED after a fall within the previous 3 months. The intervention included a multifactorial risk assessment, individually tailored intervention regimen (eg, withdrawal of psychotropic medication, balance and strength exercises by a physiotherapist; home hazard reduction by an occupational therapist; and referral to ophthalmologist or cardiologist) and reported similar results between the intervention and control groups, including mean of total healthcare costs and effects.

Health economic evaluations aim to examine the balance of costs and health effects of healthcare interventions, to inform efficient deployment of healthcare funding. Recent guidelines for conducting and reporting economic evaluation of fall prevention interventions recommend both a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) are conducted.[2] A CEA measures the consequences of the health intervention as clinical outcomes, such as falls and fall injuries, while a CUA measures the consequences using a preference-based measure, such as quality-adjusted life years (QALYs). Undertaking a CUA is considered to provide additional value as the measure of health effect is common and it can be more broadly applied by decision makers.[21]

This paper outlines the methods of an economic evaluation to be undertaken alongside the RESPOND RCT.[22] To determine the value of RESPOND to health service decision makers, it is imperative to establish whether it is cost-effective (as well as effective). It includes a CEA and CUA and is being conducted to inform resource allocation, practice change and investment in the RESPOND

programme by healthcare policy makers and hospitals, thus adopting a health system perspective.

## METHODS

### Design

This prospective economic evaluation is being conducted at two major tertiary hospitals in Australia: The Alfred Hospital, Victoria, and Royal Perth Hospital, Western Australia.[22] This trial-based economic evaluation will be undertaken over a one-year time horizon, to coincide with the duration of the RESPOND trial.[22] The methods for the RESPOND RCT have been described in detail elsewhere.[22]

The proposed evaluation will compare the RESPOND falls prevention programme with usual care (current community-based falls prevention practices) to determine its incremental cost-effectiveness according to three intermediate clinical outcomes: (1) falls prevented, (2) fall injuries prevented and (3) injurious falls prevented, and the economic outcome endpoint QALYs. Published guidelines for economic evaluations of falls prevention programmes[2] have been used to guide the methods of this evaluation.

This economic evaluation will be undertaken from the perspective of the Australian healthcare system, including all health services subsidised by state and federal governments. In Australia, state governments are largely responsible for funding public hospital services, while the federal government is responsible for funding community-based medical services (via the Medical Benefits Schedule, MBS);[23] that is, care delivered by GP and community-based specialists, as well as radiology and pathology services and specified allied health consultations and prescription medications (via the Pharmaceutical Benefits Schedule, PBS).[24]

### Study population

Data from all participants (n=528) recruited to the RESPOND RCT will be included in this economic evaluation. Inclusion criteria for the RESPOND RCT are as follows: aged 60–90 years, presented to the Alfred or Royal Perth Hospital EDs with a fall, planned discharge home within 72 hours, and living in the community. Exclusion criteria are as follows: unable to walk safely without hands-on assistance, discharged to a residential aged care facility, has a life expectancy of <12 months (as determined by the treating doctor), receiving palliative care, unable to use a telephone, need for an interpreter, cognitive impairment (based on a Mini Mental State Examination score of <23[25]), social aggression, a history of psychoses or living greater than 50 km from the participating hospitals.

### Sample size

The sample size for this evaluation is based on the clinical endpoints for the RESPOND RCT, powered to detect a 30% difference in the primary clinical outcomes of falls and fall injuries per person year, between intervention and control groups over a 12-month follow-up.[22]

### Randomisation

Participant flow through this economic evaluation is summarised in figure 1. Participants will be randomly assigned to the intervention or control group, following recruitment in the ED via a web-based randomisation sequence, using permuted block randomisation stratified by recruitment hospital. Participants and research staff will be blinded to group allocation until after a baseline assessment is completed.[22]

### Baseline assessment

Prior to concealment of group allocation, all participants will have a home-based assessment by a registered healthcare professional (within 2 weeks of discharge from hospital). At this visit, data will be collected on participant demographics, social history, index and past fall history, falls risk profile (using the Falls Risk for Older People in the Community assessment tool, FROP-Com) and health-related quality of life (using the EQ-5D-5L).[26] Following baseline assessment, a simple letter detailing the participant's risk status will be provided to the GP of all participants.

### Intervention: the RESPOND programme

RESPOND is a patient-centred, multifactorial falls prevention programme, designed to reduce secondary falls and fall injuries in older people who present to the ED with a fall or fall-related problem.[22] All participants in the intervention group will be offered the RESPOND programme, delivered by a trained healthcare professional (RESPOND clinician).

The programme has been described in detail elsewhere,[22] according to the CONSORT extension Template for Intervention Description and Replication guidelines.[27]

Briefly, the programme targets four risk key factors: poor balance and/or loss of strength, vision impairment, long-time use of benzodiazepines or z-drugs and poor bone health. It incorporates (1) home-based risk factor assessment; (2) education, goal setting, coaching and follow-up telephone support for management of one or more of the four risk factors; and (3) linkage to existing community services that meet participant goals. Motivational interviewing, delivered by trained healthcare providers, will be used to facilitate participant choice and engagement and to assist the identification of barriers to participation.

The intervention will commence with a face-to-face home visit, following baseline assessment (45 min), with subsequent coaching on strategies to support uptake and adherence with recommended intervention conducted over the telephone.

### Comparator

Control participants will undergo the same baseline home assessment as the intervention participants. However, no further intervention will be offered to participants in the control group. They are able to access all usual services within the ED and community, including referrals to community-based healthcare professionals and falls prevention programmes. No treatment recommendations by participant's treating healthcare professionals will be withheld from the control group.

### Measurement

Participants will be followed for 12 months following trial recruitment and randomisation (defined as 365 days of follow-up). Participants will be asked to complete a daily calendar and return this in a reply-paid envelope to the research office on a monthly basis. The calendars will be verified with monthly telephone follow-up by members of the research team. Box 1 provides a summary of data collected in the participant calendars. To ensure blinding during data collection, measurements by telephone at baseline, 6 and 12 months will be undertaken by an independent-blinded outcome assessor using standardised assessment and data collection tools.

### Measurement of clinical and economic endpoints

The primary clinical outcome measures used will be number of 'falls' and 'fall injuries' per person years, as per the RESPOND

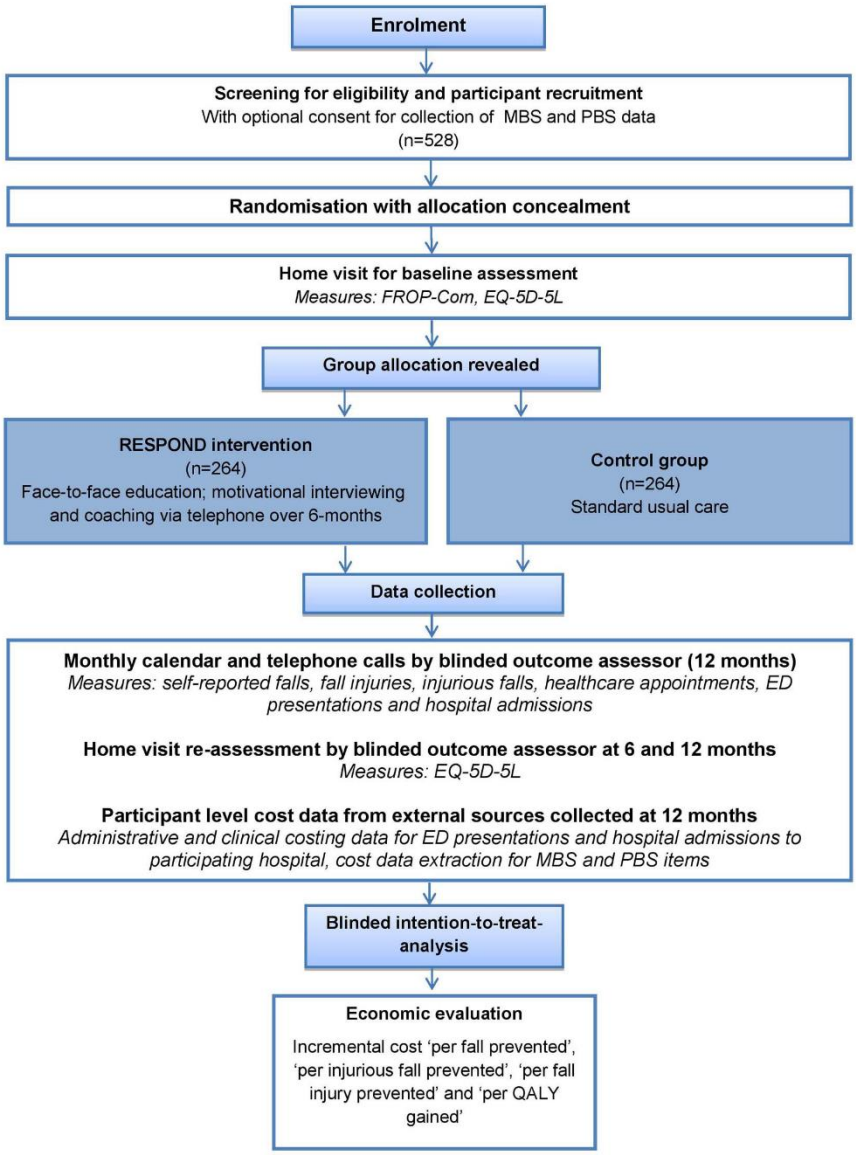


**Figure 1** Participant flow: RESPOND RCT and economic evaluation. ED, emergency department; EQ-5D-5L, health-related quality-of-life questionnaire; FROP-Com, Falls Risk for Older People in the Community assessment tool; MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Scheme; QALY, quality-adjusted life year.

RCT.[22] In addition, 'injurious falls' per person years will be estimated.

A *fall* will be defined as 'an event resulting in a person coming to rest inadvertently on the ground, floor or other lower level'.[28] An *injurious fall* defined as a fall resulting in at least one injury, where a *fall injury* will be defined as 'any physical harm resulting from a fall (including bruising, abrasions, lacerations and fractures)'.[29] Fall and fall injury data will be prospectively collected as part of the RESPOND RCT from monthly participant calendars (box 1) and verified by telephone.

*Health-related quality of life* will be measured using the EQ-5D-5L,[26] administered at baseline, 6-month and 12-month follow-up assessment. The EQ-5D-5L is a commonly used multi-attribute utility instrument that provides a single value for health-related quality of life.[30]

### Measurement of costs

Using the healthcare system perspective, this study will include all costs associated with implementing and delivering the RESPOND

**Box 1 Summary of economic data-related questions included in the participant calendar**

*Falls and fall injury record*
What time was your fall?
Where did the fall occur?
What were you doing immediately prior to the fall?
Did you sustain an injury from the fall?
What type of injury did you sustain and where was it located?
Did you seek medical attention as a result of the fall? If so what type?

*ED presentation record*
Which hospital ED did you attend?
Were you taken to the ED by ambulance?
How long did you spend in the ED? _____ (hours)
Were you admitted into hospital from the ED?

*Hospital admission record*
Which hospital did you attend?
How long did you spend in this hospital? _____ (days)
Were you taken to hospital by ambulance?
Were you discharged directly home or into the care of a friend or family member from this hospital?
Were you transferred to a rehabilitation hospital? _____ (days)
Were you transferred to respite? _____ (days)
Were you transferred to another facility? _____ (days)

*Outpatient healthcare appointment record*
Please indicate if you have used any of the following healthcare services over the past month?
- Falls specialist/clinic
- General practitioner
- Geriatrician
- Occupational therapist
- Optometrist
- Ophthalmologist
- Pharmacist
- Physiotherapist
- Podiatrist

How many times have you used this service in the last month? _____ (total number)

programme, including all healthcare and associated costs incurred by the participant during the trial period (table 1).

### Direct costs of delivering the RESPOND programme

Intervention costs will reflect all resource costs associated with running the RESPOND programme, including clinician time to deliver programme activities, programme development costs (staff training and development of intervention protocols) and ongoing support of RESPOND clinicians. Cost categories will include staff costs (RESPOND clinicians), space, capital, overheads and consumables (such as educational material). Staff costs will be based on state-specific (Victoria and Western Australia) award wage schedules. Space, capital and overheads costs will be valued using market prices and depreciation rates.

### Direct health costs arising from health behaviours of RESPOND participants

Healthcare utilisation and associated costs will be ascertained for the 12-month trial period for both intervention and control participants. Due to the multimorbidity that is often associated with falls, it is not feasible to determine which costs are directly associated with a fall. Therefore, all healthcare costs or savings incurred throughout the trial period will be included.

Costing of healthcare utilisation data will be estimated using a number of methods. Where participants presented or were admitted to one of the participating hospital sites, ED presentation and inpatient hospitalisation costs will be obtained from the hospitals' clinical costing systems[31] and triangulated with data captured by monthly calendars and telephone calls. In Australia, many hospitals use sophisticated clinical costing systems to determine patient-level costs. Resources directly employed for a patient are assigned to an individual patient episode,[32 33] generally using a 'bottom–up' costing approach to aggregate costs at the patient level.[32] National clinical costing standards for hospital cost data were developed in 2010[34] and recently updated in 2014.[35] Where participants present or are admitted to non-participating hospitals, hospitalisation costs will be calculated using length of stay and published costing data from the Independent Hospital Pricing Authority.[35] If a participant arrives to ED or hospital via ambulance, ambulance transport costs will be calculated using modelled rates per case, based on data from a study conducted by Watts and colleagues.[36] Unit costs for community-based healthcare services will be extracted from relevant MBS and PBS items,[23 24] for which there are fixed fee schedules. Costs will be expressed in Australian dollars ($A) and referenced to the year 2016 based on published Australian health price indices.[37]

### Exclusion of trial costs

All research costs related to the RESPOND trial will be excluded. These include those associated with trial administration, data collection and measurement of outcomes (including those undertaken in the baseline, 6 and 12-month home assessments) as per the trial protocol. Costs incurred by the control group for performing the baseline home assessment will not be included in the cost analysis, as they are not normally part of usual care practice and will only be undertaken for the purpose of the trial.

### Data analysis

The primary outcomes of the CEA will be 'cost per fall prevented' and 'cost per fall injury prevented', and secondary outcome 'cost per injurious fall prevented' (table 2). Differences in mean total costs (C) and effects (E) between the intervention and control groups will be calculated to generate an incremental cost-effectiveness ratio (ICER=[C1−C2]/[E1−E2]) per outcome, where C1 and E1 are the cost and effect in the intervention group and C2 and E2 are the cost and effect in the comparator group. This will allow for comparison with other similar economic evaluations of falls prevention programmes. A statistician, blinded to group allocation, will undertake the intention-to-treat (ITT) outcome analysis, as per methods specified for the primary analysis of the RCT.[22] For both the intervention and control groups, mean costs and effects will be reported, along with measures of variability and precision. Differences will be compared between groups adjusting for clustering by patient and hospital site.[38]

A CUA will be conducted comparing the cost per QALY gained in the intervention with the control group to ascertain cost or saving per QALY gained (table 2). Utility scores from the EQ-5D-5L will be converted into a utility index using Australian adult weights[39] and expressed as a QALY.

**Table 1** Economic evaluation cost items for inclusion in this study

| Cost component | Cost item | | Cost unit | Data sources |
|---|---|---|---|---|
| Direct costs of delivering the RESPOND programme | RESPOND programme implementation and monitoring | Staff salary and expenses to develop programme material and intervention protocols. Staff training and clinician support sessions | Staff time (in minutes) multiplied by relevant wage rates* | Trial administrative and financial records |
| | RESPOND programme delivery | Staff salary and expenses to deliver programme activities, including initial home visit, follow-up telephone coaching sessions, community linkage and service referrals, travel and travel time | Staff time (in minutes) multiplied by relevant wage rates* | RESPOND clinician resource utilisation captured on the RESPOND trial electronic database at each clinical contact |
| | | Consumables, including publishing of intervention protocols and clinician training and participant educational material | $A | Trial administrative and financial records, publishing cost |
| | | Capital, including equipment required for delivery of the programme (such as telephones, iPads and computers) | $A/new price depreciated by expected life of equipment or $A/rental price multiplied by time period | Trial financial records, manufacturers, consumer price index |
| | | Overheads and space | $A | Trial administrative and financial records |
| Healthcare resource utilisation costs | ED presentations† | Including ambulance, nursing costs, pharmacy, procedures and overheads | $A/ED presentation | Hospital computerised clinical costing system, participant monthly calendars |
| | Inpatient hospital admissions† | Including ambulance, nursing care, allied health, medical care, critical care, operating theatre, pharmacy, radiology, pathology and specialised procedural suites and overheads | $A/hospital admission | Hospital computerised clinical costing system, participant monthly calendars |
| | Community-based healthcare services | Including GP and other healthcare professionals such as allied health and falls specialist clinics | $A/visit | Fee for service based on Medicare Benefit Schedule items and/or participant monthly calendars |
| | Additional healthcare costs | Pharmacy and medications | $A/unit | Pharmaceutical Benefit Schedule |

*Note all wage rates will include salary on-costs for superannuation and leave loading.
†Hospital and ED cost items will include overhead costs (cleaning, heating, lighting, laundry, food, administration, orderlies, computing and telephone costs).
ED, emergency department, GP, general practitioner.

**Table 2** Economic evaluation analyses

**RESPOND falls prevention programme versus usual care practice**

| Analysis | Incremental costs | Incremental effectiveness | Incremental cost-effectiveness ($A) |
|---|---|---|---|
| Incremental cost-effectiveness analysis | $A | Falls prevented | Cost per fall prevented |
| | $A | Injurious fall prevented | Cost per injurious fall prevented |
| | $A | Fall injuries prevented | Cost per fall injury prevented |
| Incremental cost-utility analysis | $A | Quality-adjusted life year gained | Cost per quality-adjusted life year gained |

Bootstrap resampling will be used to calculate a 95% confidence ellipse around the cost-effectiveness point estimate and to generate cost-effectiveness acceptability curves. Statistical significance will be reported as $p<0.05$ for all analyses, and costs will be reported in $A.

### Sensitivity analysis

Sensitivity analyses (one way and multi way) will be undertaken to examine the robustness of the results to a range of cost and effect estimates, using 95% CIs for the parameters of interest (such as programme and healthcare utilisation costs, fall, injurious fall, fall injury and quality-of-life estimates). This may include adjusting for potential baseline predictive variables such as age and cognitive ability (using FROP-Com cognitive status score obtained at baseline assessment), if differences between groups exist that may confound cost comparisons.

### Ethics approval

Ethics approval was obtained from each participating hospital site, Alfred Health (HREC 439/13) and Royal Perth Hospital (REG 13-128) and Monash University Human Research Ethics Committee (MUHREC CF13/3869-201300).

## DISCUSSION

This paper describes the protocol for an economic evaluation that aims to determine the cost-effectiveness of the RESPOND falls prevention programme. This economic evaluation has a number of methodological strengths. It will be undertaken prospectively alongside a RCT. This allows for economic involvement through the planning, design, data collection and analysis stages of the trial.[21 40] The RESPOND trial aims to control for predictable sources of bias and confounding through concealed random allocation to groups, quality control of data integrity and blinded outcome and ITT analysis.[22] Prospective measurement of effects and costs includes comprehensive data collection, triangulated from a number of sources, such as participant-completed calendars, verified by monthly telephone calls, hospital clinical costing, and MBS and PBS data, to enhance capture of effect and cost outcomes. In addition, this is a multisite trial, being undertaken across two states, allowing for greater generalisability to the Australian population than would be possible from a single-state study.

Few economic evaluations of fall prevention programmes conduct both a CEA and CUA; however, incorporating both types of analyses increases the depth and value of this study. A

CEA allows decision makers to decide among similar falls prevention programmes because the lowest incremental cost per fall prevented can be identified. A CUA can be useful for managing the broader healthcare budget through the comparison of QALYs for all types of health services, not just fall prevention initiatives. The tool chosen to measure quality of life, the EQ-5D-5L, is brief and simple to use, and has been documented as being valid, reliable and sensitive to change in the quality-of-life literature.[41 42] In addition, the use of QALYs as an outcome is widespread internationally, allowing for greater transferability of results across countries.

Some methodological limitations should be noted. Economic evaluations can take a number of different perspectives, depending on the decision to be informed.[4] Since economic evaluations are often used by decision makers to assess the relative efficacy of alternative healthcare interventions, the commonly taken perspective is that of the healthcare system.[43] However, because health economics is concerned with society's welfare, it can be argued that an economic evaluation should include the impact of an intervention on the welfare of society as a whole,[44] measuring all costs relevant to society, including direct and indirect costs borne by fallers, their carers and families. However, the societal perspective can increase participant burden, and may lead to inaccurate or incomplete data collection.[21] The healthcare system perspective chosen for this economic evaluation will provide sufficient information to inform decision making surrounding investment in the RESPOND falls prevention programme.

The EQ-5D-5L was chosen as the measure for quality of life for the RESPOND trial; however, it may not be sensitive enough to detect change in this population group within the study period.[2] Disease-specific quality-of-life instruments are often more responsive to changes within a specific population, particularly in acute health status. However, they do not enable direct comparisons between outcomes for patients across different populations. Currently, there is no disease-specific instrument for assessing health status after a fall. If there are found to be no differences in this generic quality-of-life measure across the groups, a modelled economic evaluation may be considered, where the incremental cost-effectiveness of the programme over a life time horizon is used to determine the incremental cost per QALY gained.

## CONCLUSION

The results of this economic evaluation will add to the existing limited body of literature regarding the cost-effectiveness of fall prevention programmes. Results will assist policy makers, healthcare managers and other health service decision makers to inform decisions regarding the ongoing use or future implementation of the RESPOND programme. If this economic evaluation finds RESPOND to be cost-effective, then it could be advocated as an efficient fall prevention programme and potentially implemented as part of fall prevention services in Australia and worldwide.

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# RESPOND: a programme to prevent secondary falls in older people presenting to the emergency department with a fall: protocol for an economic evaluation

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## 9.5 Appendix 5: Rasch analyses of the HLQ and eHEALS

PLOS ONE

RESEARCH ARTICLE

# Examination of an eHealth literacy scale and a health literacy scale in a population with moderate to high cardiovascular risk: Rasch analyses

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## Abstract

### Introduction

Electronic health (eHealth) strategies are evolving making it important to have valid scales to assess eHealth and health literacy. Item response theory methods, such as the Rasch measurement model, are increasingly used for the psychometric evaluation of scales. This paper aims to examine the internal construct validity of an eHealth and health literacy scale using Rasch analysis in a population with moderate to high cardiovascular disease risk.

### Methods

The first 397 participants of the CONNECT study completed the electronic health Literacy Scale (eHEALS) and the Health Literacy Questionnaire (HLQ). Overall Rasch model fit as well as five key psychometric properties were analysed: unidimensionality, response thresholds, targeting, differential item functioning and internal consistency.

### Results

The eHEALS had good overall model fit ($\chi^2 = 54.8$, $p = 0.06$), ordered response thresholds, reasonable targeting and good internal consistency (person separation index (PSI) 0.90). It did, however, appear to measure two constructs of eHealth literacy. The HLQ subscales (except subscale 5) did not fit the Rasch model ($\chi^2$: 18.18–60.60, p: 0.00–0.58) and had sub-optimal targeting for most subscales. Subscales 6 to 9 displayed disordered thresholds indicating participants had difficulty distinguishing between response options. All subscales did, nonetheless, demonstrate moderate to good internal consistency (PSI: 0.62–0.82).

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## Conclusion

Rasch analyses demonstrated that the eHEALS has good measures of internal construct validity although it appears to capture different aspects of eHealth literacy (e.g. using eHealth and understanding eHealth). Whilst further studies are required to confirm this finding, it may be necessary for these constructs of the eHEALS to be scored separately. The nine HLQ subscales were shown to measure a single construct of health literacy. However, participants' scores may not represent their actual level of ability, as distinction between response categories was unclear for the last four subscales. Reducing the response categories of these subscales may improve the ability of the HLQ to distinguish between different levels of health literacy.

## Introduction

For patients to be able to optimally manage their health, they require an adequate level of understanding about their condition and associated management strategies [1–3]. This is related to an individual's level of health literacy and is an increasingly important area of research particularly in people with chronic disease. Cardiovascular disease (CVD), for example, is a major health burden for patients and often requires life-long behaviour changes across multiple risk factors [4]. CVD management depends on active patient participation, which requires a sufficient level of health literacy [5]. It has been shown that patients with CVD that have a low level of health literacy are less likely to adhere to prescribed medications [4–6]. Similarly, lack of adherence to prescribed medication has also been found to be associated with inadequate or marginal health literacy [4].

Electronic health (eHealth) literacy has become increasingly relevant in recent years with the development of eHealth tools to support healthcare delivery and management [7–9]. However, with these innovative developments eHealth literacy becomes an equally important area of investigation. eHealth literacy is defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" [10]. The additional challenge of eHealth relates to the skills required to use an electronic device as well as having an adequate level of health literacy to effectively make decisions regarding health [2,9]. In order to ensure the existing scales for health and eHealth literacy are clinically applicable, it therefore becomes important to examine how they perform in various populations when developing, evaluating and implementing health management strategies.

Several scales can be used to measure health literacy such as the Test of Functional Health Literacy in Adults (TOFHLA) [11] and the Rapid Estimate of Adult Literacy in Medicine (REALM) [12]. However, these scales assess different areas of health literacy which means that an individual can have a very different level of health literacy depending on the scale used [13]. A more comprehensive measure of health literacy is the Health Literacy Questionnaire (HLQ) [14]. In contrast, there are currently very few scales available to evaluate eHealth literacy [7]. One such scale is the electronic Health Literacy Scale (eHEALS) [15]. The psychometric properties of both the eHEALS and the HLQ have been examined using classical test theory and item response theory methods. Prior studies using confirmatory factor analysis (CFA) have demonstrated the eHEALS to be a valid and reliable scale [16,17]. More recent item response theory studies have confirmed these findings [18,19] and demonstrated that the scale measures the same underlying concept or construct. However, a recent study found that the eHEALS

was not able to capture the full range of eHealth literacy levels in their study population (i.e. ceiling and floor effects) [18]. The factor structure of the HLQ has also been tested with CFA and three subscales tested were found to be measuring the same underlying construct [19]. It has also demonstrated satisfactory reliability [14]. However discrimination between response categories was questioned for three of the nine scales [14,20], suggesting that response categories could be revised to improve the scales measurement properties.

There is growing evidence to indicate that the Rasch measurement model, which measures a scale's internal construct validity, is the gold standard for psychometric evaluations of outcome scales [21]. Rasch analysis has several well-recognised advantages over classical test theory including analysis of item summation legitimacy, response category distinction, hierarchical structure of item difficulty and discrepancies in item response for a given level of ability [22,23], which all strengthen scale construct validation. Having valid scales is particularly relevant in a population at risk for CVD where an adequate level of health literacy has been shown to improve effective patient disease management [24]. Moreover, there has not yet been a Rasch validation study in a population with CVD. Given that CFA may not fully resolve issues associated with the conceptual structures of psychological scales such as health literacy [20], further evaluation using the Rasch measurement model is required to extend the current knowledge on the validity of these scales. The aim of this study was to extend prior validation studies by examining the internal construct validity of an eHealth and a health literacy scale using Rasch analysis to provide clinicians and researchers with information on the usefulness of these scales.

## Materials and methods

### Design

The internal construct validity of the eHEALS and the HLQ was analysed using Rasch analysis in a population with moderate to high CVD risk. The first 397 consented participants in the CONNECT (Consumer Navigation of Electronic Cardiovascular Tools) Study [25] comprised the sample and completed the eHEALS and HLQ scales. All participants provided written, informed consent and ethical approval was obtained from the University of Sydney Human Research Ethics Committee (Project number 2013/091).

### Participants and setting

Details of the CONNECT Study have been published elsewhere [25]. In brief, it is a randomised controlled trial examining whether an eHealth strategy improves risk factor control when compared with usual health care in patients at risk of or with CVD. Participants were recruited via Australian primary care practices. To be eligible, they had to be 18 years or older, have access to the Internet at least once a month (mobile phone, tablet or computer) and have moderate to high risk for CVD. Moderate to high CVD risk was defined as (a) $\geq$ 10% 5-year CVD risk using the Framingham risk equation; (b) a clinically high risk condition (Aboriginal or Torres Strait Islander $>$ 75 years, diabetes and $>$60 years, diabetes and albuminuria, estimated glomerular filtration rate $<$ 45 ml/min, systolic blood pressure $\geq$180 mmHg, diastolic blood pressure $\geq$110 mmHg, total cholesterol $>$ 7.5 millimol); (c) an established CVD diagnosis (ischaemic heart disease, stroke/transient ischaemic attack, peripheral vascular disease). Participants with an insufficient level of English to provide informed consent or severe intellectual disability were excluded.

### Scales used for assessment of eHealth literacy and general health literacy

The eHEALS was used to assess eHealth literacy (Study 1). This scale aims to measure an individual's perception of their knowledge and skills in relation to using electronic health

information and determine whether an eHealth approach is suited to the individual [15,26]. It is an 8-item scale with each item scored on a 5-point Likert scale (Table 1). The sum across the eight equally weighted items is presented as a score out of 40. There is no fixed cut-off to distinguish high from low eHealth literacy but higher scores reflect a higher level of eHealth literacy [15,27]. The scale was completed online directly by participants themselves.

The HLQ was used to assess health literacy (Study 2). This scale aims to measure an individual's capacity to effectively use health information and services [14]. It is a 44-item questionnaire with 9 subscales (Table 1). Subscales 1 to 5 are scored on a 4-point Likert scale while the subscales 6 to 9 are 5-point Likert scale. The score for the items in each subscale is summed and divided by the number of items providing nine individual scores. There is no total score across subscales. Although there are no fixed values to classify the level of health literacy, similar to the eHEALS, higher scores indicate higher health literacy in all subscales [14,28].

## Model used to assess psychometric properties

The Rasch model was used to examine the psychometric properties of the eHEALS and HLQ. Rasch analysis is a form of item response theory, where the ordinal ratings of the questionnaire are transformed to estimates of interval measures that demonstrate the essential features of the scale [23]. Analysis with the Rasch model provides difficulty measures for each item and ability estimates for each participant located on the same measurement scale as a log of the odds units, or logits. This allows expected and observed results to be compared and the internal construct validity of each item to be determined [23]. This will determine how well the items and participants fit the Rasch model i.e. overall model fit. We also examined five key psychometric parameters detailed in Table 2. To ensure an appropriate degree of precision from the Rasch analysis, a minimum sample size between 108 to 243 participants is required [29].

**Table 1. Description of the eHEALS (electronic Health Literacy Scale) items and HLQ (Health Literacy Questionnaire) subscales.**

| | |
|---|---|
| **eHEALS** | |
| Item 1[a] | I know what health resources are available on the Internet |
| Item 2[a] | I know where to find helpful health resources on the Internet |
| Item 3[a] | I know how to find helpful health resources on the Internet |
| Item 4[a] | I know how to use the Internet to answer my questions about health |
| Item 5[a] | I know how to use the health information I find on the Internet to help me |
| Item 6[a] | I have the skills I need to evaluate the health resources I find on the Internet |
| Item 7[a] | I can tell high quality health resources from low quality health resources on the Internet |
| Item 8[a] | I feel confident in using information from the Internet to make health decisions |
| **HLQ** | |
| Subscale 1[b] | Feeling understood and supported by healthcare provider (4 items) |
| Subscale 2[b] | Having sufficient information to manage my health (4 items) |
| Subscale 3[b] | Actively managing my health (5 items) |
| Subscale 4[b] | Social Support for health (5 items) |
| Subscale 5[b] | Appraisal of health information (5 items) |
| Subscale 6[c] | Ability to actively engage with healthcare providers (5 items) |
| Subscale 7[c] | Navigating the healthcare system (6 items) |
| Subscale 8[c] | Ability to find good health information (5 items) |
| Subscale 9[c] | Understanding health information well enough to know what to do (5 items) |

[a]Response categories: strongly disagree, disagree, undecided, agree, and strongly agree.
[b]Response categories: strongly disagree, disagree, agree, and strongly agree.
[c]Response categories: cannot do, very difficult, quite difficult, quite easy and very easy.

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**Table 2. Description of the five key psychometric parameters assessed in a Rasch analysis to test the psychometric properties of a scale.**

| Parameter | Definition/Aim | Measurement |
|---|---|---|
| **Unidimensionality** | The extent to which the items of a scale measure a single construct (or concept). All items must measure a single construct for them to be summed. | Subsets of items were defined by positive and negative loadings on the first factor extracted using a principal component analysis of residuals [21,23,30]. Independent t-tests were then used to compare person estimates derived from the two most dissimilar subsets of scale items. The scale was unidimensional if independent t-test <0.05 i.e. less than 5% show a significant difference between their scores on the two subsets. If t-test >0.05, the value of 5% should fall within the 95% CI around the t-test estimate calculated with a binomial test of proportions [23,31] |
| **Response Thresholds** | Reflects the distance between response categories to determine whether participants had difficulty discriminating between them | Category probability curves [23] were used to identify the presence of disordered thresholds and attempts to order them were made by collapsing response categories. Response categories were deemed ordered when each response systematically had a point along the location/ability continuum where it was the most likely response (indicated by a peak in the curve) |
| **Targeting** | Representation of the extent to which the spread of items reflects the levels of ability (e.g. health literacy) within the sample. | Person-item threshold distribution maps, which reflect the mean location score obtained for the persons with that of the value of zero, [23] were analysed for (1) the presence of ceiling/floor effects i.e. whether extremes of ability were not accounted for by the scale, (2) to ensure that all mid-ranges of health literacy were also represented. A mean location for the persons would be around zero for a well-targeted scale. Positive mean value for the persons indicates that the sample is overqualified for the scale (e.g. have higher health literacy) and negative values, the opposite. [23] |
| **Differential Item Functioning (DIF)** | Demonstrates whether different groups with equal ability score a given item differently | Analysis of variance with a Bonferonni adjusted alpha level ($p < 0.05/(2*\text{items})$ [23]. Subgroups analysed: age (<64, 64–69, >69 years), gender (male or female), polypharmacy (active consumption of >4 or <4 medications), level of education (none/primary/secondary, university studies or technical/vocational training). Uniform DIF is indicated by a significant main effect for the person factor (e.g. age) and can be remedied by calibrating the item for each group [23]. Non-uniform DIF is indicated by a significant interaction effect and often indicates that there may be an issue around item fit [23] |
| **Person Separation Index (PSI)** | Reflects the internal consistency of the scale and the extent to which items distinguish between levels of health literacy (analogous to Crohnbach α) | PSI between 0.70–0.90 [23] with >0.90 indicating possible item redundancy |

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## Analysis

The CONNECT data were analysed using IBM SPSS Statistics 22.0 (IBM SPSS Statistics for Windows Armonk, NY: IBM Corp), with the Rasch analysis completed using the RUMM2030 package using a partial credit model for polytomous data (RUMM Laboratory Pty Ltd, Perth, Australia). Given that both the 8-item eHEALS and HLQ have multiple response category options (e.g. 'strongly disagree' to 'strongly agree'), a partial credit Rasch model was used to examine the internal construct validity of both scales, which is not possible with, for example, a two-parameter logistic (2PL) model. [21] To determine whether the observed data fit the expectations of the Rasch model (overall model fit) the item-trait interaction statistic was used, which were reported as a $\chi^2$ statistic. A significant value ($p<0.05$) indicated that the observed data did not fit the expectations of the Rasch model [23]. It is important to keep in mind that the $\chi^2$ test is sensitive to sample size, with larger samples having a tendency to generate a significant value [32]. Model fit was also assessed by examining item-person interaction statistics, where a residual standard deviation (SD) of >1.5 suggested there may be an issue with fit [23,33]

as well as residual fit statistics of individual item- and person-fit statistic where values > ± 2.5 [33] indicated misfitting items or persons. The details of the five key psychometric parameters assessed are described in Table 2 [27].

## Results

Demographic characteristics of the 397 consenting participants are presented in Table 3. Three-quarters of the sample were male, with a mean age of 66.3 years (SD 8.1), 88% were Caucasian and the majority (79%) were married or in a defacto relationship. Due to incomplete scale completion, one participant was removed from both the eHEALS and HLQ for the Rasch analysis. The mean total score for the eHEALS was 27.1 (range: 8–40; SD 6.67), 3.03 (range: 1–4; SD 0.52) for the first five HLQ subscales and 4.19 (range: 1–5; SD 0.47) for subscales 6 to 9 (Table 4).

### Study 1: eHEALS

The eHEALS met the Rasch model expectations as demonstrated by the $\chi^2$ item-trait interaction statistic (p: 0.06) (Table 4). The scale did, however, indicate some degree of item misfit (fit residual mean -0.65, SD 2.31) and person misfit (fit residual mean -0.81; SD 1.69) as reflected in the item-interaction statistics [23]. Individual person-fit statistics also revealed several participants with fit residuals > ±2.5, which could be due to the scale's limitation of detecting mid to high levels of eHealth literacy (see 'Targeting' lower down).

**Table 3. Demographic characteristics of cohort.**

| Variable | | N = 397 (%) |
|---|---|---|
| **Male, n (%)** | | 304 (77) |
| **Age (years)** | | |
| | <64, n (%) | 122 (31) |
| | 64–69, n (%) | 149 (37) |
| | ≥70, n (%) | 126 (32) |
| **Ethnicity** | | |
| | Caucasian, n (%) | 353 (89) |
| | Non-Caucasian[a], n (%) | 44 (11) |
| **Relationship status** | | |
| | Married/Defacto, n (%) | 316 (80) |
| | Single/Divorced/Widowed, n (%) | 80 (20) |
| | Missing, n (%) | 1 (0.3%) |
| **Education qualification** | | |
| | None/Primary/Secondary school, n (%) | 108 (27) |
| | Undergraduate/Postgraduate degree or diploma, n (%) | 208 (52) |
| | Technical/vocational qualification, n (%) | 81 (20) |
| **Polypharmacy[b]** | | 165 (42) |
| **Home/work access to Internet** | | 392 (99) |
| **Income** | | |
| | $ <1,000 per week, n (%) | 109 (28) |
| | $ 1,000–2,000 per week, n (%) | 126 (32) |
| | $ >2,000 per week, n (%) | 113 (29) |
| | Participant chose not to answer, n (%) | 49 (12) |
| **Private health insurance, n (%)** | | 322 (81) |

[a]Aboriginal/Torres Strait Islander/Pacific Islander/South Asian/Other Asia/Middle East/Mediterranean/Other.
[b]Active consumption of >4 medications.

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**Table 4. Mean scores and overall Rasch model fit statistics, unidimensionality, thresholds and internal consistency of electronic Health Literacy Scale (HEALS) and Health Literacy Questionnaire (HLQ)[a].**

| | Ideal | eHEALS | HLQ-1 | HLQ-2 | HLQ-3 | HLQ-4 | HLQ-5 | HLQ-6 | HLQ-7 | HLQ-8 | HLQ-9 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Mean scores (±SD) | N/A | 27.1 (6.67) | 3.38 (0.45) | 2.93 (0.47) | 2.90 (0.48) | 3.12 (0.48) | 2.79 (0.53) | 4.29 (0.52) | 4.12 (0.55) | 4.07 (0.56) | 4.28 (0.47) |
| Total item-trait interaction | | | | | | | | | | | |
| Total item $\chi^2$ | | 54.80 | 27.10 | 51.58 | 46.97 | 30.51 | 18.18 | 15.64 | 60.60 | 36.24 | 23.72 |
| df | | 40 | 4 | 8 | 15 | 10 | 20 | 5 | 24 | 10 | 10 |
| p-value | >0.05 | 0.06 | 0.00 | 0.00 | 0.00 | 0.00 | 0.58 | 0.01 | 0.00 | 0.00 | 0.01 |
| Items | | | | | | | | | | | |
| Fit residual (mean) | 0 | -0.65 | -2.8 | -2.61 | -2.58 | -2.27 | -0.9 | -3.06 | -1.72 | -2.56 | -2.58 |
| Fit residual (SD)[c] | <1.5 | 2.31 | 0.68[b] | 1.74 | 2.34 [b] | 2.19[b] | 1.35[b] | 0.79[b] | 2..51[b] | 0.63[b] | 1.01[b] |
| Persons | | | | | | | | | | | |
| Fit residual (mean) | 0 | -0.81 | -0.68 | -0.74 | -1.02 | -0.94 | -0.76 | -0.96 | -0.80 | -0.89 | -1.01 |
| Fit residual (SD)[c] | <1.5 | 1.69 | 0.72 | 0.89 | 1.52[b] | 1.43[b] | 1.43[b] | 1.15 | 1.19[b] | 1.16 | 1.41 |
| Unidimensionality | | | | | | | | | | | |
| % signification t-tests | <5% | 12.60% | 1.52% | 3.54% | 4.04% | 3.79% | 4.81% | 5.05% | 2.02% | 3.79% | 11.10% |
| (CI) | (lower limit <5%) | (0.11 to 0.15) | (-0.01 to 3.7) | (1.4 to 5.7) | (1.0 to 6.2) | (1.6 to 5.9) | (2.7 to 6.9) | (2.9 to 7.2) | (1.0 to 4.2) | (1.6 to 5.9) | (9.0 to 13.3) |
| Thresholds (Disordered items) | Ordered | Ordered | Ordered | Ordered | Ordered | Ordered | Ordered | Disordered (25) | Disordered (24, 34, 42) | Disordered (26, 29, 33, 41) | Disordered (28, 35, 40, 44) |
| Person-separation index[c] | >0.70 | 0.90 | 0.77 | 0.75 | 0.75 | 0.72 | 0.77 | 0.64 | 0.82 | 0.64 | 0.62 |

[a]As analysed using RUMM2030 (Rumm Laboratory Pty Ltd., Perth) for Windows.

[b]Contains individual item or person misfits and/or redundancies.

[c]Rasch based reliability statistic (analogous to Cronbach's alpha).

SD, standard deviation; df, degrees of freedom.

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**Unidimensionality.** We found limited evidence to support unidimensionality of the eHEALS. Analysis using principal components analysis suggested that the eHEALS may be measuring two separate constructs of the eHealth literacy (p = 0.13; 95% CI 0.11, 0.15), which may indicate that items must be scored separately.

**Response thresholds.** Inspection of thresholds maps and category probability curves showed ordered thresholds for the five response categories ('strongly disagree' to 'strongly agree') used in the eHEALS scale, demonstrating that participants were able to distinguish between response options.

**Targeting.** The eHEALS scale displayed reasonable targeting (Fig 1: overall spread of items on bottom half matched spread of persons in top half) with a mean logit score of 0.64 (N.B. ideal: 0). The scale was not, however, able to detect small but clinically important changes in participants with mid to higher levels of eHealth literacy (Fig 1: gap between logit 1 and 3 in the bottom half of the graph).

**DIF (Item bias).** No significant DIF (or item bias) was evident in the eHEALS for age, gender, polypharmacy and education indicating no influence of these characteristics on response to any of the items of the scale.

**PSI (internal consistency).** With a PSI of 0.90 (Table 4), the scale demonstrated good internal consistency.

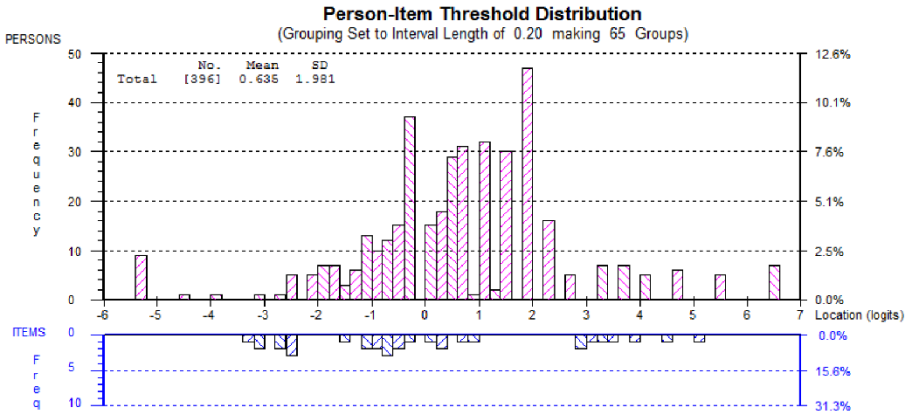


**Fig 1. Targeting of the eHEALS as demonstrated by the person-item threshold distribution.**

https://doi.org/10.1371/journal.pone.0175372.g001

## Study 2: HLQ

Only subscale 5 met the Rasch model expectations for good overall model fit ($\chi^2$ item-trait interaction statistic <0.05). The remaining HLQ subscales did not reflect hierarchical ordering of the items across all levels of health literacy (Table 4). Inspection of individual item-fit statistics revealed the presence of misfits and redundancies (S1 Table).

**Unidimensionality.** All subscales, apart from subscale 9 (p = 0.11; 95% CI 0.09, 0.13), displayed unidimensionality.

**Response thresholds.** Ordered thresholds were obtained for subscales 1 to 5 ('strongly disagree' to 'strongly agree'). However, inspection of category probability curves for subscales 6 to 9 showed that participants had difficulty distinguishing between their response categories ('cannot do' to 'quite easy'), as seen by the confluence of peaks in Fig 2A. When the response categories 'very difficult' and 'quite difficult' were collapsed into one category, response thresholds for these subscales became ordered (Fig 2B: distinct peaks for each response category).

**Targeting.** Targeting was suboptimal for all subscales of the HLQ (mean logit: 1.02 to 4.26) indicating the sample was slightly overqualified for the level of health literacy measured by the scale. This was further highlighted by the ceiling effect (Fig 3: absence of items in bottom half of graph for higher levels of health literacy represented on the top half). There were also gaps in the mid to high health literacy range.

**DIF (Item bias).** Uniform DIF (p<0.05) was observed in HLQ subscales 2, 3, 4 and 8 for education, polypharmacy, gender and age, respectively. Subscale 3 displayed non-uniform DIF (p<0.05) for item 13 ("Despite other things in my life, I make time to be healthy"). However, in all cases, the DIF was not marked and isolated to one item per subscale with minor effect on each respective subscale.

**PSI (internal consistency).** The PSI varied between 0.62 and 0.82 indicating moderate to good internal consistency for all nine HLQ subscales (Table 4).

## Discussion

This study found that the eHEALS had good overall fit to the Rasch model, distinct response categories, no item bias and reasonbale targeting. This provides evidence supporting the use of the 8-item eHEALS as a measure of eHealth literacy with higher scores truly representing

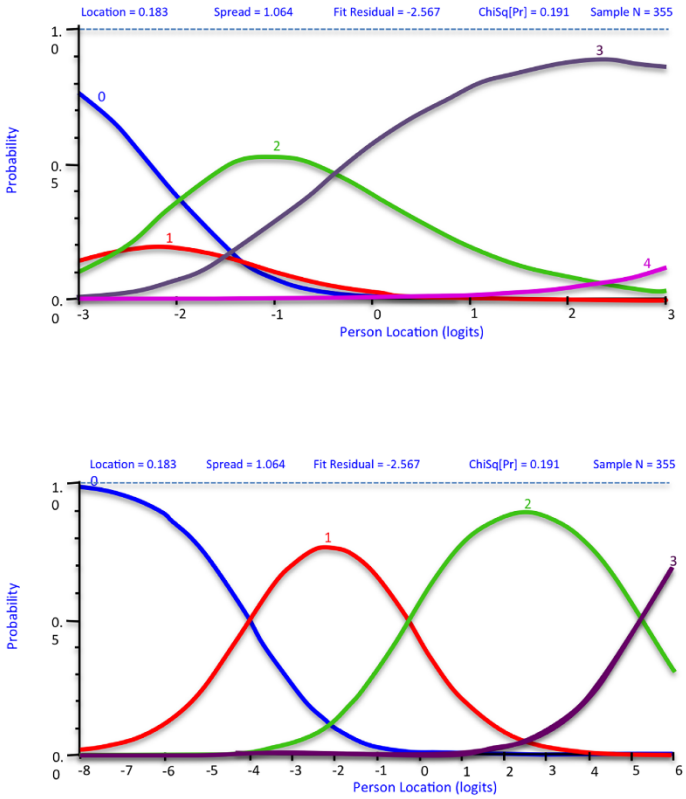


**Fig 2.** Category probability curve showing (a) disordered thresholds in HLQ subscale-9, Item 26 (b) ordered thresholds when response categories 'very difficult' and 'quite difficult' are collapsed into one.

https://doi.org/10.1371/journal.pone.0175372.g002

higher levels of eHealth literacy. All subscales of the HLQ except for subscale 5, on the other hand, did not fit the Rasch measurement model and had suboptimal targeting. Nevertheless, all subscales apart from subscale 9 did demonstrate unidimensionality, had no major item bias and moderate to good internal consistency. This indicates that the HLQ suitably measures nine aspects of health literacy. Both scales were, however, unable to reflect mid to high ranges of health literacy. Consequently, when they are used to measure changes in ability over time, an individual would have to acquire a substantial increase in health or eHealth literacy for it to be reflected in their score. This could account for the presence of misfitting items and persons and highlights the potential for further scale testing and refinement.

Prior studies using factor analysis or principal component analysis (PCA) and item response theory (IRT) have found the eHEALS to be internally consistent (Crohnbach α: 0.87 to 0.94) with modest to good stability [7,16,17,34] and have supported the construct validity of the scale. The high internal consistency found in this study (PSI: 0.90) further supports these findings [7,16]. A recent study using IRT in a population with diverse chronic diseases demonstrated good model fit and distinct response categories for the eHEALS [19]. Good model fit

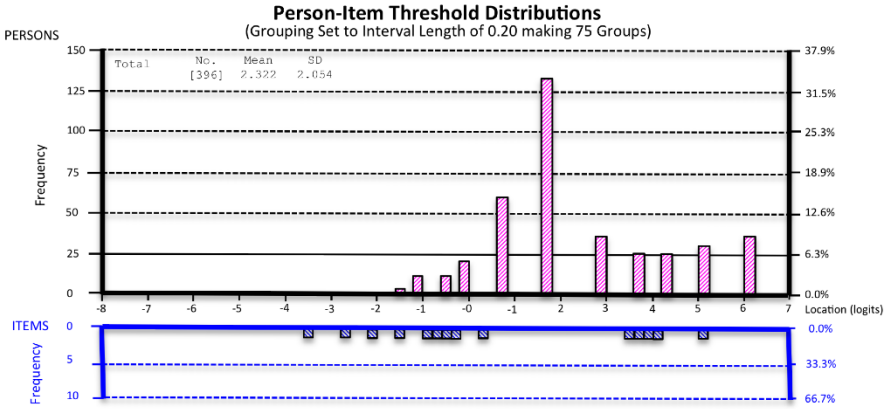


**Fig 3. Targeting of the HLQ subscale-4 as demonstrated by the Person-item Threshold Distribution.**

https://doi.org/10.1371/journal.pone.0175372.g003

was also found in another IRT study (in a student population and adults who use the Internet) with similar findings around targeting, notably a marked ceiling effect [18]. Unlike the current study, however, response categories were not distinct in the 'strongly disagree' and 'disagree' categories [18]. Further research is needed to test whether reducing the number of eHEALS response categories would better reflect the range of eHealth literacy levels.

Contrary to our findings, previous studies using classical test theory and item response theory (in a student population, healthy adults using the internet and patients with rheumatic disease) have supported unidimensionality of the eHEALS [17,34]. In our analysis, we identified two constructs, or concepts, of eHealth literacy: (1) items 1–5 (around knowledge about resources) and (2) items 6–8 (around evaluation of resources). A Likert-scale, such as the eHEALS, depends on unidimensionality to be able to sum its items [35]. A possible explanation for this discrepancy may be related to the age of the population studied with this study focusing on an older population (mean age: 66 years old). It could be that the knowledge to use the Internet and the ability to evaluate online resources are two distinct skills for an older population but not for a younger one that is more familiar with the electronic medium. Further research is therefore required in different populations to explore whether the eHEALS is indeed composed of two separate constructs, which may then mean summing item scores across constructs is not appropriate.

The HLQ has previously been found to have a good level of construct validity and a composite reliability of $\geq$0.8 for almost all subscales [14,36]. However, the scale developers had noted that participants had difficulty distinguishing between the response categories for subscales six to nine ('very difficult', 'quite difficult', 'quite easy' and 'very easy') [14]. This was confirmed in their follow-up paper using a Bayesian model approach where subscales six to eight were found to have disordered thresholds [20]. Similar findings were observed in this Rasch analyses as subscales six to nine displayed disordered thresholds. Disordered thresholds are not uncommon in scales with multiple response categories or when wording between them is similar [23,35]. If participants are not able to distinguish between response categories, the sum of the items does not truly reflect the individual's ability i.e. selecting 'quite' difficult would be equivalent to selecting 'very difficult'. The Rasch analysis demonstrated that collapsing two response categories ('very difficult' and 'quite difficult') resulted in ordered thresholds. This improved the ability for participants to distinguish between the response categories and

ultimately, could enable healthcare providers to accurately measure the range of health literacy levels.

This is the first study to have assessed and compared the internal construct validity of the eHEALS and the HLQ scales using Rasch analysis in a population with CVD. Validation of such scales is particularly important in order to accurately measure the health literacy of patients with chronic disease, such as CVD, who are active participants in the management of their health. This study was able to provide new insight into the measurement properties of two commonly used scales for eHealth and health literacy by comparing prior findings. It was also able to provide information regarding item bias (ie. DIF), which has not yet been examined in the eHEALS. Furthermore, Rasch was able to analyse several psychometric aspects of the scale, such as the hierarchical structure of items, ordering of response categories, DIF and the summation of the scale, which are beyond the scope of classical test theory. We were, therefore, able to highlight aspects of both scales which require further investigation such as whether the eHEALS measures two distinct constructs of eHealth literacy and provide further support for rescoring subscales six to nine of the HLQ response categories in order to better reflect hierarchical distribution of health literacy. Further validation is now required to test these changes in a different population.

This research does have several limitations. Firstly, the cohort is mostly male and the group is known to have home Internet access, reducing generalizability of the findings. Secondly, both scales had many misfitting items and persons, which may in turn have contributed to the degree of misfit observed between the data and the Rasch measurement model. However, achieving model fit would have entailed deletion of items or persons, which was beyond the scope of this paper. Thirdly, this study did not seek to confirm whether individuals with higher eHealth or health literacy scores truly had better disease management. This is particularly noteworthy since a Dutch study found that perceived skills as measured by the eHEALS did not predict actual performance [34], although it is the only study to have done this analysis and further research is required to confirm this finding. Furthermore, we were not able to assess the external validity of both scales, which is an important area of health literacy. Finally, Rasch analysis is one among many tools for internal construct validity and the results of this study should be considered among the already existing validation work that has been done on these two scales.

## Conclusions

Electronic resources are valuable tools to access health information, however, patients must acquire the skills to effectively engage with and benefit from the plethora of resources available online. This is particularly true for CVD in which disease management and prevention depend largely on patients' health literacy. For healthcare providers to optimally assess a patient's level of health literacy, valid and reliable scales are essential. This study demonstrates the good psychometric properties of eHEALS and highlights that the HLQ appropriately measures its nine distinct aspects of health literacy. Further research is now needed to determine the extent to which higher eHEALS scores correctly identify those individuals with greater eHealth capacities and whether collapsing response categories in the last four subscales of the HLQ improves boundaries between response categories.

## Supporting information

**S1 Table. Rasch item and fit statistics for the electronic Health Literacy Scale (eHEALS) and Health Literacy Questionnaire (HLQ) scales.**
(DOCX)

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