

One step at a time

*Disentangling the complexity of
preventing falls in frail older persons*

Miriam F. Reelick

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***Disentangling the complexity of
preventing falls in frail older persons***

Een wetenschappelijke proeve op het gebied van de
Medische Wetenschappen

Proefschrift

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***Disentangling the complexity of
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Medical Sciences

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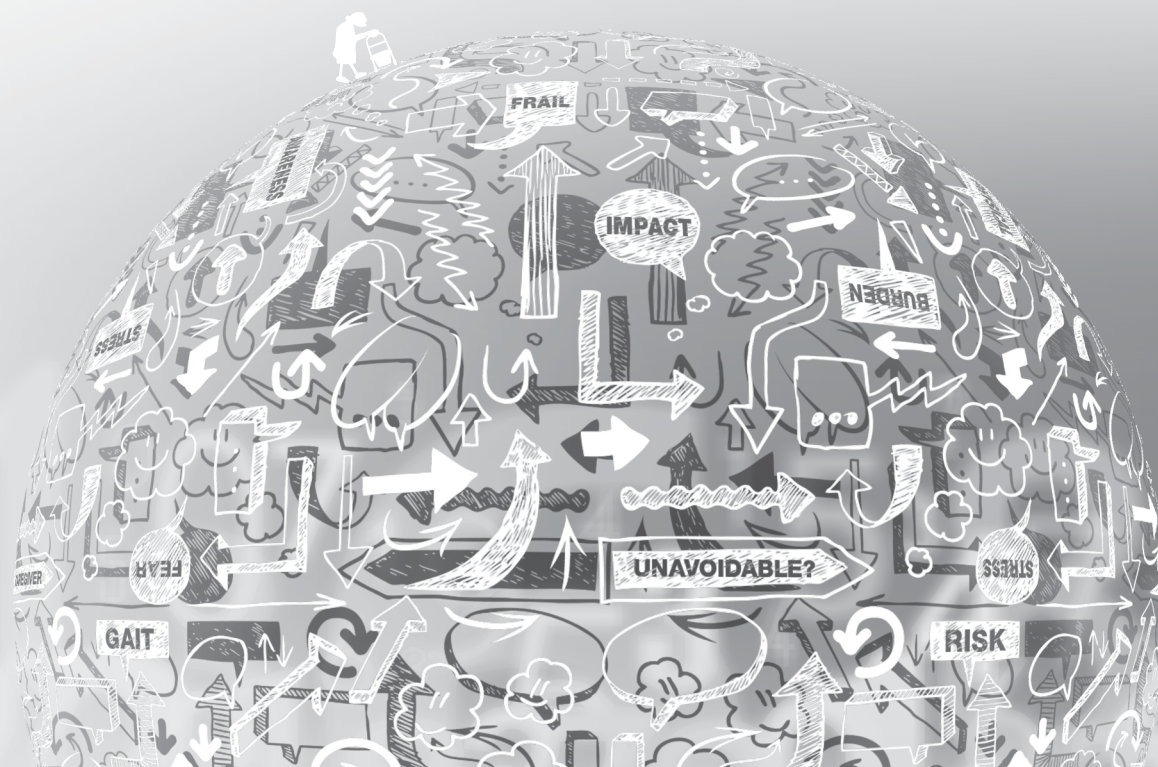
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1

General introduction





Background and aims

Background

Our society is aging. Worldwide, the number of persons aged 65 and over will increase from 390 million at present to 800 million in 2025, at which point this age group will comprise ten percent of the total population.¹ In the Netherlands, it is projected that in 2037, 4.3 million people will be aged 65 years and over, comprising 25% of the total population.² Falls are a common problem among older persons. As the population ages, falls will become a more prominent health issue.

A fall is defined as “an unexpected event in which a person comes to rest on the ground, floor, or lower level”.³ More than one third of the persons aged 65 years or older experience a fall each year, and of these, half fall more than once.⁴⁻⁶ The risk of falling increases with age: up to half of persons aged 85 years and over experience a fall.⁵⁻⁷ Frail older persons, including those with cognitive impairment, are at an even higher risk of experiencing a fall.⁸⁻¹⁰

Below, the consequences and risk factors for falls in older persons are reviewed and interventions to prevent falls are discussed.

Consequences

Falls present a major health issue for older persons and have both physical and psychological consequences. Because older persons have a high prevalence of other diseases, such as osteoporosis, even a minor fall may result in serious injuries. In about 10% of the falls, the person suffers a major injury, such as a serious soft-tissue injury, a fracture, or a traumatic brain injury.¹¹⁻¹³ These injuries may result in functional decline, immobility, loss of independence, or reduced quality of life.^{14, 15} Furthermore, by the one-year follow-up, 20% of frequent fallers have been hospitalized, institutionalized with full-time care, or died.^{16, 17} Frail older persons are at a higher risk for such negative consequences.^{8, 18} These alarming figures warrant major research efforts.

Besides the immediate physical injuries, other consequences of a fall should be recognized. A non-injurious fall may have serious consequences if the person is unable to get up from the floor or call for help. Almost half of the older persons who fall require help in getting up after at least one fall.¹⁹ In particular, older persons with cognitive impairment often remain on the floor for a long period of time.²⁰ Remaining on the floor for more than 12 hours is associated with pressure sores, dehydration, hypothermia, pneumonia, and death.²⁰

The psychological consequences of falls include increased levels of anxiety and depressive symptoms. Up to 70% of fallers and 40% of those who have not reported a recent fall experience fear of falling.^{14, 21-23} Persons who have never fallen may be fearful due to a near-fall or because they have observed the consequences when their peers

have fallen. The prevalence of the fear of falling is probably underestimated because this fear is not easily admitted. Diminished self-confidence or a fear of falling may result in decreased activity, social isolation, and functional decline.²⁴⁻²⁷ Up to half of those who are fearful of falling restrict or eliminate social and physical activities because of their fear.^{24, 26, 27} This decreased activity and functional decline may cause a person to enter a vicious cycle of an increased risk of falling and increased fear. Consequently, a fear of falling predicts the occurrence of falls at the one-year follow-up, and vice-versa.²⁸

Falls also have an impact on informal caregivers.²⁹ Caregivers fear that their relative will fall, which leads to an increase in both objective and subjective burden and a decline in the quality of life. Caregivers may feel frustrated and depressed when they are unable to help their relative or their relative is unwilling to accept their help or advice.²⁹

Risk factors

Falls in older persons rarely result from a single cause or risk factor. Falling is one of the “geriatric giants”, symptoms caused by multiple independent but interacting risk factors. Several studies have shown that the risk of falling increases exponentially as the number of risk factors increases.^{6, 30} Risk factors can be divided into extrinsic and intrinsic factors. Extrinsic risk factors include environmental hazards, such as uneven or slippery ground, poor lighting, obstacles, poor footwear or clothing, and inappropriate walking aids or assistive devices.^{6, 31, 32} Extrinsic factors can increase the risk of falls independently, but they often interact with intrinsic factors. Intrinsic risk factors are factors within a person, such as cardiovascular and cerebrovascular causes of syncope, loss of vision, and disease-related functional impairments.^{6, 32}

Risk factors that are merely predictive should be differentiated from causal risk factors. For example, a previous fall is predictive of future falls, but it is not a causal risk factor in itself. The underlying pathology causing the first fall is likely to cause future falls. Causal risk factors may be used as targets for fall prevention.

Together with previous falls, gait and balance impairment are the most important risk factors for falling.³³ However, despite extensive research, no adequate tool has been found to discriminate between fallers and non-fallers.³⁴ For example, the Berg Balance scale and multi-factorial assessment tools, such as the STRATIFY instrument, are unable to accurately predict future falls.^{35, 36} Although some risk factors are irreversible, others can be modified.

Fall prevention

For the community-dwelling older population, there is strong evidence that multi-factorial fall risk assessment combined with a multidisciplinary targeted treatment may reduce the number of falls.^{37, 38} At the geriatric falls clinic of the Radboud University Nijmegen Medical Centre, the Netherlands, frail older persons with unexplained falls receive a comprehensive multidisciplinary assessment of risk factors. Identified risk factors are adjusted or treated when possible.

Important targets for assessment and treatment are impaired vision, foot disorders, musculo-skeletal disorders, orthostatic hypotension, drug use, and environmental risks that can be changed by the occupational therapist. Vision may be adjusted with new glasses or surgery. For foot and musculo-skeletal disorders, drugs or surgery may be necessary for calluses or rheumatoid arthritis. Adjusted orthopedic footwear or a walking aid may be provided, although their use may be inconsistent because of fear of social stigma. In addition, the use of a walking aid may result in pain in the upper limbs, deterioration of motor function, and even an increased risk of falling. Orthostatic hypotension, a dysregulation of blood pressure, may be caused or exaggerated by cardiovascular drugs or other drugs such as the urological alpha1-blocking drugs. In general, psychotropic drugs should be avoided or actively withdrawn when possible, and alternative non-pharmacological treatments should be used for anxiety, depression, behavioral disturbances, or sleeping problems. In addition, an environmental risk assessment may be required, although merely home visit-based eliminations of environmental risk factors seem to be ineffective.^{39, 40}

In addition to these risk factors, the risk of falls may partly result from factors that are more difficult to modify, such as balance impairment or high-risk behavior. In these cases, reducing the fall risk may require a more extensive fall-prevention intervention. The results of research on fall-prevention interventions, although inconsistent, show that multi-factorial and/or exercise interventions are most effective at improving performance and/or reducing the risk of falls and their associated injuries.⁴¹⁻⁴³ However, the content of the optimal exercise program and its optimal duration and intensity have not yet been established. Exercise programs may include balance, strength, endurance, and training activities for daily living.⁴⁴ The different types of training are briefly discussed below.

Balance and strength training

Because balance impairment and muscle weakness are important risk factors for falls, exercise programs that include balance training and/or muscle strengthening have been shown to be the most effective in older persons who fall.^{43, 45} For example, Tai Chi significantly reduced falls in older persons who were fit and possibly among transitional older persons, although effects probably were partly caused by increased

balance confidence.^{46,47} However, the results were less promising for frailer older persons.^{46,48} Tai Chi may be too difficult for such persons, or it may require too much time and practice to be beneficial.⁴⁹ Strength exercises may be beneficial for frailer persons with muscular atrophy to prevent a decline in muscle strength and even lower the number of falls, with high intensity forms appropriate for more fit older persons.⁵⁰⁻⁵²

Endurance training

There is limited evidence of the effectiveness of endurance training as a fall-prevention intervention.⁵³ Increasing aerobic capacity, such as through walking programs, has not been successful in reducing the number of falls or their risk.^{54,55} However, endurance training may be an important component of training when combined with other types of exercise because of its positive effects on general health and energy level.

Training activities of daily living

Functional training programs have been shown to reduce falls and improve functional performance.⁵⁶⁻⁵⁸ Such intervention programs often include exercises in an obstacle course, training activities for daily life, and situations that are based on the circumstances of falls.⁵⁶⁻⁵⁸ For frail older fallers, an additional advantage of this approach is that the activities of daily life exercises are familiar and do not require learning new movements. Moreover, the participants learn to recognize high fall-risk situations and how (not) to handle these situations.

The effectiveness of fall-prevention interventions varies among different populations. Randomized trials have studied older persons (community-dwelling and institutionalized) with and without a history of falling.^{53,59} The results of these studies have shown that the intervention's effectiveness is population- and setting-specific.^{53,59} Interventions that effectively reduced falls in community-dwelling older persons were less effective or ineffective in residential care settings. Although the cognitive functioning of participating persons is not often reported, it seems to be an important factor because a multi-factorial fall-prevention intervention was not effective for persons with cognitive impairment attending the hospital after a fall.⁶⁰

For the frailest populations, such as those seen at a geriatric falls clinic, the effectiveness of fall-prevention interventions remains unclear. Frailer older persons are excluded from most trials, because of anticipated problems with recruitment and adherence, and reduced physical and learning abilities. However, because this group has multiple (intrinsic) risk factors for falling and because their frailty leads to more serious falls with lasting consequences, developing a fall-prevention intervention is a high priority. This intervention requires a thorough development process that considers this population's specific capabilities, impairments, attitudes, and expectations. This developmental process requires multiple cycles to gather information, model, and continuously optimize an intervention in an area that lacks clinical evidence.

Aim and outline

Falls, especially in frail older persons, may have disastrous consequences for both the faller and his or her informal caregiver. Falls are often caused by a complex interaction of multiple factors. Therefore, it is likely that only multi-component interventions can prevent future falls. Thus far, studies evaluating fall-prevention interventions in frail older persons are lacking, especially because most studies on fall-prevention interventions exclude frail persons. The aim of this study was to develop and evaluate a fall-prevention intervention for frail older fallers.

This aim has been translated into a series of studies that are presented in the following chapters. The process and the results are presented in three parts:

- I. *Development of a fall-prevention intervention for frail older fallers and their informal caregivers (Chapters 2 and 3)*
- II. *Evaluation of a fall-prevention intervention for frail older fallers and their informal caregivers (Chapters 4 and 5)*
- III. *Adaptations for fall prevention in frail older fallers (Chapters 6 to 9)*

Chapter 1B provides a background of the methods and outcome measures that are used in the experimental studies throughout this thesis. The methods concern gait and balance measurement with the GAITRite™ and SwayStar™ system, respectively. Cognition, specifically reaction decision time and spatial working memory, is assessed with the Cambridge Neuropsychological Test Automated Battery (CANTAB™) and the Box task, respectively.

Chapter 2 explores frail older persons' views, experiences, emotions, and needs regarding falls and fall prevention. The sample includes persons with and without cognitive impairment who had experienced a recent fall. The opinions and experiences of the informal caregivers of frail older fallers are also considered. These interviews provide important background information for the fall-prevention intervention and shape its key components.

Chapter 3 describes the phases of the Medical Research Council framework for the development, evaluation, and implementation of complex interventions. This chapter also illustrates the use of this framework in the development and design of the evaluation of the complex fall-prevention intervention. The results of each phase and implications for the newly developed fall-prevention interventions are described.

Chapter 4 describes the contents, rationale, and structure of the fall-prevention intervention per session.

Chapter 5 compares the effectiveness of this new fall-prevention intervention with the usual care provided by the geriatric falls clinic. The main outcome measures are fall incidence rates and the fear of falling in patients and caregiver burden in informal caregivers.

Chapter 6 provides a guideline for structured process evaluations in complex interventions illustrated by the process evaluation of the fall-prevention intervention. Implications of the findings for the current intervention and process are described.

Chapter 7 introduces a new and possibly less burdensome method to register falls during follow-up in research studies: the fall telephone. A qualitative study evaluates the feasibility, reliability, and validity of this method in fifteen frail older persons.

Chapter 8 introduces a new, single intervention to improve balance in frail older persons with the use of biofeedback. This balance training is developed based on previous studies in other populations and evaluated for its feasibility and efficacy of reducing trunk sway both immediately and a few days after training.

Chapter 9 studies and compares gait and cognitive measures as discriminators for falls in geriatric outpatients and their informal caregivers. Both mean performance and dispersion (intra-individual variability within one trial) of stride length and decision time are examined in recurrent and non-recurrent fallers. Using an electronic walkway, stride length is assessed during walking with and without performance of a secondary task. Decision time is assessed with a choice reaction time task.

Chapter 10 prospectively studies and compares variability in repeated performances of gait, balance and cognition. We assess stride length, roll angle, spatial working memory, and decision time, and we monitor falls during six months of follow-up. Variability within one task (*dispersion*) and variability over time between different sessions on different days (*inconsistency*) are studied and compared between participants with and without a fall at follow-up.

Chapter 11 provides a summary of the main findings of this thesis and discusses the implications of these results.

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1B

**Measurements of gait and balance
and assessment of cognition**

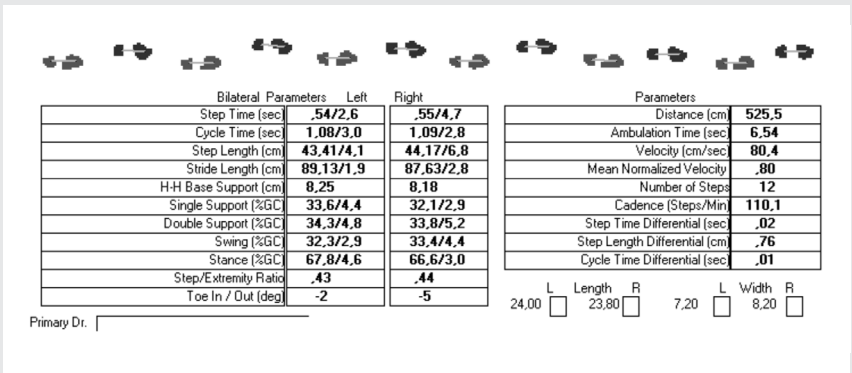


In this thesis, we quantify gait and balance using an electronic walkway (GAITRite™ system) and a trunk angular velocity device (SwayStar™ system), respectively. We assess cognition using computerized tests for attention, information processing speed, and spatial working memory with the choice reaction time task of the Cambridge Neuropsychological Test Automated Battery (CANTAB™) and the Box task, respectively. In this chapter, we clarify these methods and the most important outcome measures. The uses of these methods are illustrated on the DVD included at the end of this thesis ('Gait and balance assessment' and 'Choice reaction time task').

Quantifying gait: the GAITRite™ system

The GAITRite™ system is used to objectively examine participants' walking patterns in detail. It consists of a 6.1-meter electronic walkway connected to a computer. The walkway resembles a normal carpet and contains multiple sensor pads that respond to pressure. As a person walks across the walkway, the system continuously scans the sensors to detect objects and stores information from the activated sensors. This process results in an image of the participant's feet along the walkway and detailed pressure profiles of each footfall. Figure 1 shows an example of the data view. The raw data of the activated sensors are then processed using algorithms provided in the software package to calculate both timing (temporal) and distance (spatial) gait parameters. Temporal measures include stride time and gait velocity, and spatial measures include stride length and width. The GAITRite™ system records individual footstep data, which allow for assessment of the step-to-step variability of gait

Figure 1 Example of the GAITRite™ data view showing the footprints and calculated parameters of an older person while walking at preferred velocity.



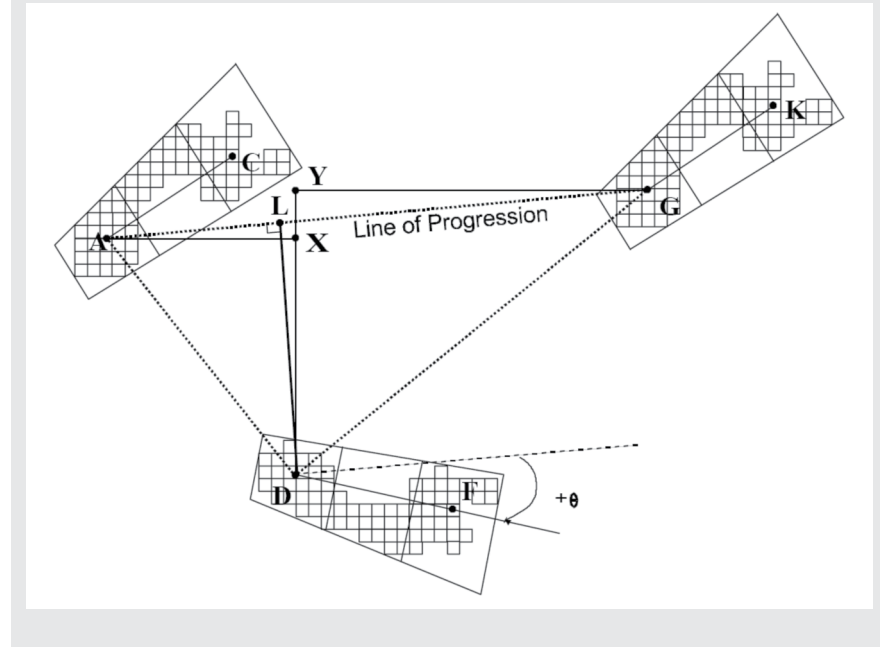
parameters. The GAITRite™ system has been shown to be a reliable and accurate method for measuring both averaged and individual step parameters in older populations.¹⁻⁴ Gait variability has been suggested to be an important predictor of the risk of falling.⁵⁻⁷

In this thesis, we assessed gait velocity as well as mean performance and variability of stride length, width and time. Table 1 clarifies these variables with reference to the foot images and the data points A to K, as shown in figure 2.

Table 1 Definitions of the gait measures used in this thesis.

Main outcome measures	
Velocity (cm/sec)	Distance (cm) divided by the time (sec) necessary to cover this distance. The distance is measured between the heel centers of the first and last footprints.
Stride Length (cm)	Distance (cm) between the heel centers of two consecutive footprints of the same foot (thus, from left to left). In figure 2, the distance A-G is the stride length of the left foot.
Stride Width (cm)	Right-angled distance (cm) between the heel centers of two consecutive footprints (thus, from left to right). In figure 2, the height (DL) of the triangle (ADG) is the stride width of the right foot.
Stride Time (sec)	Time (sec) between the first contacts of two consecutive footprints of the same foot.

Figure 2 Explanation of the spatial gait measures using three footprints as an example. Points A, D, and G are the heel centers. Distance AG=Stride length of the left foot; DL=Stride width of the right foot. *Reprinted with permission of GAITRite™.*



Quantifying balance: the SwayStar™ system

The SwayStar™ system is used to objectively assess participants' balance control capabilities. The SwayStar™ device is strapped around the waist (at the level of the lumbar spine [lumbar 2-3]) and measures the movement of the upper body (trunk) as it angles near the body's balance point (the center of mass). Because the device is wireless, it is possible to assess participants' balance while walking. The SwayStar™ device contains two sensors to accurately assess angular movement and angular velocities in two planes: front-to-back (pitch) and side-to-side (roll). Figure 3 shows an example of the data view.

This system has been proven to be a reliable and objective method to quantify balance during stance and gait tasks. The outcome measures can be used to discriminate between age groups and between different balance disorders and to detect potential fallers.⁸⁻¹¹

In this thesis, we used the mean performance of trunk pitch angle, pitch velocity, roll angle and roll velocity (Table 2) and day-to-day variability in roll angle.

Figure 3 Example of the SwayStar™ data view. Sway is presented by two separate lines: the sway in roll and in pitch direction.

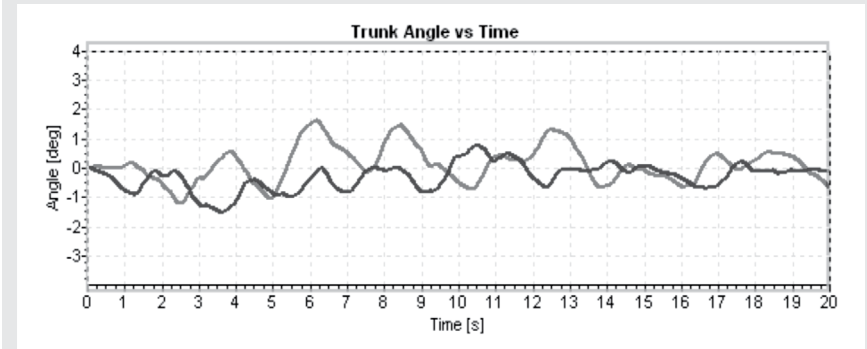


Table 2 Definitions of the balance measures used in this thesis.

Main outcome measures	
Pitch Angle (deg)	Angular displacement from front to back
Pitch Velocity (deg/sec)	Angular velocity from front to back
Roll Angle (deg)	Angular displacement from side to side
Roll Velocity (deg/sec)	Angular velocity from side to side

Gait and balance were measured simultaneously. Participants walked across the GAITRite™ walkway with the SwayStar™ balance device attached to their lower back (Image 1). Participants walked at their preferred speed, both with and without the performance of a cognitive dual-task. Outcome measures were assessed during steady-state walking to avoid the influence of an increase or decrease in gait velocity. Participants were asked to start and stop walking two meters before and after the walkway. They completed the task wearing their own comfortable shoes and using a walking aid if necessary. Walking aid prints were manually erased from the raw GAITRite™ data files to derive the gait variables.

Image 1 The left image shows an older person on the GAITRite™ electronic walkway with the SwayStar™ balance assessment device attached to the lower back. The right image shows the SwayStar™ balance device.



Assessment of cognition: Cambridge Neuropsychological Test Automated Battery (CANTAB™)

The computerized Choice Reaction Time (CRT) subtest of the Cambridge Neuropsychological Test Automated Battery (CANTAB™) was used to assess participants' speed of response to a visual target as a measure of processing speed and attentional capacity.¹² Participants held down a press-pad button until a yellow spot (the stimulus) appeared at random for a moment at one of five possible locations on a touch-sensitive screen. They then released the press-pad button and touched the position where the stimulus was presented as quickly as possible. Image 2 shows an older person performing the Choice Reaction Time task.

The task was divided into practice and test components. In the first practice block, the participant was required to complete at least nine out of ten correct responses before moving to the test phase. If the participant was unsuccessful in the first practice block, a second practice block was administered. After the second practice block, the task proceeded to the test block irrespective of how well the participant had performed. The test block consisted of 15 stimuli. Instructions by the researcher emphasized the speed of performance.

This task allowed for differentiation of reaction time into decision time (DT) and motor time (MT). In this thesis, we used decision time, motor time, and response type as outcome measures (Table 3).



This system has been proven to be a reliable and objective method of quantifying attention and processing speed.¹²⁻¹⁴ Moreover, CANTAB™ has been used for assessing cognitive function in a very wide variety of neuropsychological and psychiatric disorders and is able to monitor change.^{12, 14-17}

Table 3 Definitions of the reaction time measures used in this thesis.

Main outcome measures	
Decision Time (ms)	Duration (ms) from the moment the stimulus appears to the moment that the person makes the initial response (stops pressing the button).
Movement Time (ms)	Duration (ms) from the moment at which the person makes the initial response (stops pressing the button) to the moment the person makes the final response (touches the screen).
Response Type	Depending on the location and timing of the response, the type of response is described as 'correct' (correct location in time), 'incorrect' (touched the wrong location in time), 'premature' (touched before stimulus appeared), 'inaccurate' (touched screen background rather than the response location) and 'none' (made no response before the 'response duration allowed' elapsed).

Image 2 The image shows an older person performing the Choice Reaction Time task on the touch-sensitive screen. The stimulus appears at random in any of the five outer circles.



Assessment of cognition: the Box task

The Box task was used to assess updating of information and spatial working memory (prefrontal processing).¹⁸⁻²⁰ The test was performed on a touch-sensitive screen that showed a number of identical boxes and a series of easy-to-name 'target objects' (for example shoe, umbrella, or penguin) at the bottom of the screen, one at a time.

Participants were asked to search through the boxes to find the target object presented at the bottom of the screen. An opened box will either be empty or will contain the target object. If the box is empty, it closes within two seconds so that the next box can be opened. If the box contains the target object, the target object remains visible for two seconds and then closes. The next target object then appears at the bottom of the screen. All previously found target objects within a trial remain hidden inside their boxes. The participant is expected to remember which boxes contain previous target objects and which empty boxes have already been searched for the current target object. At the end of the trial, all of the boxes contain one of the target objects presented. Then, the next trial begins, showing a screen with new boxes at different locations.

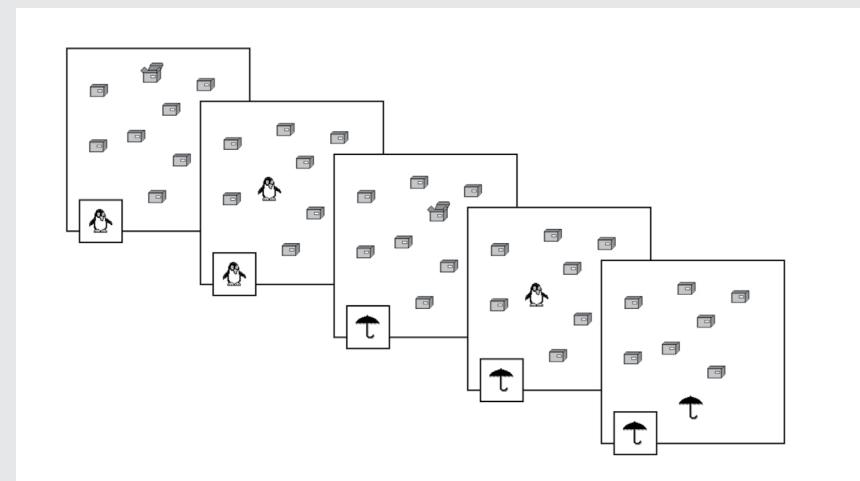
After one practice trial with three boxes, the number of boxes is increased, resulting in set-sizes of four, six, and eight boxes. The main outcome measured is the number of between search errors (in other words, the number of times a participant returns to a box that contained a previous target item) for the set of eight boxes.

The Box task has been shown to be a reliable and valid method that is sensitive to aging effects and discriminates between different levels of cognition.²⁰

Figure 4 shows an example of the Box task with eight boxes. Panel four shows a between-search error, in which the participant has opened a box containing a previous target object.



Figure 4 Example of the Box task. Panel four shows a between-search error, where the participant has opened a box containing a previous target object.

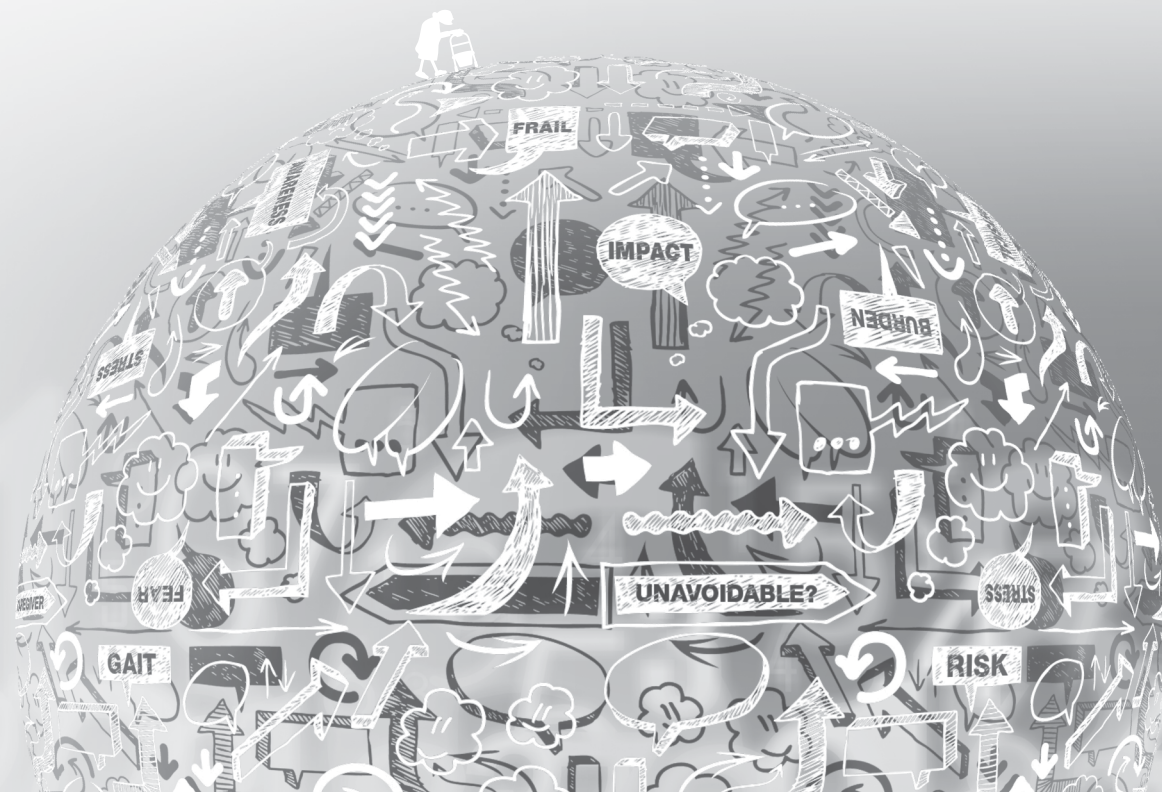


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PART I

**Development of a fall-prevention
intervention for frail older fallers and
their informal caregivers**



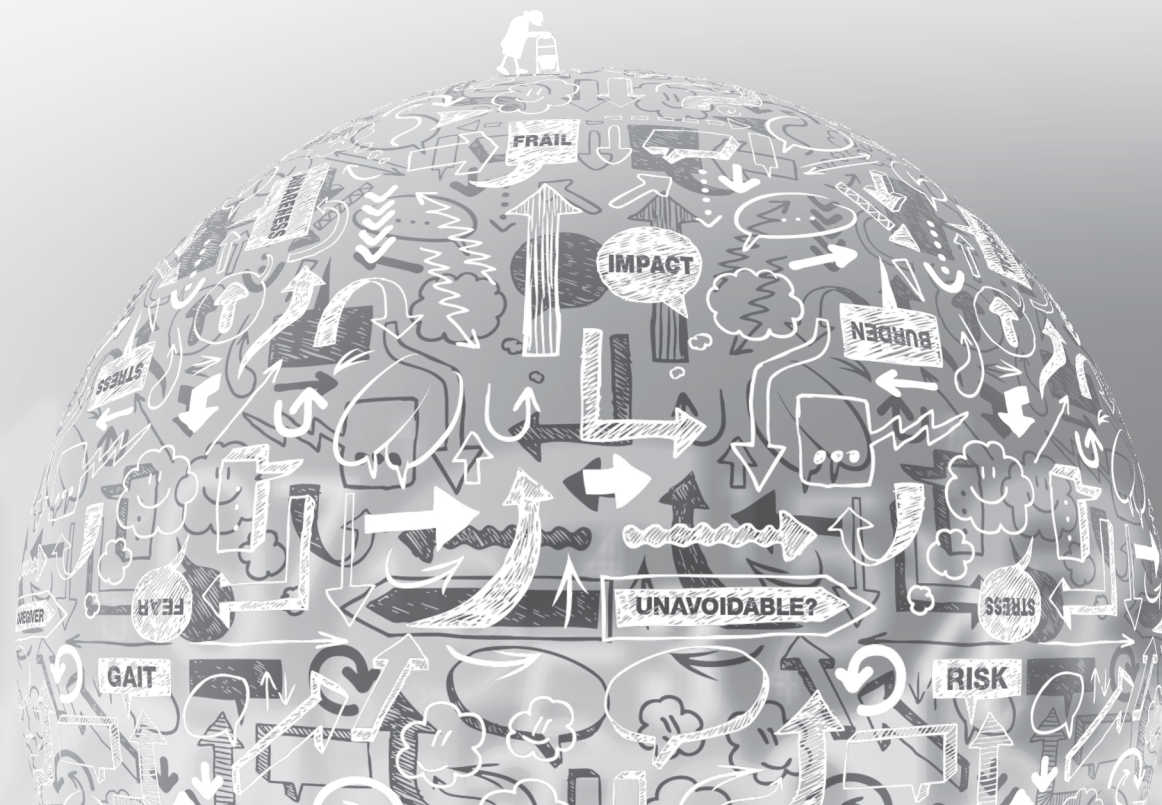
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Impact of falling on frail older persons and informal caregivers

Published as:

Qualitative study on the impact of falling in frail older persons and family caregivers: foundations for an intervention to prevent falls.

Faes M.C., Reelick M.F., Joosten-Weyn Banningh L.W., de Gier M., Esselink R.A.J., Olde Rikkert M.G.M. *Aging & Mental Health*: Sept 2010; 14 (7): 834-842.



Abstract

Aims The primary aim of this study was to explore the impact of falling for frail community-dwelling older persons with and without cognitive impairments who have experienced a recent fall, and their primary family caregivers. The secondary aim was to define components for a future fall-prevention intervention.

Methods Grounded theory interview study, with ten patients (three cognitively unimpaired patients, four patients with mild cognitive impairment, and three patients with dementia) and ten caregivers.

Results All patients described a fear of falling and social withdrawal. Caregivers reported a fear of their care recipient falling. Most patients were unable to name a cause for their falls. Patients rejected the ideas that falling is preventable, and that the fear of falling can be reduced. Some caregivers rated the consequences of their care recipients' cognitive problems as more burdensome than their falls and believed that a prevention intervention would not be useful because of the care recipients' cognitive impairment, physical problems, age, or personalities.

Conclusion Falling has major physical and emotional consequences for patients and caregivers. A fall-prevention intervention should focus on reducing the consequences of falling, and on promoting self-efficacy and activity. The causes of falls should be discussed. The intervention should include pairs of patients and caregivers because caregivers are highly involved and also suffer from anxiety. Before beginning such an intervention, providers should transform negative expectations about the intervention into positive ones. Finally, caregivers must learn how to deal with the consequences of their care recipients' falling, as well as their cognitive impairment.

Introduction

Falls are a major health problem in older persons; they lead to immediate effects such as fractures, and long-term problems such as a fear of falling, disability, and loss of independence.¹ Frail older persons are at an increased risk of falls.² The first three of the five components defining frailty (weakness, slow walking speed, low physical activity, self-reported exhaustion and weight loss) are risk factors for falling,^{2,3} and cognitive impairment is an additional risk factor.³ The annual incidence of falls in cognitively impaired older persons is 60%, which is twice the incidence in cognitively normal older persons.⁴ About 25% of the frail older persons are cognitively impaired.⁵ In frail older persons, falls often coexist with cognitive impairment.⁶ However, quantitative and qualitative research on falling and the fear of falling have focused on non-frail older persons without cognitive impairments rather than on frail older persons, both with and without cognitive impairments.⁷⁻¹³

In addition, little is known about the consequences of falling for informal caregivers, who are predominantly the family members of frail older persons. Caregivers of patients with dementia mainly deal with fall risk by controlling all of their care recipient's actions, often increasing the dependence of their care recipient.¹⁴ A cross-sectional study showed that among frail community-dwelling older persons, falls are positively correlated with caregiver burden.¹⁵ Caregivers of older persons who experienced recurrent falls and suffered from Parkinson's disease (PD) or stroke were concerned about possible future falls and felt unprepared for their caregiving role. These caregivers need more support and advice, especially about managing falls.¹⁶⁻¹⁸ Few fall-prevention interventions have been effective in high-risk, frail, community-dwelling older persons without cognitive impairment. Furthermore, currently there is no falls prevention intervention with proven effectiveness in frail community-dwelling patients with dementia.^{8,19} In older persons with milder cognitive deficits, only one intervention significantly reduced falls. However, the trial that evaluated the intervention also included cognitively unimpaired older persons and no sub-group analysis in relation to cognitive impairment was performed.²⁰ Evidence-based strategies to reduce the fear of falling in frail community-dwelling older persons, especially those who suffer from cognitive impairment, are lacking.^{13,21}

Older persons with mild-to-moderate dementia are often good informants who are able to describe their subjective states and articulate their feelings, perspectives and experiences.²² Therefore, there is no reason to exclude them from qualitative studies. To provide adequate fall prevention and psychosocial support for frail community-dwelling older persons and their caregivers, in-depth knowledge of the impact of falling on both patients and caregivers is essential. Our primary aim is to explore the views, experiences, emotions, and needs regarding falling in frail community-dwelling older persons with and without cognitive impairments who have experienced a

recent fall, as well as in their primary caregivers. Our secondary aim is to define key components for a future fall-prevention intervention.

Methods

Participants

We drew a sample of patients and family caregivers from the geriatric outpatient fall clinic of the Radboud University Nijmegen Medical Centre, the Netherlands. Patients were eligible for participation in the study if they were community-dwelling, met the frailty criteria² and had fallen at least once in the month before their visit. Caregivers were eligible if they were the primary family caregiver, which was defined as the family member who was most involved in caring for the frail older person who experienced a fall; this caregiver assisted with at least one personal or instrumental activity of daily living and monitored the patient.

We used the method of purposive sampling, which involves a deliberate selection of subjects, to obtain a full view of the impact of falls on both patients and caregivers.²³ Patients differed in their level of cognitive functioning (indicated by their Mini-Mental State Examination [MMSE] score); this factor has been associated with a fear of falling and falls.^{3, 24} Patients with mild cognitive impairment (MCI) or dementia disagree and argue with their spouses about the causes of cognitive decline.²⁵ Half of the study participants were involved in care recipient-caregiver dyads. The remaining participants were not related to each other.

Participants (patients and caregivers) were informed about the study and received written consent material matched to the cognitive capacities of the patients. Before the interview, the researchers (MF and MG) answered participants' questions by phone. Patients' geriatricians (who were not involved in the study) and the researchers (MF and MG) judged all patients to be mentally competent to give informed consent. Ethical approval of this study was obtained from the Medical Ethical Committee Region Arnhem-Nijmegen.

Data collection

Two well-trained researchers (MF and MG) conducted the face-to-face interviews. The interviews were arranged at a time and place that suited the interviewees (home n=13, outpatient clinic n=7). Before the interview all interviewees gave their written informed consent. The interviews were audio-taped with the interviewees' permission and transcribed verbatim. Transcripts were anonymised and only two researchers (MF and MG) had access to the interviewees' names. The interviewees were told that they could stop the interview at any time and decline to answer questions without giving a reason. They were given the opportunity to discuss any concerns at the end of the

interview and were asked to comment on the manuscript of their interview. The interviews lasted an average of 35 minutes (SD 14). An interview guide was used and included topics derived from the literature^{10, 11, 14, 15, 26, 27} and from daily practical experience. A panel of three experts (two in geriatrics and one medical psychologist) evaluated the validity of the two versions of the topic list. Topics were included when the majority of the experts agreed. After piloting the interview guide, several questions were excluded or reformulated. The following topics were discussed within the interviews: the consequences (physical, emotional, behavioral and social) of falling for their daily lives, the cause of the falls and the expected impact of a fall-prevention intervention. The caregivers were asked about the same topics, but from the point of view of their personal experience with their care recipients' falling. A care recipient is a proxy with a fall problem the caregiver cares for.

Analysis

We used the qualitative method of the grounded theory: a constant comparative analysis to identify common themes and issues.²⁸ Findings that emerged from the first interviews were used to adjust the topics for subsequent interviews. Interviewees were included until the saturation point of qualitative data was reached. Transcripts of the first four interviews were independently read and analyzed by three researchers (MF, MG, and LJ) using the principle of open coding of early data. The researchers decided on the preliminary code list and initial themes. Later interviews were coded by MF and MG using the code list; new codes were added when data were encountered that did not fit an existing code. In regular meetings, MF, MG and LJ confirmed the refinement of the themes and ensured that no themes had been overlooked and that the saturation point was reached. ATLAS-ti (Atlas-ti version 5.2; (computer software). Berlin, Germany: ATLAS-ti Scientific Software Development GmbH) was used to manage the dataset and to allow for systematic searching and cross-referencing.

Results

Ten patients and ten caregivers participated in the study. Tables 1 and 2 present the socio-demographic characteristics of the patients and caregivers, respectively. Table 2 also shows some characteristics of the caregivers' care recipients (CR). Interviewees were numbered (patients: P#1-P#10, caregivers: C#1-C#10) to allow for the identification of quotations. Reported quotations are translated literally into English. Patients and caregivers #6 through #10 are dyads, so P#6 through P#10 are the same persons as CR#6 through CR#10. All of the interviewees were able to understand the interview questions and to articulate their feelings, views and experiences. However, three cognitively impaired patients experienced difficulty describing falls in detail.

Table 1 Socio-demographic and health characteristics of patients.

Variable		n
Gender	Female	6
	Male	4
Age (years)	70-80	6
	81-90	4
Marital status	Married	7
	Widowed	2
	Divorced	1
Level of education (range 1-7^a)	1-3	3
	4-5	5
	6-7	2
MMSE-score (range 0-30^b)	15-20	2
	21-27	5
	28-30	3
Cognitive impairment	None	3 (P#1, P#5, P#10)
	MCI ^c	4 (P#3, P#4, P#6, P#9)
	Alzheimer's disease (CDR1 ^d)	2 (P#2, P #7)
	Vascular dementia (CDR1)	1 (P#8)
Number of falls in the past year	1-5	4
	6-9	3
	≥10	3
Relationship to caregiver	Mother	2
	Father	1
	Spouse	7

^aEducation level was determined using Verhage's seven-point scale, where 1 denotes less than elementary school and 7 university education or higher; ^bMMSE=Mini-Mental State Examination, lower scores mean greater disability; ^cMCI=Mild Cognitive Impairment; ^dCDR=Clinical Dementia Rating, range 0-3, higher scores mean greater disability.

The mean age of the patients was 78.5 years (SD 4.3) and the mean age of the caregivers was 66.5 years (SD 4.3). Seven patients and eight care recipients suffered from MCI or dementia. The patients' mean MMSE score was 24.3 (SD 4.1, range 19-30) and the care recipients' mean score was 22.8 (SD 4.8, range 16-29). Patients reported physical consequences of their falls, including fractures and minor injuries, such as soft tissue injuries and head wounds.

Emotions (patient and caregiver)

Both patients and caregivers described a constant fear of (the care recipient) falling; they also described a fear of unknown and serious consequences, such as fractures and hospitalizations, regardless of their number of previous falls, gender, and cognitive

Table 2 Socio-demographic and health characteristics of caregivers and their care recipients.

Variables		n
Caregivers		
Gender	Female	5
	Male	5
Age (years)	40-60	4
	61-80	3
	81-90	3
Marital status	Married	9
	Single	1
Relationship to care recipient	Son (in law)	3
	Daughter	2
	Spouse	5
Living together with care recipient	Yes	6
	No	4
Duration of care giving in years	<1	2
	2-5	3
	6-10	2
	>10	3
Level of education (range 1-7^a)	1-3	2
	4-5	3
	6-7	5
Occupational status	Retired	7
	Employee	3
Care recipients		
Gender	Female	6
	Male	4
Age	70-80	5
	81-90	5
MMSE-score (range 0-30^b)	15-20	4
	21-27	3
	28-30	3
Cognitive impairment	None	2 (CR#5, CR#10)
	MCI ^c	3 (CR#1, CR#6, CR#9)
	Alzheimer's disease (CDR1 ^d)	3 (CR#2, CR#3, CR#7)
	Vascular dementia (CDR1)	1 (CR#8)
	Dementia not otherwise specified	1 (CR#4)
Number of falls in the past year	1-5	4
	6-9	2
	≥10	4

^aEducation level was determined using Verhage's seven-point scale, where 1 denotes less than elementary school and 7 university education or higher; ^bMMSE=Mini-Mental State Examination, lower scores mean greater disability; ^cMCI=Mild Cognitive Impairment; ^dCDR=Clinical Dementia Rating, range 0-3, higher scores mean greater disability.

status. In addition, they all described fear of (the care recipient) being alone, in case of a fall accident. Some interviewees expressed fear related to not knowing the cause of the fall.

P#6: I am afraid of falling again, especially when I am outside the house and I am alone.

When I fall, then you never know, maybe I will fracture my hip.

P#5: You don't understand what happened, or know what could happen; that frightens me.

C#3: The biggest fear I have, is that I enter the living room one day and she has been lying on the floor for a couple of hours with a fracture or worse.

Patients also described undirected fear, fear of losing independence, and negative emotions, such as frustration, anger, and disappointment associated with falls and the awareness of limited physical capabilities. Several patients felt embarrassed when falling in public.

P#1: I can't attend birthday parties. It is too hot for me, I will collapse. I feel disappointed.

P#2: The fear stuck with me. I am sensitive to fear. I'm just frightened.

P#3: If I fracture my leg in a fall, before I know it, I will be admitted to a nursing home.

P#4: I don't dare, there are many things I don't dare to do anymore when it's just the two of us. I think it is annoying.

P#9: I always hope no one saw me; falling is embarrassing. (He starts to cry.)

Caregivers of cognitively impaired care recipients expressed feelings of stress, anger, helplessness, and frustration when their care recipients refused to follow advice on fall prevention.

C#2: I feel helpless. I can't stand that. We don't control the situation; my mother-in-law (care recipient) doesn't listen to our advice.

Social consequences (patients)

Patients described social withdrawal and attributed this to their fear of falling and the loss of physical capabilities after falling. Patients recognized that they became (more) dependent on their caregiver after falling. One patient experienced social benefits from her fall, since she now receives more attention from her children.

P#1: I can't travel anymore because of my limited mobility. I injured my leg in a fall.

P#4: I stay at home more often and don't visit my friends anymore. I am afraid to fall when I go out.

P#5: My grandson is almost one year old. I still haven't seen his room. His room is upstairs; I am too anxious to fall when climbing the stairs.

Attributions (patients and caregivers)

Patients offered a wide range of explanations for falls and often named several causes for one fall. Falling was ascribed to ageing, intrinsic factors (somatic origins and personal traits or habits) and extrinsic factors (poor lighting and loose carpets). However, all but one patient (P#1), said they could not identify a cause for all of their

falls. Patients described their falls as unexpected, uncontrollable, and elusive.

P#2: In my opinion, falling is a vicious disease; I am overwhelmed by it.

P#4: There are a lot of people my age who fall.

P#5: I lost the feeling in my lower legs and then I collapsed.

P#7: I think my clumsiness must have been the cause. However, sometimes I stumble on a loose carpet.

P#9: Suddenly you fall, suddenly you black out. When you come round again, you wonder how this could happen? I can't do anything about it.

Caregivers ascribed the falls to ageing and intrinsic factors. Two caregivers mentioned intrinsic factors identified at the outpatient clinic. One caregiver ascribed the falls to an unknown origin, although she witnessed the fall (C#5). Caregivers described the falls as uncontrollable and unchangeable.

C#1: She (the care recipient) fell that time, but sometimes I also fall. It will happen more often when you get older. I can't prevent her from falling.

C#6: If she stands up her blood pressure drops and that causes the fall, the doctor told us.

C#8: She takes a huge fall risk by keeping on doing things while she is too tired; she is too stubborn.

C#10: I think he falls because of his eye disease...macula something.

Care recipients and caregivers in dyads had incongruent ideas about the causes of falls. Caregivers attributed the falls to intrinsic factors, while their care recipients either had no idea what caused the falls or mentioned an extrinsic factor (P#7).

Coping (patients and caregivers)

We observed three coping mechanisms with respect to falling in general: problem-focused coping, emotion-oriented coping and avoidance-oriented coping.

Both patients' and caregivers' problem-focused coping was reflected in actions taken to prevent future falls. Caregivers expressed strategies, such as adaptations in the home environment, vigilance through frequent calls and/or visits, leaving the patient alone for as little time as possible, giving advice about posture and walking, and promoting use of a walking aid.

C#2: I installed grab rails, I removed doorsteps and arranged for better lighting. I locked the door to the cellar.

C#3: When I am home, I check on her every half hour. I leave when she is safe in her chair. When I am at work, I call her every 45 minutes to check on her; during lunch break I rush home to check on her again.

C#5: At home, he uses a cane; I thought that would be safer.

C#6: I told her to stand up from a chair cautiously.

Strategies expressed by patients involved the use of walking aids, adapting their behavior, developing new activities to compensate for activities they could not perform any more, and talking about the problem with someone they trust.

P#1: Because I can't travel anymore, I started to read more papers and magazines to keep myself informed.

P#3: I decided to use a walking frame; it feels more secure.

P#10: When I get out of my car, I wait a moment and then I start walking, just to avoid falling.

The main problem-focused coping strategy for patients and one caregiver who were unsure what actually caused the falls was to use repeated searches until they arrived at an acceptable explanation for their accident. All patients came up with the same extrinsic cause, namely stumbling over an uneven pavement. Three cognitively impaired patients did not mention a search for an acceptable explanation. Some interviewees said that their coping was hindered by not having an explanation for their fall.

P#2: I still don't know why I fell. I thought that tile was the cause, but later on I think no, that wasn't the cause, I fell at a different location than where the tile was located. But in my mind, I think it must have been the tile. It is not clear, is it this, is it that, or is it a bit of both? Maybe if I knew more about it, I could deal with it; now I can't.

C#5: I don't know the cause. Sometimes I think it is because he walks so badly, sometimes I think it is something in his head.

Emotion-oriented coping in caregivers and patients was evident in thoughts reflecting acceptance of the fall problem and its consequences.

P#10: People get used to falling, they say. I will probably get used to it too.

C#1: Worrying is of no use, as it will not solve anything.

C#2: I accepted that she stays in her own home and at some point she will fall and then die.

Both patients and caregivers expressed avoidance-oriented coping methods. Patients' avoidance-oriented coping was reflected in their prevention of falls by avoiding certain situations or activities, denying falling, and hiding their falls from their caregiver or others.

P#1: I just continue with my chores, thinking it (falling) will not happen.

P#2: I avoid going to places where there is no one to help me.

P#3: I have only fallen twice; all the other times I stumbled.

Caregivers concealed their worries and ignored the fall problem of their care recipients and the possible negative outcomes.

C#3: If I don't talk about it, the falls don't exist. I grit my teeth and just get on.

C#7: My wife doesn't know I worry a lot; I don't want to make her feel guilty.

Burden and rewards of care giving (caregivers)

Caregivers described caregiving in terms of objective and subjective burden and rewards. Objective burden refers to the amount of time spent on caregiving and the nature of the caregiving tasks that are performed. Caregivers describe tasks, such as

accompanying the care recipient to social activities or grocery shopping for them. Subjective burden refers to how the caregivers perceive the impact of the objective burden. Several caregivers mentioned that the possibility of their care recipient falling again resulted in a constant worry, vigilance and reluctance to leave the care recipient alone. This reluctance was highly burdensome since it leads to social withdrawal.

C#2: We are on standby 24 hours a day. We take our cell phones everywhere. She (mother-in-law) might fall.

C#3: My husband and children hate it when I don't join them at parties. When I am at a party, I am constantly thinking about my mother. Therefore, I better stay home; I can check on her and I am more comfortable.

In addition, caregivers experienced subjective burden because of the awareness of their care recipient's dependency, role changes, fatigue, and the feeling of being overwhelmed by duties.

C#3: After I (daughter) told her (care recipient/mother) not to go upstairs anymore, she said: 'Yes boss.' She makes me feel I am her mother; I hate it when she does that.

C#4: If something happens to me, he will be in trouble. It's quite a responsibility and hard to acknowledge.

Furthermore, caregivers mentioned that consequences of dementia or mild cognitive impairment such as forgetfulness, lack of understanding, and communication problems were more burdensome than falls, and represented obstacles to care and fall prevention.

C#2: She not only falls regularly, but she is demented too, you know! Her Alzheimer's is the biggest problem.

C#8: I have the feeling I am met by a wall of incomprehension if I advise her not to climb the stairs anymore, but that's only because of her dementia.

Two caregivers experienced rewards of caregiving, including satisfaction from caregiving and a heightened sense of self-esteem. Only spouse caregivers mentioned caregiving as a sense of duty.

C#5: He often says to me: 'If you weren't here to support me, what would happen to me'. I get an energy boost and feel proud.

C#7: We are married in sickness and in health. Of course I care for her.

All caregivers emphasized that day care, home care, family support, and respite care relieved the burden of caregiving by allowing them to be temporarily relieved of the responsibility of preventing their care recipients from falling.

C#3: Fortunately, from this week on, a nurse from home care is with her during lunchtime. It provides me with some rest. I know the nurse prevents her from falling.

Fall-prevention intervention (patients and caregivers)

At the end of the interview, interviewees were informed about a future intervention to support older persons and prevent them from falling. When asked what they

expect from such an intervention, the first reaction of most patients was that they could not be helped: falling was considered inevitable and impossible to prevent. Furthermore, they felt that nothing could be done to reduce their fear of falling. Only one patient, cognitively unimpaired, had a positive view of fall prevention.

P#1: To prevent people from falling is extremely important for older persons, but not for me. I now know what to do to avoid falling.

P#3: They can't take my fear of falling away, they can't.

P#5: To be able to get up after a fall by myself I need strength. They can't give me the strength in a course. I'd rather be told how not to fall, if that is teachable.

Most caregivers believed the intervention would not be useful because of their care recipients' cognitive impairment, physical problems, age, and personalities. One caregiver described the advantages of such an intervention.

C#1: My mother doesn't take to a thing quickly; she will tell the other participants how to deal with problems. Because of her memory problems, she is not teachable anymore.

C#3: A fall-prevention intervention has no added value. My mother is not that athletic anymore. She is already 80 years old. With all her medical problems, such an intervention is useless.

C#6: My wife (care recipient) has fallen a couple of times, but I am old too; maybe it is useful for both of us. We may learn to avoid falls.

After insistence of the interviewers, patients and caregivers named issues that patients should learn in such an intervention: awareness of the risk factors and consequences of falling, how to walk more safely, the best way to fall and stand up, and how to feel more secure. Only one caregiver directly described an area with which he needed help.

C#2: Situations that are normal to us can be dangerous for my mother-in-law; maybe we can learn how to make such situations safer.

Patients stressed that it would be helpful to contact other patients in the intervention with similar experiences:

P#2: Maybe my fellow sufferers can help me?

Discussion

This qualitative study is the first to examine the impact of falls on cognitively impaired frail older persons and primary family caregivers. Our findings shed new light on the impact of falls and fall prevention in frail older persons, especially for those suffering from cognitive impairment.

First, nearly all patients ascribed some or all falls to an unknown origin; this unawareness of origins was a source of fear and hindered coping. In two other studies that evaluated older persons without cognitive disorders and post-stroke patients, only a minority

did not know what caused their fall.^{10, 17} The unawareness of the cause in this study is probably due to the cognitive problems of our patients. Only a few interviewees attributed falls to the causes identified in the outpatient clinic. No interviewee mentioned cognitive impairment as a cause. Several patients and one caregiver who did not know the actual causes of the falls tried to establish an acceptable cause through repeated searches. One way that people regain a sense of control in the face of a threatening event is through such a causal attribution.²⁹ Healthcare workers should make sure that both patients and caregivers understand the cause of the falls to avoid fear and promote successful coping.

Second, the study underlines that a fall-prevention intervention for frail older persons, especially those with cognitive impairments, should include dyads of patients and their caregivers. In this way, caregivers could be trained to function as co-therapists at home and to overcome the problems of limited learning ability in cognitively impaired patients. A study has found that the benefits of intervention interventions are better maintained when caregivers supervise the patients.³⁰ Training and individualized support for caregivers of dementia patients reduced the caregiver burden.³⁰ Furthermore, caregivers and patients gain insight into each others' physical and mental capacities. They may be able to agree on the cause of the falls, although they did not report arguing with each other about the cause.

Third, caregivers rated the forgetfulness, lack of understanding, and communication problems that arise from their care recipients' cognitive impairment as a higher burden than their falls. Cognitive decline is also felt to be an obstacle to care and fall prevention. This indicates that before inclusion of dyads in a fall-prevention intervention, the caregivers should learn how to deal with the consequences of their care recipient's cognitive impairment.

Fourth, patients, especially those with cognitive impairment, and caregivers both expressed a fatalistic view on falls and a nihilistic expectation of fall prevention efforts. Patients described their falls as unexpected, uncontrollable, and elusive, indicating a low level of self-efficacy. They stated that a fall-prevention intervention could not prevent falls or reduce the fear of falling. This is in contrast with research on cognitively unimpaired older persons, which revealed that the main barriers to participate in a fall-prevention intervention included denial of falling risk and the belief that no additional fall prevention measures were necessary.²⁷ Caregivers described the falls as uncontrollable and unchangeable. In earlier research, caregivers of patients with dementia also expressed such fatalistic views of falls.¹⁴ Caregivers attributed the falls to intrinsic factors (for example, somatic origins and personal traits) and mentioned no extrinsic factors; similar attributions were seen from caregivers of PD patients as well.¹⁶ Intrinsic factors are seen as less controllable than extrinsic factors since they are caused by physiological changes.³¹ Since both patients and caregivers have a fatalistic view of falls and a negative attitude towards fall prevention, the chance that they will

engage in, and benefit from, an intervention is low (a negative self-fulfilling prophecy). Therefore, it is important that the potential participants are well-informed about the perceptions of falls, fall risk factors and the benefits of fall prevention, especially caregivers; such knowledge may promote a positive attitude towards fall prevention. Caregivers have an important role in fall prevention because they are trusted sources of information, and they are in a position to engage the older person in prevention interventions and to motivate them to adhere to the intervention.

Furthermore, our findings confirmed the consequences of falls in cognitively unimpaired older persons that are mentioned in the literature; these include a fear of falling and social withdrawal due to the fear of falling and physical limitations.^{9, 10, 13, 16, 21, 24} The coping styles found in our caregivers and patients were characterized by efforts to prevent falls and to avoid the problem; this resembles the coping styles of caregivers of demented and PD patients who fall^{14, 16} and of older persons who fall.^{9, 10} Caregivers reported that the constant fear and worry that the care recipient would fall, which resulted in a reluctance to leave the care recipient alone, was highly burdensome. Similar findings have been reported in other caregiver populations.^{15, 16, 26}

Fall-prevention intervention

In addition to the issues named by interviewees, the intervention should result in more awareness of the risk factors and consequences of falls, of how to walk, to fall and to stand up safely, and how to feel more secure. Activity should be promoted; in addition to reducing the fear of falling, this may result in less social withdrawal. Providers should discuss the causes of falls with individual patients, promote patients' and caregivers' self-efficacy, and help them to gain insight into each others' capacities.

Caregivers should be supported in order to reduce the caregiver burden, and they should be trained to supervise and motivate their care recipients. Since patients felt that contacting other patients with similar experiences would be helpful, a group format should be used.

Strengths and limitations

This study has some important methodological strengths. We followed quality guidelines for qualitative research with respect to purposive sampling, triangulation (interviewing both patients and caregivers), iterative analysis, and multiple coding.^{32, 33} The sampling and data analysis achieved saturation. The manuscripts of the interviews were tested with interviewees (in other words, member checking), and the interviewees had no comments. This study has some limitations. Our sample size was small, which is typical of qualitative research, and the results are not statistically valid for other populations. However, since the interviewees were broadly representative of patients and family caregivers at our outpatient falls clinic, our results may be generalized to

other similar outpatient populations. We did not monitor the effects of the geriatric consultation, which prevented us from discriminating the interviewees' direct fall-related experiences from those caused by the information they received. However, diagnostic labels can significantly influence a persons' emotional responses, attributions, and coping skills.³⁴

Conclusion

The consequences of falls for frail community-dwelling older persons, including fear of falling and social withdrawal, are comparable to the consequences for non-frail, cognitively unimpaired, older persons. However, frail older persons, especially those suffering from cognitive impairment, could not name a cause for their falls; this inability is probably a major source of fear and hinders coping. A fall-prevention intervention should focus on reducing the consequences of falling, provide advice on walking and standing more safely, and promote self-efficacy and activity. The causes of falls should be discussed.

We suggest that such an intervention should include dyads of patients and caregivers. Through this approach, caregivers can be trained to provide supervision to the patients and function as co-therapists to overcome the problems of limited learning ability in cognitively impaired patients. The highly burdened caregivers can be more directly supported and their fear of their care recipient falling can be reduced. Furthermore, caregivers should also receive instruction about dealing with the consequences of both their care recipients' cognitive impairment and falling. However, before starting a fall-prevention intervention in frail older persons and their caregivers, providers should notice the dyads' attitudes towards fall prevention and try to transform nihilistic attitudes into positive ones; this transformation would promote uptake and improve the chances of success of such an intervention.

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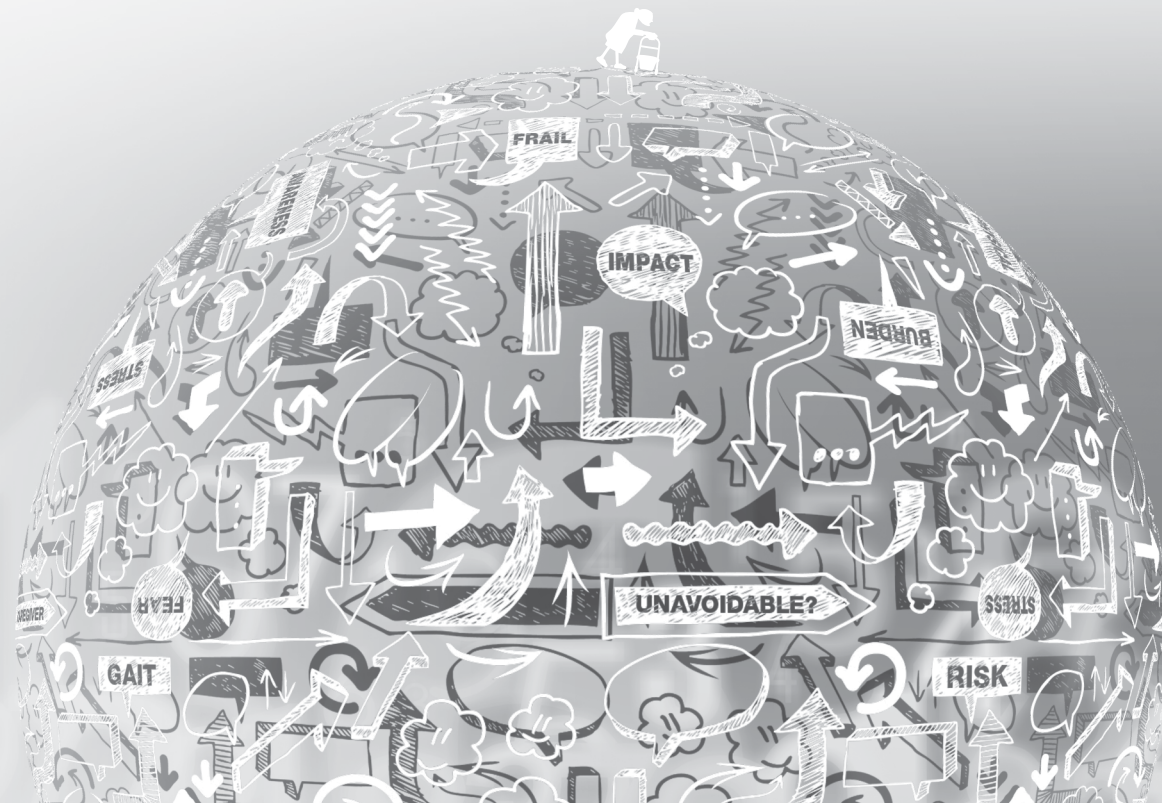
Development and evaluation of complex health care interventions

Published as:

Developing and evaluating complex health care interventions in geriatrics: the use of the Medical Research Council framework exemplified on a complex fall prevention intervention.

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Abstract

Geriatrics focuses on a variety of multi-organ problems in a heterogeneous older population. Therefore, most geriatric health care interventions are complex interventions. The UK Medical Research Council (MRC) has developed a framework to systematically design, evaluate, and implement complex interventions. This paper provides an overview of this framework and illustrates its use in geriatrics by showing how it was used to develop and evaluate a fall-prevention intervention. The consecutive phases of the framework are described:

Phase I: Development. This phase began with a literature review, which provided the existing evidence and the theoretical understanding of the process of change. This understanding was further developed through focus groups with experts and interviews with patients and caregivers. The intervention was modeled using qualitative testing of the preliminary intervention through focus groups and through the completion of Delphi surveys by independent specialists.

Phase II: Feasibility and piloting. In this phase, a pilot study was conducted in a group of patients and caregivers. The feasibility of the intervention and evaluation was also discussed in focus groups of participants and instructors.

Phase III: Evaluation. The information from phases I and II shaped the design of a randomized controlled trial to test the effectiveness of our intervention.

Phase IV: Dissemination. The purpose of the final phase is to examine the implementation of the intervention into practice.

The MRC framework provides an innovative and useful methodology for the development and evaluation of complex geriatric interventions that deserves greater dissemination and implementation.

Introduction

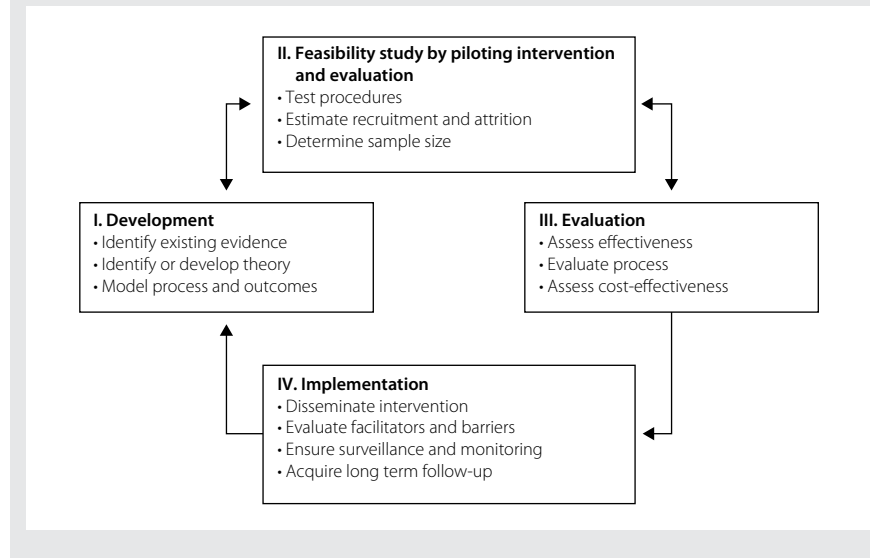
Geriatric medicine focuses on diagnosing and treating geriatric syndromes and their underlying multiple causes or contributing factors, rather than on diagnosing and treating single diseases. In addition, the geriatric population is a highly heterogeneous population, and most health care interventions in geriatric populations are therefore complex interventions. Complex interventions are defined as interventions that contain several (multifaceted) components that may act both independently and interdependently.¹ Based on the predominant geriatric paradigm of multi-causality, complex multi-factorial interventions are generally considered to be more powerful in this population than single-component interventions because they can address more potential risk factors.²

Complex interventions are difficult to develop, document, and reproduce. Randomized controlled trials (RCTs), which are required to demonstrate their effectiveness, are usually costly and challenging.³ The extension of the CONSORT statement on trial reporting emphasizes that sufficient details regarding the intervention should be reported, although it does not specifically address the problems associated with describing complex interventions.⁴ In 2000, the UK Medical Research Council (MRC) developed a framework based on the linear sequenced phases of drug development for use in the design, evaluation, and implementation of complex interventions.⁵ In 2008, a revised version was published in which the process of developing and evaluating complex interventions was described by cyclical phases (Figure 1).^{3,5}

The major strength of the MRC framework is the systematic way in which it proposes developing the best intervention and the best evaluation methods. This involves using the best available evidence and appropriate theories. The intervention and evaluation should be tested and adapted to clinical practice using a carefully staged approach, starting with a series of small studies targeted at each of the important uncertainties in the design and the intervention. It should then move on first to an exploratory and subsequently to the definitive design of the evaluation, as well as from the pilot content to the final content of the intervention. Finally, the results should be disseminated as widely and persuasively as possible, and further research should be undertaken to assist and monitor the process of implementation.⁵ Taken together, the various phases of MRC framework may be of great value in geriatric research, although this framework has not yet been widely referenced in the geriatric literature.^{2,6-8}

The MRC framework was used to guide the development and evaluation of a multi-factorial fall-prevention intervention for frail community-dwelling older persons, with and without cognitive impairment, and their informal caregivers. To the authors' knowledge, no fall-prevention intervention has proven to be effective in frail community-dwelling patients with dementia or mild cognitive impairment.⁹⁻¹¹ This justifies new

Figure 1 Important elements of the phased development and evaluation of complex interventions in general terms (adapted from Craig et al.⁵).



research investments, but asks for a very thorough developmental stage to overcome the many restrictions found in this frail population.

The first section of this paper describes the four phases of the MRC framework for the development and evaluation of complex interventions. The second section describes the application of the MRC framework in geriatrics by illustrating its value in developing and evaluating our 'Carthage-Phoenix study', a complex fall-prevention intervention.

Medical Research Council framework (MRC)

The MRC framework has four phases: development, feasibility and piloting, evaluation, and implementation.

Phase I: Development

Identify existing evidence

The first step is to define and quantify the target population and to identify previously published data regarding similar interventions and the methods that have been used

to evaluate them.^{5, 12} This may help exclude implausible interventions, reveal possible facilitators or barriers to the research project, and predict major confounders. This process helps ensure that the best choices are made regarding the intervention and proposed hypothesis, and also elucidates strategic design issues.^{1, 13}

Identify or develop theory

The second step is to develop a theoretical understanding of the process by which change is likely to occur in one's intervention by drawing on existing evidence and theory from literature. If necessary, new primary research can supplement this.⁵ Insight into the theoretical basis of change may lead to adjustment of the hypothesis and identification of potential useful components or organization structure of the intervention.¹³

Model process and outcomes

Modeling refers to defining and combining the components of the intervention. An understanding of the intervention and its possible effects should also be developed. This involves delineating an intervention's components, identifying how they may be interrelated, and understanding how important components may relate to surrogate endpoints or final outcomes. Modeling may identify the potential vulnerabilities of an intervention. The researcher should overcome these vulnerabilities to improve the intervention. Modeling the intervention will inevitably prompt the planning of strategies for randomization and the selection of outcome measures and analytical methods.¹ A series of small studies may be required to define most relevant interventional components and reveal ways to tailor the intervention contents to the participants.¹ Complex interventions often work best if they are tailored to local contexts as opposed to being completely standardized.⁵

Another useful approach to modeling is to undertake a pretrial economic evaluation. This may identify weaknesses and lead to refinements or even show that a full-scale evaluation is unwarranted.^{5, 14}

Phase II: Feasibility study by piloting intervention and evaluation

The feasibility and piloting phase includes the implementation of testing procedures to assess the feasibility of the intervention and subsequent evaluation, the estimation of the likely recruitment rate and retention rate of the participants, and the calculation of appropriate sample sizes. Special attention should be paid to the burden the intervention and evaluation poses on the participants. The benefit-to-burden ratio should be maximized.¹⁵

A combination of qualitative and quantitative methods is likely to be needed during this phase. Several guidelines are available for the conduct and report of qualitative research.^{16, 17} A variety of assessments must be performed, including those that will help the investigators understand barriers to participation, estimate response rates, and identify the critical components of the intervention that should be standardized or controlled versus those that could be varied systematically. Depending on the results in this phase, a series of studies may be required to progressively refine the design before embarking on a full-scale evaluation.¹ Piloting results in moving forward (evaluation) or backwards (re-modeling), depending on the pilot study's outcome.

Phase III: Evaluation

To design and conduct a trial, researchers must make final decisions about the nature of the intervention and address standard design concerns.⁵

Assess effectiveness

Randomization is always preferred, in order to prevent selection bias. If an experimental approach is not feasible, a quasi-experimental or observational design may be considered.⁵

Measuring outcomes

Researchers need to decide on primary and secondary outcome measurements and how to address multiple outcomes in the analysis. It is also important to consider potential sources of variation in outcomes and to plan appropriate subgroup analyses so as to further examine them.⁵

Understand change process

Process evaluations, which explore the way in which the intervention under study is implemented, can provide valuable insight into why an intervention fails or has unexpected consequences. Conversely, they can also provide insight into why a successful intervention works and how it can be optimized. Researchers should consider including a process evaluation nested within a trial to clarify causal mechanisms, identify contextual factors associated with variations in outcomes, and assess the fidelity and quality of the implementation.⁵

Assess cost-effectiveness

To ensure that the potential benefit of the evidence the intervention will generate justifies its costs, an economic evaluation should be included in the study design. This will make the results far more clinically useful for decision-makers.³

Phase IV: Implementation

Dissemination

A full description of the intervention, allowing any planned variation and facilitating further publications, is essential for successful dissemination. Furthermore, to ensure that the findings are translated into routine practice or policy, they should be made available such that the material is accessible and convincing to decision-makers and can be easily and actively disseminated.^{3, 13}

Surveillance, monitoring, and long-term follow-up

It should be assessed whether others can reliably replicate the intervention and results in uncontrolled settings over the long term. Particular attention should be paid to the rate of uptake, the stability of the intervention, any broadening of participant groups, and the possible existence of adverse effects. As in the case of drug trials, this might be done by using long-term surveillance.^{3, 13} The implementation phase can be conducted after, or partly alongside, the evaluation. The challenge is to phase the implementation such that the choice is not between doing nothing until the evidence is ready, or going for broke and hoping that observational data will show that the intervention works. The stepped wedge design may be used as an acceptable solution for this dilemma. In this experimental design, the whole population receives the intervention but with randomization built into the phasing of implementation.³

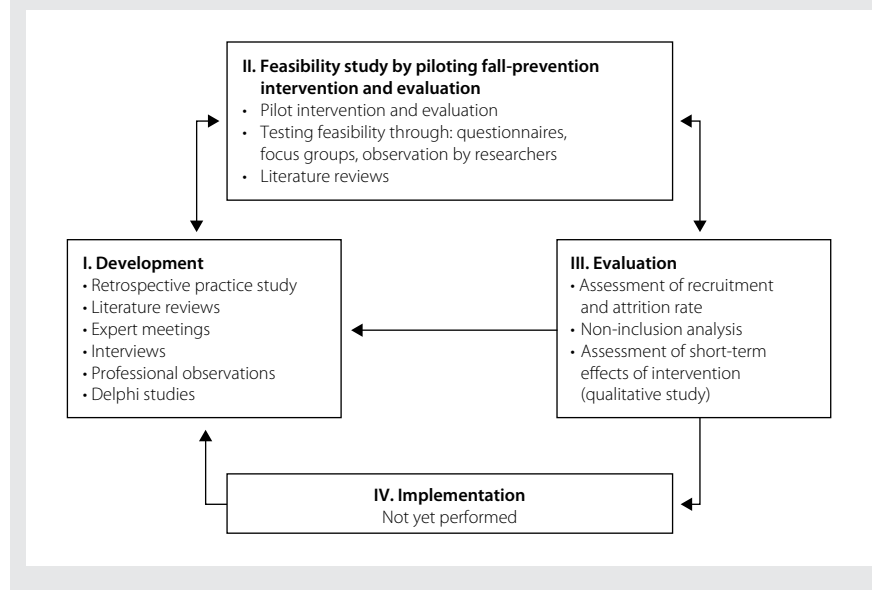
The MRC framework applied to a complex geriatric intervention: the Carthage-Phoenix Study

The motivation for the development of this intervention arose from the lack of an evidence-based fall-prevention intervention for frail community-dwelling older persons, including patients with cognitive impairments. Existing interventions were not effective or excluded patients with cognitive decline.¹⁰ The study was named the 'Carthage-Phoenix Study' (CPS) in reference to the fall and resurrection of this ancient city, and targeted the intervention, among others, at helping cognitively frail older persons to rise after falling. The guidelines for the development and evaluation of behavior change interventions of the National Institute for Health and Clinical Excellence (NICE)¹⁸ the causal modeling approach of Hardeman and colleagues,¹⁹ and the recommendations of Campbell and colleagues,¹³ regarding complex interventions were used to supplement the official recommendations of the MRC framework. Table 1 shows methods that were used to design the intervention and the evaluation. Figure 2 gives an overview of the content of the specific phases as they were specifically applied to the CPS. Below, a summary of the findings on each of these tasks is provided.

Table 1 Methods used for the development phase and the piloting and assessing feasibility phase of the Carthage-Phoenix study.

General phases according to the MRC framework	Specific methods applied in the CPS fall-prevention intervention
Phase I: Development	
Identify existing evidence	
<i>Define and quantify the target population</i>	<ul style="list-style-type: none"> - Descriptive analysis of the characteristics of the cohort of 43 patients seen in an outpatient geriatric fall clinic between January and July 2007 (results not published) - Literature review of epidemiological studies on falls in frail community-dwelling older persons, focusing specifically on cognitively impaired older persons - Project team meeting (geriatrician, neurologist, clinical human movement scientist, resident in geriatrics) - Literature review of the available evidence regarding the importance of falls (for example, the physical, psychological, and social consequences of falls) - Project team meeting
<i>Define the health outcome</i>	<ul style="list-style-type: none"> - Literature review of the available epidemiological evidence regarding risk factors of falls - Project team meeting
<i>Understand the pathways that cause and sustain the problem</i>	<ul style="list-style-type: none"> - Literature review of the available evidence regarding risk factors of falls
<i>Identify similar interventions</i>	<ul style="list-style-type: none"> - Literature review of interventions to prevent falls and reduce fear of falling in frail community-dwelling older persons with and without cognitive impairment
<i>Identify outcome measures</i>	<ul style="list-style-type: none"> - Literature review of the outcome measures used in fall prevention trials and objective ways of measuring falls and fear of falling
<i>Predict major confounders, barriers, and strategic design issues</i>	<ul style="list-style-type: none"> - Literature review of the methodology used in fall prevention trials - Project team meeting
Identify or develop theory	
<i>Specify changes that are expected and theory-based determinants</i>	<ul style="list-style-type: none"> - Semi-structured interviews with ten frail community-dwelling older patients (three cognitively unimpaired patients; four patients with mild cognitive impairment, and three patients with dementia) who experienced a recent fall and ten primary family caregivers - Literature review of behavioral change theories and strategies to reduce fear - First expert meeting: focus group with the project team and additional experts in various fields (geriatrics, human movement sciences, medical psychology, geriatric physical therapy, geriatric nursing, and geriatric psychiatry) - First professional, non-participatory observation: cognitive-behavioral group and individual therapy to reduce fear, as delivered by psychologists
<i>Specify intervention points and behavior change techniques</i>	<ul style="list-style-type: none"> - Literature review on behavioral change techniques and cognitive restructuring techniques - First expert meeting - Meetings with a medical psychologist and a geriatric physical therapist
Model process and outcomes	
<i>Select the best available combination of intervention components and intensities</i>	<ul style="list-style-type: none"> - Second expert meeting - Semi-structured interviews with experts - Semi-structured interviews with patients and caregivers - Project team meeting - Delphi study including independent specialists recognized in the different domains of the intervention (geriatric nursing, clinical neuropsychology, geriatric physical therapy, occupational therapy, geriatric psychiatry, geriatrics, human movement science, rehabilitation medicine, gerontology, and medical psychology) - Second professional, non-participatory observation: session for physical therapists, who were trained to deliver a fall-prevention intervention for non-frail older persons
<i>Identify barriers to application of the intervention</i>	<ul style="list-style-type: none"> - Literature review - Third professional, non-participatory observation: physical training sessions for patients with dementia, as conducted by physiotherapists
<i>Plan strategies for randomization, blinding, recruitment, adherence, outcome measures, and analysis</i>	<ul style="list-style-type: none"> - Literature review on the available evidence regarding the recruitment and adherence of older persons in aging research - Second expert meeting - Project team meetings - Consultations with a biostatistician - Consultations with an expert in health technology assessment
Phase II: Feasibility study by piloting intervention and evaluation	
<i>Test the feasibility of the recruitment process, intervention, and measurement</i>	<ul style="list-style-type: none"> - Observation of the intervention by independent researchers - Project team meetings - Evaluation of each session with the researchers and the instructors - Focus group with patients, caregivers, instructors, and researchers - Focus group with researchers and instructors - Questionnaires administered to patients, caregivers, and instructors evaluating the performance of the intervention, attendance and adherence of participants; and opinion of patients, caregivers, and instructors on the intervention - Evaluation of the baseline assessment with patients and caregivers - Third expert meeting
<i>Estimate recruitment and retention</i>	<ul style="list-style-type: none"> - Project team meeting - Literature review
<i>Determine sample size</i>	<ul style="list-style-type: none"> - Project team meeting - Literature review of the effectiveness of similar interventions - Experiences and data on attrition in former studies - Consultation with a biostatistician

Figure 2 Content of the specific phases as exemplified for the Carthage-Phoenix Study.



Phase I: Development of the Carthage-Phoenix Study

Identify existing evidence

Define and quantify the target population

The descriptive analysis of our target population revealed that all of these patients were frail according to the criteria of Fried and colleagues,²⁰ that 50% of the patients experienced a fall at least every month, and that seven percent of the patients fell daily. The mean Mini-Mental State Examination (MMSE) score of these patients (range 0-30) was 24.5 (SD 4.6).²¹ These patients had a high level of fear of falling, as measured with the Falls Efficacy Scale.²²

Define the health outcome

The main health outcome of the study was fall reduction. Our research on the characteristics of the population and the existing literature revealed that fear of falling is a frequently reported and serious consequence of falling. Therefore, the project team targeted the intervention to two outcomes: fall reduction and decreasing fear of falling.

Understand the pathways that cause and sustain the problem

The risk factors for both falling and fear of falling are well known,^{11, 23} and it has been suggested that different pathways exist for different groups of fallers. Patients with dementia walk relatively too fast in the context of their frailty, which leads them to have a high risk of falling.²⁴ Cognitively unimpaired patients with an inappropriately low fear of falling based on their fall risk also seem to overrate their physical capacities,²⁵ and this lack of insight leads to a higher fall risk in these patients. Another group of patients has an inappropriately high fear of falling, which is a contributing factor to falling because this fear results in activity restriction, which leads to loss of strength and joint mobility, which in turn increases the risk of falling.^{26, 27} Therefore, this intervention should address two types of patients: fearful individuals and impulsive individuals with a lack of insight.

Identify similar interventions

Although contradictory evidence exists on this topic, most evidence suggests that community-dwelling older persons at high absolute risk for falling, with MMSE scores of 20 or above, or both should be offered a multi-factorial intervention to prevent falls. Such an intervention begins with a multi-factorial fall-related patient assessment and is followed by an individualized multi-component exercise intervention that focuses on gait, balance, strength, flexibility, and endurance.^{9-11, 28-32} In the outpatient geriatric fall clinic at the Radboud University Nijmegen Medical Centre, this type of assessment was already part of the usual care algorithm, so there was no need to develop an assessment.

Research in community-dwelling older persons with dementia has demonstrated that these individuals can adhere to interventions known to reduce risk of falls in cognitively healthy populations and has also shown that these interventions can modify targeted risk factors for falls in this population, but no convincing evidence exists that falls can be prevented in older persons with dementia.¹⁰

In cognitively unimpaired older persons, fear of falling can be reduced,³³ but evidence regarding reducing fear of falling or fear in general in cognitively impaired older persons is lacking, indicating that this intervention is the first intervention aiming at the reduction of fear of falling in frail older persons with and without cognitive impairment.

A recent investigation of cognitive-behavioral therapy (CBT) treatment for older persons with generalized anxiety disorder (GAD) found that some individuals with executive dysfunction showed positive treatment response, whereas others showed virtually no response.³⁴

Identify outcome measures

The Prevention of Falls Network Europe (ProFaNe) has recommended important

domains (falls, fall injury, physical activity, psychological consequences, and generic health-related quality of life) for outcome assessment in fall prevention trials. It has also suggested specific outcome measures within each domain.³⁵ Based on these recommendations, fall incidence rate and the Falls Efficacy Scale-International (FES-I) score, which is a valid and reliable measure of fear of falling,³⁶ were selected as the major outcome measures. Among others, physical activity and quantitative gait and balance analysis were selected as secondary outcome measures.

Predict major confounders, barriers, and strategic design issues

The benefits of interventions in cognitively impaired older persons are better maintained when caregivers act as co-therapists for the patients.³⁷ Patients indicated that the negative attitudes of others (for example, family and friends) regarding an intervention were a barrier to participation and adherence.³⁸ To overcome this problem, it is important to explore the attitudes of the caregivers towards fall prevention and to transform a negative attitude into a positive one when performing this type of study. The project team suggested including informal caregivers in the intervention and addressing their attitude concerning the fall prevention program. The project team sent a review of the acquired evidence to the participants of the expert meetings (Table 1) to further shape the intervention and evaluation.

Identify or develop theory

Specify changes that are expected and theory-based determinants

At their first meeting, the experts agreed with the project team that informal caregivers should be included in the intervention, which is unique in fall prevention programs. To gain insight into the role of the caregiver and the needs of both patients and informal caregivers, in-depth interviews were conducted with both patients and caregivers. The interviews revealed, among other things, a high caregiver burden among caregivers of frail fallers and resulted in the addition of several active ingredients to the intervention.

Because primary informal caregivers were included in the intervention, the hypothesis was extended to state that the intervention should also be able to reduce caregiver burden.

At the expert meeting, it was decided that the intervention should have two interacting components: a physical component and a psychological component. The physical component consisted of exercises focusing on the functional performance of activities of daily living, familiar to patients even with (mild) cognitive impairment, and known to reduce falls. The intensity of the exercises was based on recommendations in the literature.^{9, 39} The psychological component focused on reducing patients' fear of falling and decreasing the avoidance of activities, but also on high-risk behavior in impulsive fallers and changing the home environment to reduce fall risk.

To accomplish the goals of the intervention, patients and caregivers had to change their health-related behaviors. Psychological theories providing a way to link beliefs about health and motivation (for example, intention and self-efficacy) with behavior (for example, adopting falls preventive advices) were also applied. Specifically, the Theory of Planned Behavior (TPB), which specifies causal links between determinants of intentions to change, and actual behavior,^{18, 19} was chosen as one of the theories to underpin the intervention. This theory The bolstering of individuals' intentions is important, because the interviews revealed that risk awareness and the associated motivation to adopt measures to prevent falling were not always present in both patients and family caregivers. The interviews also revealed that these groups both expressed a low level of self-efficacy.

CBT has been shown to be effective in older patients with fear of falling and has also been shown to have some effectiveness in older cognitively impaired persons with GAD.^{34, 40} Therefore, the experts decided to use elements of this therapy to reduce patients' fear of falling.

Specify intervention points and behavior change techniques

In the interviews, patients had expressed that contacting other patients with similar experiences would be helpful. Therefore, a small-group learning environment was used for this intervention, with groups including both patients and caregivers. An additional argument for using a small-group learning environment was the proven effectiveness of group interventions to reduce falls in patients without cognitive impairment.⁹

The NICE behavior change techniques used in this intervention are based on the TPB and other behavioral change theories.¹⁸ Cognitive restructuring (element of CBT) was chosen as a technique to reduce patients' fear of falling. It employed the technique of promoting realistic and adaptive views regarding individuals' fall risk and fear of falling.⁴⁰ Moreover, experts stated that fear should be elicited during the intervention to teach participants how to cope with it.

Model process and outcomes

Select the best available combination of intervention components and intensities

Based on two Delphi studies, an earlier literature review, and expert opinion, the project team decided on the total number, frequency, duration of the sessions of the intervention; selection of intervention instructors; and ways to involve caregivers in the intervention. The team ultimately decided to have ten sessions (twice a week) that lasted two hours each and were administered by a psychologist and geriatric physical therapist.

To tailor the intervention to a specific pair, both caregivers and patients should be asked to set realistic goals that they hope to accomplish during the intervention.

Furthermore, the intervention should include a supportive session for the caregivers. The experts suggested several measures to facilitate habit formation of healthy behavior in both patient and caregivers, namely homework exercises (mainly physical exercises), repetition of the main topics of a session several times in the current session and repetition in the next session, and a booster session three months after the last regular session had been completed. The Delphi studies determined the content and amount of homework. From a second professional, non-participatory observation (Table 1), it became clear that, teaching our patients about how to fall safely was not suitable for our population of frail patients and should not be part of the intervention.

Identify barriers to application of the intervention

In the interviews, patients and caregivers expressed their opinions on the requirements the venue should meet to in order stimulate their adherence to the intervention. Although it is beneficial to include caregivers in these types of interventions, the experts also identified their inclusion was as a potential barrier. For example, it might be challenging for caregivers to attend the sessions because of work or childcare obligations. Therefore, the experts suggested that the researchers should clearly explain the benefits of the intervention and the need for their caregiver participation to those who were considering taking part in the study.

Plan strategies for randomization, blinding, recruitment, adherence, outcome measures and analysis

Because randomization at the level of the individual patient was judged possible with this type of intervention, a randomized controlled trial was considered to be the most appropriate design. Pairs in which both the patient and the caregivers provided informed consent were chosen as the unit of randomization.

Recommendations were adopted from the literature regarding the engagement and the adherence of older persons in activities to prevent falls and aging research in general,^{15, 38} as well as recommendations regarding type and number of outcome measures, and lowering attrition rate in RCTs in frail older persons. Frail older persons are more likely to miss appointments because of disease, tiredness, or lack of transportation to the hospital. To lower the attrition rate, it was decided that the actual assessment date should be within one month before or after the intended assessment date.⁴¹ One of the recommendations regarding enhancing patient adherence, stressed the need for investigators to tailor interventions to the specific situation and values of each participant.³⁸ The independent specialists proposed this recommendation (among several other measures) as well.

Based on the practical experiences with the target group, a multistage recruitment process was designed for the RCT. Geriatricians would first identify eligible patients in the outpatient geriatric fall clinic by completing a screening form for every patient.

Next, the eligible patients and caregivers would be given a flyer with information about the study, and their personal details would be passed on to the researchers. The researchers would subsequently call the patients and caregivers to provide a short overview of the study. Next, extensive written information would be sent to the patient and caregiver or a follow-up visit would be scheduled to provide more information. Finally, the researchers would call the patients and caregivers in order to address remaining questions and ask for their participation. The expert panel endorsed this multistage personalized recruitment and inclusion process, which is in line with recommendations that were made in an earlier article in this series on clinical aging research methods.¹⁵

Fall incidence rate was measured by asking patients to mail a follow-up fall calendar to the researchers every two weeks. Each fall was further characterized by directly telephoning the patients.⁴¹ If a patient could not complete a fall calendar independently, the caregiver was asked to do so. Nonresponders were contacted over the telephone so that the fall history for the missing calendar weeks and underlying reasons for their lack of response could be assessed.

Outcome measures that were applicable to both cognitively impaired and cognitively unimpaired patients were chosen based on the outcome measures recommended by ProFaNe.

The project team and a health technology assessment specialist designed the economic evaluation. Main outcomes of the economic evaluation are the total care costs per successfully treated patient (no fall in the six months follow-up, or a 20% reduction in fear of falling or both) and per fall prevented.

Phase II: Feasibility study by piloting intervention and evaluation of the CPS

Test the feasibility of the recruitment process, intervention and measurement

Once the draft intervention had been designed and described in a series of guideline, the researchers explicitly trained the instructors to deliver the intervention in the pilot study. Next, a guide was written for the patients and caregivers that included practical information regarding the intervention, the goals of the intervention, and a brief outline of the intervention.

Recruitment process

The participating geriatricians completed screening forms for all patients they saw during the pilot period. Based on the screening form, eight pairs received written information. Researchers provided additional information and answered questions, which patients and caregivers greatly appreciated. Four pairs provided informed

consent for their participation in the pilot study. After the first session, one pair dropped out because of hospitalization of the patient.

Intervention: content

During the first pilot session, it became clear that the functional and the cognitive levels of the patients were lower than had been expected. Therefore, it was necessary to reduce the number of exercises and psychological components in the intervention.

Instructors', patients' and caregivers' opinions about the intervention were evaluated through focus groups and questionnaires. Based on these questionnaires, the recommendations that resulted from the expert meeting, and the suggestions of the researchers and instructors, a basic set of intervention components and several additional components were established in order to tailor the intervention to each individual participant.

Intervention: organization

The presence of the caregivers indeed proved to be of added value for the intervention, although they needed encouragement from the instructors to help the patients with their homework exercises.

As the instructors, caregivers and patients indicated in the questionnaires and focus groups, they were all satisfied with the duration, number, and frequency of the sessions. The intervention was not burdensome to the patients and instructors. The caregivers felt burdened by the need to attend all sessions. The project team decided that caregivers should attend as many sessions as possible, but could be replaced by another caregiver in case of prior obligations. Caregivers and patients reported that a group with three pairs was too small, and that one with eight pairs would be better. However, to ensure patient safety, a maximum of five pairs will be included.

Based on the results of the pilot study and the discussion in the third expert meeting, the intervention was revised. Eventually, a final intervention emerged that all of the experts and stakeholders thought would function in a real-world setting and would be suitable for the evaluation.

Measurements

The patients in the pilot study used the fall calendar to record their falls during the five-week pilot period. The caregivers had to remind their care recipients to fill out their calendars. Patients reported that if they were asked to continue to fill out calendar over a longer period of time, they would probably forget to do so. Furthermore, obtaining high-quality reports of falls is resource-intensive for the researcher, as well as the patient and the caregiver, so a pilot study was initiated to be performed alongside the randomized controlled trial to evaluate the feasibility, validity, and reliability of a telephone inquiry system to detect falls.⁴²

The feasibility of the baseline assessment (questionnaires in patients and caregivers, and quantitative gait and balance assessment only in patients) was also tested in this pilot study. We sent the questionnaires to participants' homes a week before they visited the hospital for their baseline assessment, which allowed patients and caregivers to complete the questionnaires at their convenience. The researchers asked the patients and caregivers to give their opinion on the assessment in a focus group. The baseline assessment was completed in a timely fashion for patients and caregivers. The assessment was not overly burdensome for patients or caregivers.

Estimate recruitment and retention and determine sample size

The main goals of the pilot study were to evaluate the feasibility of the intervention and to make the final selection of intervention and outcome measures, although the sample size estimations had to be based largely on reports available in the literature.⁴³ An attrition rate of 15% was estimated based on a pilot study and prior research that had been performed in frail older persons.⁴⁴

To identify as many eligible patients as possible, patients were recruited from all geriatric outpatient clinics, and two neighboring hospitals were recruited to participate in the study.

Phase III: Evaluation of the Carthage-Phoenix Study

This section provides examples of parts of the evaluation process that required specific attention based on the MRC framework.

The multicenter RCT began recruitment in January 2008 and closed in September 2009.

Assess effectiveness

For logistic and capacity-related reasons, the pairs entered the allocation procedure in batches of ten pairs: five controls that received usual care and five pairs that received the intervention. To overcome allocation predictability and imbalance, treatment allocation was based on a recently developed minimization algorithm. This algorithm balances prognostic factors between treatment groups within batches and overall. Prognostic factors were identified based on the literature and the pilot study.

In May 2008, it became clear that only 20% of the eligible patients had consented to participate in the study. According to the framework, a second feasibility study was started and a non-inclusion analysis conducted to reveal the reasons for non-consent and to identify differences in the characteristics of patients and caregivers who consented to participate in the study and those who did not.

Following the recommendations of the instructors, the project team moved up the booster session from three months to six weeks after the last regular session.

Based on results of the non-inclusion analysis and the preliminary results of the full-scale evaluation, the researchers developed an additional intervention alongside the RCT in which the original intervention was adapted to a home program. This meant moving backward in the framework from phase III to phase I again.

Measure outcomes

To determine whether short-term changes persisted in the patients, long-term follow-up measurements (questionnaires in patients and caregivers, and quantitative gait and balance assessment only in patients) were scheduled at the hospital. The three follow-up assessments are similar to the baseline assessment. After the start of inclusion, the project team omitted one of the quantitative gait and balance assessments in patients for which a hospital visit was required. As a result, patients and caregivers needed to complete only a mailed questionnaire that could be returned in the pre-addressed stamped envelope.

If patients were too ill or exhausted to come to the hospital for the quantitative gait and balance assessment or to complete the questionnaires, they were offered a brief telephone assessment to measure falls and fear of falling (the primary outcome measures).

As recommended in the literature, missing data were re-collected where possible, and the demographic characteristics of participants who had missing data and the reasons that the data was missing were added.⁴¹

Evaluate process

Questionnaires were administered to patients, caregivers, and instructors in order to gain insight into the factors that were potentially influencing the effectiveness of the intervention and to identify factors that would facilitate the future implementation of the intervention. Three main process factors that the researchers felt had the potential to modify primary outcome measures were assessed: 1. study population; 2. intervention components; 3. evaluation data. These process measures also represent potential confounders.

Phase IV: Implementation of the fall-prevention intervention

Because it was decided to adapt the original intervention, which meant that it was necessary to move backward again in the framework, the original fall-prevention intervention was not implemented, so the implementation phase is not exemplified in this article.

Funding of complex interventions

The resources needed to develop, evaluate, and disseminate a complex intervention are highly dependent on the type of intervention and evaluation. It is the challenge for geriatric researchers to explicitly explain the preconditions to be met to enable scientifically sound research on complex interventions with frail older persons. This article and the MRC framework may contribute to the body of evidence that can be referred to when specifying special needs for design and funding of such studies.³ Apart from researchers, funders may use this article and the MRC framework to assess whether developmental research sufficiently addresses the challenges of the four subsequent MRC framework phases and the criteria directly related to this (Table 2).³

Table 2 Checklist for researchers and funders for effective and efficient research on developing complex interventions in geriatrics (adapted from Medical Research Council³).

- Are the MRC framework phases of development, feasibility and piloting, evaluation and dissemination sufficiently elaborated?
- Are stakeholders involved in the choice of the main research question and design of the research to ensure relevance and feasibility?
- Is the (existing) evidence provided and evaluated in an integrated and graded way? Is it based on systematic reviews and not solely on individual studies or clinical experience?
- Is the subtype of frail older persons, whom the intervention aims at, sufficiently described?
- Are all harms, benefits, and costs identified?
- Is the context and environment in which the evaluation is undertaken, sufficiently explored and the intervention adapted to this?
- What user involvement is going to facilitate in recruitment and carrying out the study?
- Is the study ethically sound and already judged on proportionality, with regard to the vulnerable patients involved, by the ethical review board?
- What arrangements are put in place to monitor and oversee evaluation, feasibility, effectiveness, and efficiency of the (evaluation of the) intervention?

Discussion

Developing and evaluating complex healthcare interventions is a high priority in geriatrics. This process is challenging, as it requires excellence in patient care and research, and rewarding, because it can improve patient care. This study illustrated that the MRC framework for the development and evaluation of complex interventions is a useful tool that describes, underlines, and supports this specific innovation technique. The framework successfully guided the development, evaluation, and reshaping of a fall-prevention intervention. Moreover, in the past it also helped design an occupational therapy intervention for patients with dementia and their caregivers that can be performed in the home that is currently the intervention that has the largest effect size on functional performance of all existing drug and non-drug interventions in dementia.^{37, 45} The framework is useful for complex geriatric interventions in general, particularly in the evaluation of geriatric syndromes.⁴⁶

The use of the MRC framework eliminates the risk of evaluating unfeasible interventions and using designs that do not fit, and maximizes the chance of developing a successful intervention and evaluation. In this way, resources are saved and the benefit-to-burden ratio of frail participants is maximized. Furthermore, for interventions that fail to demonstrate effectiveness, it is useful to move backward in the cyclical process. In this way, deficits in the development process or evaluation design can be determined, rather than abandon the intervention altogether.

It was possible to refine the fall-prevention intervention and evaluation by using a number of methods and resources. Conducting in-depth interviews with patients and informal caregivers ensured that the intervention was appropriate and relevant to the needs of the target population. Furthermore, experts and independent specialists (through expert meetings and Delphi studies, respectively) in all of the different domains of the intervention. Previous studies have found that expert groups provide valid representations of the opinions of the fields that they represent.⁴⁷

The framework stresses the importance of piloting and process evaluation, and the publication of these data. The published literature on fall-prevention interventions shows that it may impair the chances for future research, because only the negative RCTs of a complex intervention are published. For example, after the last negative trials on fall prevention in patients with cognitive impairment, no other interventions seem to have been attempted in these patients. To prevent such deadlocks, systematic methodological guidelines, such as the MRC framework, stimulate researchers to publish data on piloting and on careful process evaluations in conjunction with negative outcomes on complex interventions.

In conclusion, a fall-prevention intervention for frail older fallers, including patients with cognitive impairment, and their caregivers, was successfully developed and tested in a RCT. The cyclic evaluation and modeling process still continues, leading to

greater understanding of the components of the intervention, higher feasibility, and increasing the chances for optimal investment of research efforts.

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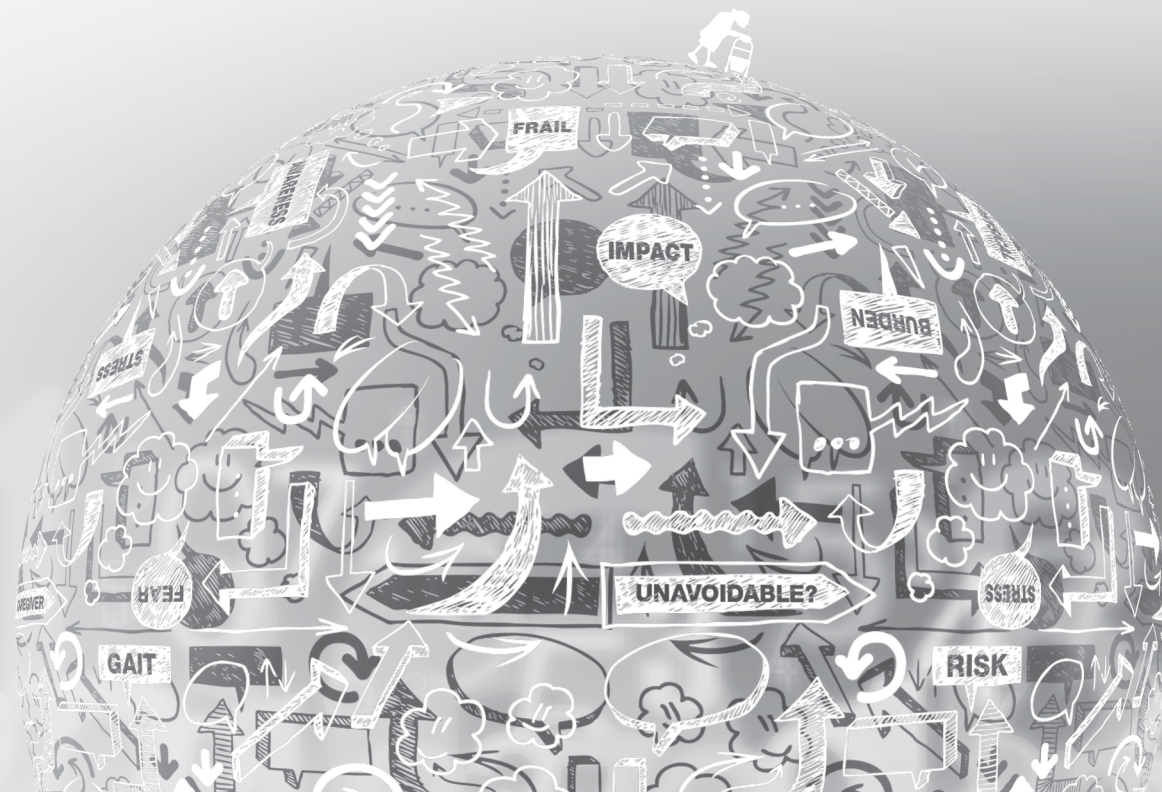
Contents of the complex fall-prevention intervention

Published as:

E-appendix of: Multifactorial fall prevention for pairs of frail community-dwelling older fallers and their informal caregivers: a dead end for complex interventions in the frailest fallers

Reelick M.F., Faes M.C., Melis R.J., Borm G.F., Esselink R.A.J., Olde Rikkert M.G.M.

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Background

This intervention is designed as a treatment for frail community-dwelling older persons who fall, following diagnostic assessment at the geriatric falls clinic. (Note: the diagnostic assessment of the geriatric falls clinic is illustrated on the DVD included at the end of this thesis; "Geriatric falls clinic") A fall is defined as an unexpected event in which the individuals came to rest on the ground, floor or lower level.

Existing effective fall-prevention interventions are not feasible for this frail population, which requires a specific approach because of the presence of physical and cognitive impairments. The intervention was developed following the Medical Research Council framework (MRC) for developing and evaluating complex interventions.

Target population

Geriatric outpatients are eligible for the fall-prevention intervention if they have experienced at least one fall in the last six months, are community-dwelling, are able to walk 15 meters independently (use of a walking aid allowed), and were frail. Frailty was defined as the presence of two or more of the frailty indicators (muscle weakness, weight loss, exhaustion, low physical activity, and slowed walking speed, respectively), in addition to the fact that they experienced at least one fall in the past six months. In addition, patients should have an informal caregiver. Patients participate in pairs, together with their primary informal caregiver. The primary informal caregiver is defined as the non-professional who is most involved in caring for the patient and assists with at least one personal or instrumental activity of daily living.

Patients with (mild) cognitive impairment are not excluded unless their Mini-Mental State Examination score is below 15 (range 0-30). A lower score indicates a cognitive impairment that is too severe for this group intervention. In addition, patients with a severe hearing impairment are not able to participate.

The fall-prevention intervention

Primarily, the fall-prevention intervention aims to reduce fall frequency and fear of falling in frail community-dwelling older fallers. Secondary aims concern both patient and caregiver (Table 1).



Table 1 Aims of the fall-prevention intervention.

Primary aims	
<ul style="list-style-type: none">• Reduce the fall frequency in patients• Reduce the level of fear of falling in patients	
Secondary aims	
For the patients	For the caregivers
<ul style="list-style-type: none">• Improve quality of life• Improve mood• Improve gait and balance parameters• Increase the level of activity and performance of activities of daily living	<ul style="list-style-type: none">• Decrease caregiver burden• Improve well-being• Improve quality of life• Improve mood

Important aspects and preconditions

The intervention is a multi-factorial intervention and consists of ten sessions given twice-weekly for five weeks, and a booster session six weeks after the initial ten sessions. Each session lasts two hours. The structure of each session is the same, so that participants know what to expect from the session (Box 1). The intervention consists of several components, both physical and psychological. These components work in complement, and the combination and interaction of these components is an important aspect in this intervention. Box 2 gives a brief overview of these components, which are described more extensively in the following pages along with their rationales. The fall-prevention intervention is illustrated on the DVD at the back of this thesis: “Fall-prevention intervention”. There are two instructors for each session: a physiotherapist and a psychologist with cognitive behavioral skills and experience in coaching groups. Experience with the specific patient population is a requirement because some of the participants will have a cognitive impairment or (severe) multiple morbidities. The presence of two instructors is necessary to ensure the participants’ safety. The physiotherapist leads the components that are primary physical, and the psychologist leads both the educational components and the discussions. Participants have an active role during all aspects of the intervention, discussing problems, and solutions within the group. An important aspect of this intervention is that caregivers actively participate in the intervention. Consequently, they can help patients during the session and, more importantly, also help them at home and stimulate them to practice at home. Moreover, caregivers learn how to provide adequate support to the patients during the physical intervention, and they gain insight into the limitations and abilities of the

patients. Caregivers also participate in the physical intervention to experience what the patients experience. During the conversations and the educational parts of the sessions, the participants and instructors are seated in a semi-circle. This promotes eye contact and interaction between participants. The caregiver sits beside the patient to provide support. Especially in groups of frail older persons, it is important that a patient has a person next to him/her whom he/she trusts and may fall back on. However, in some cases this arrangement may be disturbing to the group, for example when there is too much talking between the patient and caregiver, or because a negative interaction between the patient and caregiver exists. In those cases, the caregiver and patient are separated. The patient-caregiver interaction is an important aspect in determining whether the intervention will be successful. Instructors need to be aware of their interaction and respond appropriately to this ‘system’ during the intervention, and address both the patient and caregiver as separate entities and as a whole to be able to achieve change. The intervention is delivered in groups of a maximum of six pairs to enable the participants to learn more by recognition, based on shared experiences and similar needs. Participants may identify with one another, thereby increasing acceptance. However, to ensure the participants’ safety and to be able to provide enough individual attention, the group should not exceed six pairs. Considering the heterogeneous nature of the group, an important aspect of the intervention is that it is tailored for each participant. The components can be used and adapted according to the needs and limitations of the participants. To ensure that participants adapt the way they move and behave, and to promote fitness and strength, they receive homework exercises. Participants receive an intervention booklet to note their individual aims, homework and progress, and to collect brochures handed out in the sessions. Because the participants of the intervention are frail, there are high demands on the facility. It should be easily accessible, without stairs, have a toilet nearby (preferably a toilet for the disabled), and have easy parking at the entrance. In addition, the acoustics should be good because participants may have (mild) hearing problems. The intervention was advertised as a movement course with the aim to stimulate independence in the patients, since research suggested that older adults are more likely to engage in fall prevention strategies when the interventions are couched in terms of preserving independence rather than preventing falls.

Components

Below, the components and their rationales are discussed in more detail. Although the boxes suggest a fixed program, this is only a guideline that can and should be

adapted to the needs of the pairs. Consequently, the components may be discussed in different sessions, and the emphasis on various components will differ in each group.

Box 1 Structure of each session.		
1	Agenda for this session	To provide structure for the participants, the agenda for the session is listed on a flipchart and briefly explained at the start of each session.
2	Important points of previous session and questions (not in session one)	Repetition is an important aspect of the learning process, especially in participants with cognitive impairment. Repetition promotes habit formation, which is essential for behavioral change. Therefore, in each session the important aspects of the previous session are discussed, and participants have the opportunity to ask any remaining questions.
3	Falls	Participants note the falls that occur during the intervention. Should a fall have occurred, the causes of the fall, and consequences for both the patient and caregiver are discussed.
4	Homework from previous session (not in session one)	The purpose of the homework is to practice at home and to stimulate reflection on important issues. By discussing the homework, its importance is emphasized. Participants are encouraged to share experiences and answer each other's questions. Positive feedback on their efforts and on participating in the discussion increases motivation. When participants did not complete their homework, the reasons for this should be explored and solved, preferably together with the other participants.
5	Education, conversation, and practice	This part differs for each session; see Box 2.
6	Homework for next session (not in session ten)	The individual homework assignments for the next session are discussed and noted in the intervention booklet. The importance of performance of the homework assignments is emphasized.
7	Questions or remarks	Participants have the opportunity to ask questions or make remarks concerning this session. The instructor stimulates other participants to reply to the questions or remarks because this improves information uptake.
8	Individual learning points	The instructor asks the participants to identify and note their individual learning points, facilitating repetition of the important points.
9	Summary and closing of the session	The instructor summarizes the learning points based on the answers of the participants and the content of this session. Instructors thank everyone for their attention and active participation, and remind participants of their homework, and of the date and time of the next session.

Box 2 Brief overview of the components and targets of the fall-prevention intervention for frail community-dwelling older persons and their informal caregivers.		
Psychological component	Physical component	
Introduction of the intervention, participants and instructors Expectations and aims	Getting out of bed (safely and efficiently)	
Individual expectations and aims Individual causes of falls Causes of falls in general Ageing and falls	Rising from a chair (safely and efficiently)	
Home safety Emotions concerning falls Fear of falling; the vicious cycle Limitations and abilities: acceptance	Walking (safely and efficiently, with a walking aid if applicable)	
Fear of falling; the vicious cycle Impulsiveness; risk behavior and the vicious cycle Impact of falls on the caregiver	Rising from a chair and walking (safely and efficiently, with a walking aid if applicable)	
Activity pattern Stop-think-go	Activities of daily living (ADL)-based circuit training (outdoors if possible)	
Methods/aids to prevent falls	Getting up after a fall (safely and efficiently)	
Experiences and emotions associated with the practice of getting up after a fall Asking for assistance	ADL-based circuit training (outdoors if possible)	
Evaluation methods/aids for preventing falls Coping	Getting up after a fall (safely and efficiently)	
Physical activity Caring for significant others	ADL-based circuit training (outdoors if possible)	
Falls Evaluation of the individual aims and goals Individual effects of the intervention Evaluation of the intervention	ADL-based circuit training; elements at the request of the participants	

Session 1

1. Introduction (different from the other sessions)

Welcome	Instructors welcome the participants and try to reassure/relax participants. It is important to realize that all participants experience participation in such an intervention in their own way and that they may be nervous or scared.
Introduction of the instructors	Instructors briefly introduce themselves, giving some information about their background.
Intervention booklets	Intervention documents are handed out and explained. The first pages of the intervention booklet contain practical information concerning the instructors, the rules that apply to the group, directions to the facility and contact information. Behind each tab, there is session-specific information and blank pages to take notes.
Group rules	Group rules are discussed. Instructors emphasize the importance of asking questions and discuss the confidentiality within the group.
Introduction of the participants	Participants introduce themselves. They are encouraged to give some information regarding their personal situation and their fall history. Instructors ask participants to name the cause(s) of their fall(s). Older persons who are convinced that the cause of their fall is extrinsic (in the environment) are less likely to adapt their behavior to reduce their fall risk. Instructors respond to and, where necessary, adapt these attributions during the intervention.

2. Education, conversation and practice

Expectations and aims	The instructors introduce the topic of "expectations and aims" and ask the participants what they hope to learn and achieve during the intervention. Instructors guide the participants in setting realistic goals.
Homework	After the introduction and guidance by the instructors, the participants draw up a list of expectations and goals as homework.
Getting out of bed (safely and efficiently)	Getting out of bed is practiced with each participant. The manner in which participants currently get out of bed is demonstrated and discussed, and suggestions are made individually to increase safety and efficiency. This may include teaching the caregiver how to support the patient in this task. After the exercise, participants receive the folder "Getting out of bed", which contains photo-material with supporting text on the correct performance of the exercise.
Homework	Participants practice getting out of bed safely and efficiently a few times a day (depending on the abilities and endurance of the patient) with their caregiver.

3. Closing the session (Box 1; items 6-9)

Session 2

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Individual expectations and aims	Participants explain their expectations and aims. Instructors guide the participants to set realistic goals and discuss what it takes to achieve these goals. Similarities between the participants' aims are discussed.
Aging and falls	Many older persons consider falling a normal part of aging. It should be emphasized that falling is not normal but is rather pathological and preventable. Many older persons of comparable age do not experience falls. The reasons for this difference are discussed. Emphasis is on knowing your limitations, acceptance of these limitations, and keeping active within these limitations.
Individual causes of falls	Instructors explain that falling is a common and serious problem that can have multiple causes. The group discusses causes of the participants' falls. Unawareness of the cause of a fall can be a source of fear and can hinder the coping process. The instructors help both patients and caregivers understand the causes of the falls.
Causes of falls in general	Situations with a high fall risk are discussed, with intrinsic and extrinsic risk factors being distinguished, both indoors and outdoors. The group collectively thinks of solutions and methods for fall-risk reduction. Instructors ensure that all major causes are discussed. Participants receive additional brochures on "Causes of falls" and "Home safety".
Rising from a chair (safely and efficiently)	Participants practice and receive instructions regarding how to safely and efficiently rise from a chair and sit down again. If necessary, caregivers are instructed on how to support the patient. First, this is practiced in a chair with armrests, and depending on the ability level of the pair, it is then practiced in a chair without armrests. Participants receive the brochure "Rising from a chair; safely and efficiently", which contains photo-material with supporting text on the correct performance of the exercise.
Homework	Participants practice, with their caregiver, to rise from a chair safely and efficiently a few times a day (dependent upon the abilities and endurance of the patient) at home. In addition, strength, balance, and endurance are trained by squatting with chair support. Pairs receive the brochure: "Quadriceps training", which contains photo-material with supporting text on the correct performance of the exercise. The frequency and intensity dependent on the abilities and endurance of the patient.

3. Closing the session (Box 1; items 6-9)

Session 3

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Home safety	The "Home safety" brochure, handed out in session two, is discussed in detail.
Homework	Participants use the brochure to check the safety in their home and to check on the need for adjustments.
Emotions concerning falls	Falls have a high impact on older persons. Thirty percent of older persons develop a fear of falling after experiencing a fall. This often results in feelings of helplessness and fear of losing independence. Both the patient and caregiver may develop anxiety and depression. These consequential feelings are discussed, and participants are asked whether they recognize and identify with these feelings and how they feel after experiencing a fall. The group discusses which feelings are functional and realistic, and which feelings should be adjusted. To support this discussion, the beliefs and preconceived opinions on falls are discussed as well.
Fear of falling; the vicious cycle	As a result of fear of falling, older persons may restrict their activities, which results in deconditioning and an increased risk of falling. This fear of falling vicious cycle is discussed with the participants to increase insight and to raise awareness. The relevance of performing activities to stop and reverse this negative cycle is highlighted.
Limitations and abilities; acceptance	There is an important balance between a person's limitations and abilities. People should not perform activities beyond their ability, but also should not avoid activities that they are capable of performing. Participants discuss negative and positive consequences of avoidance and of performing activities beyond their abilities.
Walking (safely and efficiently, with a walking aid if applicable)	Participants walk around the room, using their walking aid if necessary. Each participant receives instructions on how to walk as safely and efficiently as possible. Emphasis is on the proper use of a walking aid.
Homework	The homework from session two is continued. Additional instructions are provided and the intensity and frequency are adapted, if necessary.

3. Closing the session (Box 1; items 6-9)

Session 4

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Fear of falling; the vicious cycle	The fear of falling vicious cycle is reproduced by the participants. Both the negative consequences of the fear of falling and positive consequences of a decreased fear of falling are discussed.
Impulsiveness; risk behavior and the vicious cycle	In addition to the fear of falling vicious cycle, the impulsiveness vicious cycle is discussed. Cognitive impairment, overestimation of personal abilities or not willing to accept limitations may lead to high-risk behavior (performing activities one should not be performing). This mechanism is explained and discussed.
Impact of falls on caregiver	Falls also have a high impact on caregivers. Caregivers share the feelings they experience when the patient has fallen. It is discussed to what extent these feelings are realistic and which feelings should and can be modified.
Homework	Patients note the activities they perform in the following days in detail to increase insight into behavior and activities associated with falls and fear of falling.
Rising from a chair and walking (safely and efficiently, with a walking aid if applicable)	Patients walk around the room, using their walking aid if necessary. Each caregiver receives instructions on the best position relative to the patient and how to support the patient to walk as safely and efficiently as possible. Walking is combined with rising from different types of chairs, to practice switching between tasks, handling different situations, and repeat rising from a chair safely and efficiently.
Homework	The homework from session two is continued. Additional instructions are provided and the intensity and frequency are adapted, if necessary.

3. Closing the session (Box 1; items 6-9)

Session 5

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Activity pattern	Patients' daily activities are discussed, in which possible high-risk or activity avoiding behavior is identified, and possible solutions are discussed.
Stop-think-go (STG)	Following the impulsiveness vicious cycle, the stop-think-go method (STG) is introduced as a method to decrease high-risk behavior. Instructors emphasize the benefits of carefully considering and planning tasks and activities before performing them. Planning should also take into account 'planning moments' to take a break from activities. Participants will be regularly reminded of the stop-think-go method during the ADL-based circuit training.
Activities of daily living (ADL)-based circuit training	Participants practice multiple elements combined in an ADL-based circuit. Elements include balance, strength, endurance, coordination, planning, dual-task performance, and use of the STG method. Caregivers are observed and then instructed on how to support the patient in different situations and with complex tasks. In addition, each patient's capacity to perform dual tasks is evaluated and discussed.
Homework	The homework from session two is continued. Additional instructions are provided and the intensity and frequency are adapted, if necessary.

3. Closing the session (Box 1; items 6-9)

Session 6

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Methods/aids to prevent falls	Previously, individual causes of the patients' falls and possible methods/aids to prevent falls were discussed. In this session, the use of the suggested methods/aids is evaluated. Reasons for not applying the suggested method/aid are discussed and, where necessary, new solutions are suggested. Specifically, embarrassment concerning the use of such methods/aids is discussed. In session eight, these methods/aids will be evaluated again.
Getting up after a fall (safely and efficiently)	Participants demonstrate how they get up after a fall. The instructor then demonstrates how to get up after a fall as safely and efficiently as possible. Both patient and caregiver practice getting up after a fall following the advice of the instructor.
Homework	The homework from session two is continued. Additional instructions are provided and the intensity and frequency are adapted, if necessary. In addition, patients receive balance exercises on reaching. The exercise is demonstrated, practiced, and patients receive the brochure "Reaching", which contains photo-material with supporting text on the correct performance of the exercise.

3. Closing the session (Box 1; items 6-9)

Session 7

1. Introduction (Box 1; items 1-4)	
2. Education, conversation and practice	
Experiences and emotions associated with the practice of getting up after a fall	Experiences and emotions associated with the practice of getting up after a fall are discussed. The cause for negative emotions is discussed, and may (in part) be solved. Positive emotions are also discussed to emphasize progress when applicable.
Asking for assistance	Many older persons have difficulty asking for assistance. However, because this may decrease high-risk behavior, asking for assistance is an important aspect of fall risk reduction. The group discusses feelings and experiences associated with asking for assistance (patients) or being asked for help (caregivers). Success stories and benefits are emphasized.
ADL-based circuit training outdoors	The outdoor circuit is introduced by the instructors first so that participants know what to expect. Safety during the circuit has priority, and, if necessary, a (wheel) chair is brought along to use for patients to rest. Then, participants practice how to deal with high fall risk situations outside. Emphasis is on the appropriate use of a walking aid (if applicable) and efficient support by the caregiver.
Homework	The homework from session two is continued, with the additional reaching exercises. Additional instructions are provided and the intensity and frequency are adapted, if necessary.
3. Closing the session (Box 1; items 6-9)	

Session 8

1. Introduction (Box 1; items 1-4)	
2. Education, conversation and practice	
Evaluation methods/aids for preventing falls	Evaluation of the methods/aids suggested in sessions two and six. If applicable, the reasons for not using the method should be discussed and other solutions should be sought.
Coping	The coping strategies of the participants are explored. Avoidance-oriented coping strategies are discouraged. A problem-focused coping strategy is encouraged to increase the level of self-efficacy.
Getting up after a fall (safely and efficiently)	Participants demonstrate how they get up after a fall. The instructor provides additional advice if necessary. Both the patient and caregiver practice getting up after a fall following the advice of the instructor.
Homework	The homework from session two is continued, with the additional reaching exercises. Additional instructions are provided and the intensity and frequency are adapted, if necessary.
3. Closing the session (Box 1; items 6-9)	

Session 9

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Physical activity	The vicious cycles of fear of falling and impulsiveness are repeated, and the benefits of regular physical activity and negative consequences of inactivity are discussed. Participants establish a plan to permanently increase their activity, for example, by participating in a group activity nearby.
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The pairs are separated; caregivers engage in a conversation with the psychologist, and patients practice with the physiotherapist.

Caring for significant others	The caregivers carry on a conversation regarding the positive and negative aspects of caring for their significant other.
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ADL-based circuit training	Participants practice multiple elements combined in an ADL-based circuit. Depending on the level and abilities of the patient, variations are applied to the circuit or the tasks during performance of the circuit such as increasing the frequency and difficulty. The caregivers join in at the end of the exercise so they can see how the patients perform on the circuit.
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3. Closing the session (Box 1; items 6-9)

Session 10

1. Introduction (Box 1; items 1-4)

2. Education, conversation and practice

Falls	The group discusses whether the frequency of falls or the risk of a fall has been reduced by this intervention and what other changes have been established. Explanations for (lack of) change are discussed.
Goals and expectations	At the start of the intervention, each participant has set individual goals. It is evaluated to what extent these goals were reached and what requires additional attention. Reasons for not reaching a goal are discussed, and additional suggestions are made.
ADL-based circuit training	Circuit: elements at the request of the participants or as identified by the instructor.
Evaluation of the intervention	The intervention is summarized and evaluated, including positive and negative aspects of the intervention and overall opinion of the intervention and instructors. Adherence to homework assignments and advice is evaluated, and perceived benefit is discussed.

3. Closing the session (Box 1; items 7 and 8, and closing session as below)

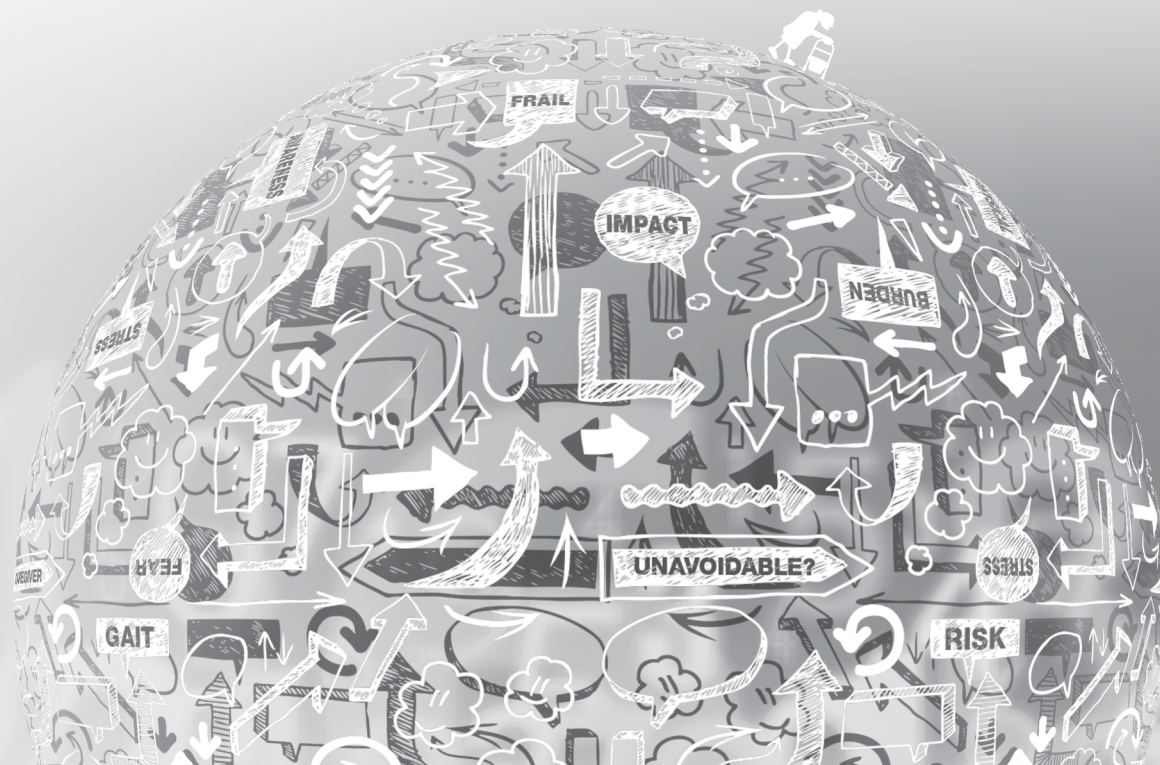
Summary and closing of the session	Instructors thank everyone for their active participation and hand out certificates to all participants. Instructors remind participants of the date and time of the booster session, which takes place six weeks after session ten. Instructors emphasize that although the intervention is over, participants should continue to put what they have learned into practice.
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Booster session

The booster session monitors the progress and/or deterioration of the pairs and gives additional training and suggestions if necessary. Instructors and participants discuss to what extent the pairs have adapted their daily behavior to include what they have learned in the intervention. Barriers to changing behavior are discussed and solved when possible.

PART II

Evaluation of a fall-prevention intervention for frail older fallers and their informal caregivers



5

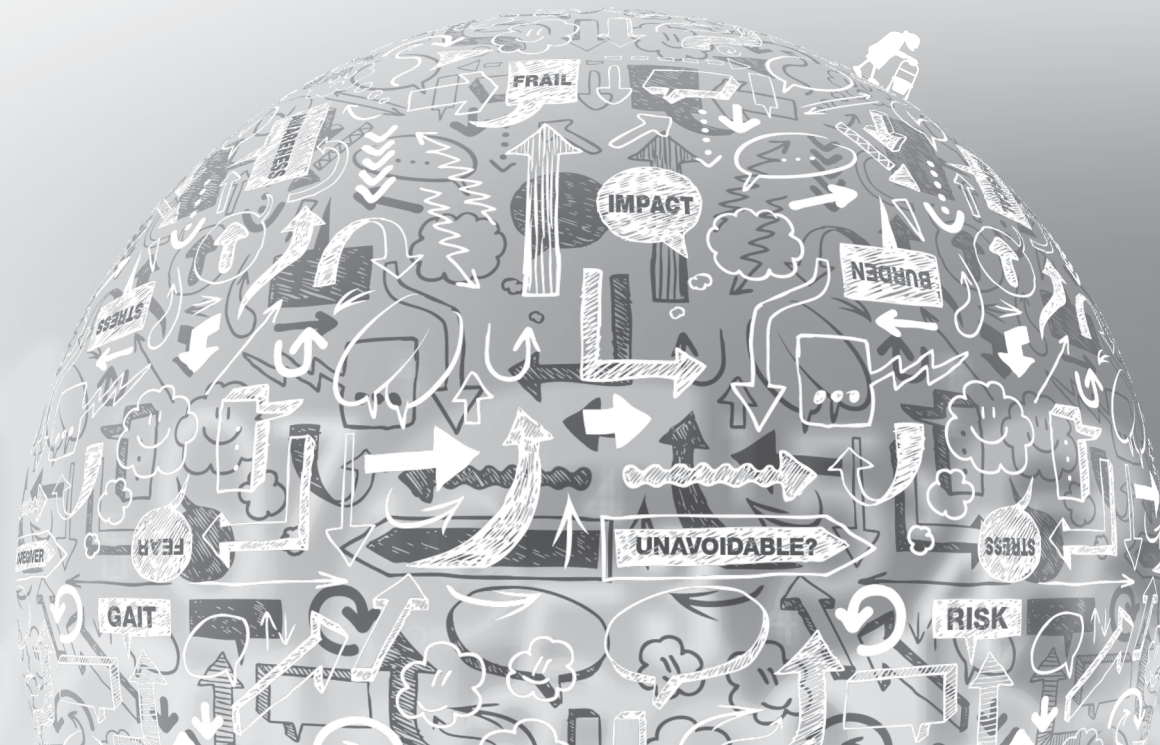
Efficacy of the fall-prevention intervention: a randomized controlled trial

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Multifactorial fall prevention for pairs of frail community-dwelling older fallers and their informal caregivers: a dead end for complex interventions in the frailest fallers. *Reelick M.F., *Faes M.C., Melis R.J.,

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*Both authors contributed equally as first author.



Abstract

Aim To assess whether a multi-factorial fall-prevention intervention was more effective than usual geriatric care in preventing falls and reducing fear of falling in frail community-dwelling older fallers, with and without cognitive impairment, and in alleviating subjective caregiver burden in caregivers.

Design, setting and participants A randomized, two parallel-group, single-blind, multicenter trial conducted in 36 pairs of frail community-dwelling fallers, who were referred to a geriatric outpatient clinic after at least one fall in the past six months, and their informal caregivers.

Intervention Groups with a maximum of six pairs of patients and caregivers received ten twice-weekly, two-hour sessions with physical and psychological components, and a booster session.

Measurements The primary outcome was the fall rate during a six-month follow-up. Additionally, we measured fear of falling and subjective caregiver burden. Data on the secondary outcome measures were collected at baseline, directly after, and at three and six months after the last session of the intervention.

Results Directly after the intervention and at the long-term evaluation, the rate of falls in the intervention group was comparable for the two treatment groups (RR=7.97, $p=0.07$ and RR=2.12, $p=0.25$, for the fall-prevention intervention and regular care, respectively). Fear of falling was higher in the intervention group, and subjective caregiver burden did not differ between groups.

Conclusion Although we meticulously developed this pairwise multi-factorial fall-prevention intervention, it was not effective in reducing the fall rate or fear of falling, and was not feasible for caregivers, as compared to regular geriatric care. Future research initiatives should be aimed at how to implement the evidence-based principles of geriatric fall prevention for all frail fallers rather than developing more complex interventions for the frailest.

Introduction

The high need for prevention of falls and associated injuries in community-dwelling older persons raises urgent questions for research and care innovation. Especially in frail older persons with cognitive impairments, as they have the highest risk of falls and of the associated fear of falling,¹⁻⁴ and are less likely to achieve a satisfactory recovery from a fall-related injury.^{1,5,6} Falls also result in a high burden on the fallers' informal caregivers, including high levels of stress and fear related to potential falls of the care recipient.^{4,7,8} Thus, the need for effective strategies to reduce falls and fear of falling in community-dwelling frail older persons, including those with cognitive impairment, and to increase support for their informal caregivers is substantial.

The preponderance of evidence suggests that multi-factorial interventions are effective in reducing falls in high risk community-dwelling older persons.^{4,9} However, the exact target group and intervention context still have to be defined, as an important number of multi-factorial interventions showed a lack of effect in the frail community-dwelling older fallers with the highest risk for falling.^{4,9-11} Furthermore, older persons with cognitive impairments were excluded from most trials evaluating multi-factorial interventions.^{4,9} To our knowledge, there has not been any prospectively evaluated multi-factorial fall-prevention intervention proven to reduce the fall rate in frail community-dwelling patients with dementia or mild cognitive impairment (MCI).⁹ In frail cognitively impaired community-dwelling older persons, evidence-based strategies to reduce fear of falling are lacking as well.^{12,13} In addition, it is unknown whether fall-prevention interventions alleviate the caregivers' high subjective burden related to recurrent falls of their care recipients.

To compensate for the lack of data on effectiveness of fall-prevention interventions in the frail community-dwelling populations with or without cognitive decline, we developed¹⁴ and evaluated a fall-prevention intervention to reduce the fall rate and fear of falling in these patients and to alleviate subjective caregiver burden. Here, we report the results of the randomized controlled trial (RCT) that evaluated this program.

Methods

From January 2008 to September 2009, we recruited pairs of patients and their primary informal caregivers from the geriatric outpatient clinics of the Radboud University Nijmegen Medical Centre and two non-university, teaching hospitals (Rijnstate Hospital and Canisius Wilhelmina Hospital in Arnhem en Nijmegen, the Netherlands, respectively). Patients were eligible if they fell at least once in the six months before the visit to the outpatient clinic, were able to walk 15 meters independently (use of a

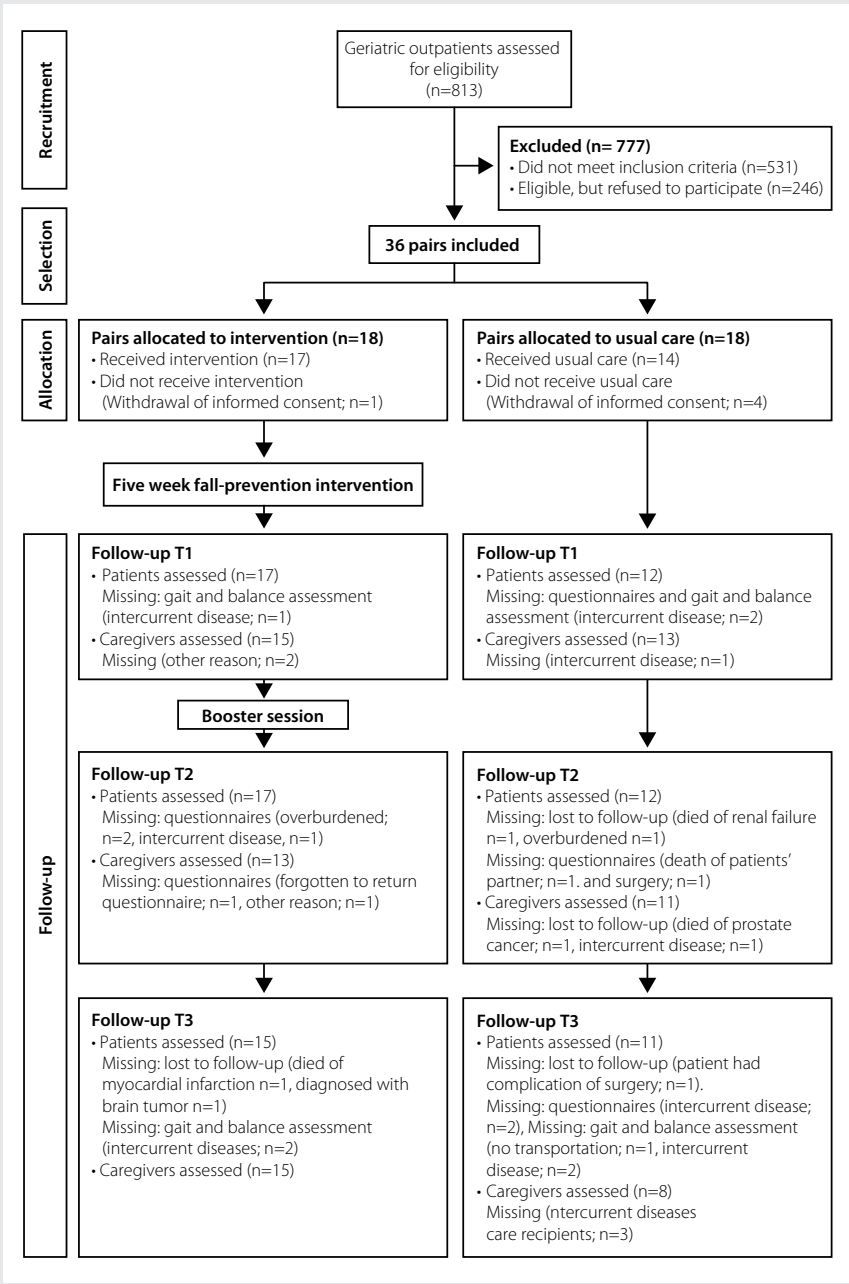
Box 1 Brief overview of the components and targets of the fall-prevention intervention.

Psychological teaching and training components	Physical training component
Introduction of the program, participants and instructors Expectations and aims	Getting out of bed (safely and efficiently)
Individual expectations and aims Individual causes of falls Causes of falls in general Ageing and falls	Rising from a chair (safely and efficiently)
Home safety Emotions concerning falls Fear of falling; the vicious cycle Limitations and abilities: acceptance	Walking (safely and efficiently, with a walking aid if applicable)
Fear of falling; the vicious cycle Impulsiveness; risk behavior Impact of falls on the caregiver	Rising from a chair and walking (safely and efficiently, with a walking aid if applicable)
Activity pattern Stop-think-go	ADL-based circuit training (outdoors if possible)
Methods/aids to prevent falls	Getting up after a fall (safely and efficiently)
Experiences and emotions associated with the practice of getting up after a fall Asking for assistance	ADL-based circuit training (outdoors if possible)
Evaluation methods/aids for preventing falls Coping	Getting up after a fall (safely and efficiently)
Physical activity Caring for significant others	ADL-based circuit training
Falls Evaluation of the individual aims and goals Individual effects of the program Evaluation of the program	ADL-based circuit training; elements at the request of the participants

walking aid allowed), had a primary informal caregiver, were community-dwelling, had a life expectancy of longer than one year, and were frail. Patients were excluded if they were awaiting nursing home admission or had a Mini-Mental State Examination (MMSE) score lower than 15.¹⁵

Frailty was defined as the presence of two or more of the widely accepted frailty indicators,¹⁶ in addition to the fact that all patients fell at least once in the previous six

Figure 1 Flow diagram of the recruitment, selection, allocation and follow-up.



months. A fall was defined as an unexpected event in which the individual came to rest on the ground, floor, or lower level.¹⁷ The primary informal caregiver was defined as the nonprofessional who was most involved in caring for the patient who experienced falls, assisted with at least one personal or instrumental activity of daily living, and monitored the patient at least two times a week. The researchers obtained written informed consent from both the caregiver and patient.

Intervention

A small-group training environment was chosen for this intervention, with groups including a maximum of six pairs of patients and caregivers. The instructors of the program were a geriatric psychologist and a geriatric physiotherapist. The program, comprising ten twice-weekly, two-hour sessions and a two-hour booster session six weeks after the initial ten sessions, included both physical and psychological components (Table 1). Caregivers received training in serving as a co-therapist at home, and in strategies to sustain their own autonomy. Considering the heterogeneity of the group, the program was tailored to each participant by adapting the facultative components of the program (Table 1 and, for a more detailed description, chapter 4 of this thesis). Both the patients in the intervention and the control group received the usual care of the geriatric outpatient clinic, according to the guideline on falls. The predisposing and precipitating factors for patients' falls were assessed and managed in collaboration with their general medical practitioners.

Randomization and procedures

Treatment allocation, carried out by an independent statistician, was based on a minimization algorithm that balanced for the minimization factors: sex, MMSE score (15-23 versus 24-30), age (≤ 80 versus > 80), and number of falls in the past 12 months (1 fall versus > 1 fall). Half of the pairs received usual care of the geriatric falls clinic, and half of the pairs received the intervention in addition to usual care. The instructors, patients and caregivers were aware of the treatment assigned, the assessors (MR and MF) were blinded. If the patient withdrew or was lost during follow-up, both the patient and caregiver left the study. In case a caregiver withdrew or was lost during follow-up, the patient continued the trial.

Outcome assessment and measures

We assessed the following patient's characteristics: age, sex, history of falls, household composition, use of walking aids, multimorbidity (Cumulative Illness Rating Scale for Geriatrics; CIRS-G),¹⁸ global cognitive function (MMSE score),¹⁵ dementia¹⁹ or mild cognitive impairment (MCI)²⁰ diagnoses (diagnosed by the geriatric team), number and type of drugs used, and handgrip strength with a hand-held dynamometer (Jamar-type, Sammons Preston, Inc.).

The primary outcome in this study was the fall rate. Falls were registered daily using a preaddressed, reply-paid two-weekly fall calendar throughout the whole trial.²¹ As secondary outcomes, we assessed fear of falling (Falls Efficacy Scale-International; FES-I),²² anxiety (Hospital Anxiety and Depression Scale, anxiety subscale; HADS-A),²³ depression (15-item Geriatric Depression Scale-Short Form; GDS15),²⁴ disability in (instrumental) activities of daily living (IADL) (Groningen Activity Restriction Scale; GARS),²⁵ mastery (5-item Pearlin Mastery Scale),²⁶ and perceived health-related quality of life (HRQoL) (European Quality of life-five Dimensions Visual Analogue Scale; EQ-5D VAS).²⁷ Data on the secondary outcome measures were collected at baseline (T0), directly after (T1), and at three (T2) and six months (T3) after the last session of the intervention.

Additionally, we collected gait, dynamic balance, mobility, and activity performance parameters at baseline, T1, and T3. To quantitatively analyze gait, patients walked at their preferred velocity on an electronic walkway (GAITRite™). Balance during walking was measured with a wireless device, which was attached to the trunk, with two angular velocity sensors measuring trunk sway (SwayStar™). The secondary outcome measures were gait velocity, stride-length variability (measured as coefficient of variation [CV]; which is $[\text{Standard Deviation}/\text{Mean}] \times 100$), and medio-lateral trunk sway (roll angle and roll velocity (90% range)). Overall mobility was assessed with the timed up and go test.²⁸ The intensity of daily activities performed (LASA physical activity questionnaire; LAPAQ),²⁹ as well as the mean daily physical activity (using an accelerometer with activity log) were assessed. Patients wore the accelerometer for seven consecutive days.

The caregiver characteristics that were assessed were age, sex, relationship with the patient, employment status, and fear of the care recipient falling (yes/no). Caregiver outcomes were subjective caregiver burden (12-item Zarit Burden Interview Short Form),³⁰ depression (Center for Epidemiological Studies-Depression scale; CES-D),³¹ anxiety (Hospital Anxiety and Depression Scale, anxiety subscale; HADS-A), objective caregiver burden (total caregiving time [hours per week], based on the number of caregiving tasks performed [from a predefined set of 16 ADL, HDL and IADL tasks]³² and average time per task during the week preceding the completion of the questionnaire) and European Quality of life-five Dimensions Visual Analogue Scale (EQ-5D VAS).

Statistical analysis

In our pilot study of a cohort of 43 patients, who were seen in our outpatient clinic between January and July 2007, the rate of falls (FR) showed some extreme outliers. Therefore, in the power calculation, we truncated the rate of falls at 12 per year (truncated fall rate [FRT]). The mean and standard deviation of the logarithm of the FRT in this group were 1.2 and 0.8, respectively. To reach clinical relevance, we assumed that the intervention would require an effect of approximately 0.5 SD, which

is generally considered to represent a substantial effect.³³ For $\alpha=0.05$ (two-sided) and $\beta=0.20$, and an attrition rate of 15%, the total required sample size was 160 pairs. In the analyses only the first five falls per 1.5 months for each patient were used in the analysis (maximum 24 falls in three months) to avoid overweighting outliers.

Direct efficacy was evaluated at the end of the intervention. For long-term efficacy, we used the sum of the assessments at T2 and T3 in the analysis of the fall rate and the mean of these assessments in the analysis of the secondary outcome measures.

To compare the fall rates between the groups, a linear model with a negative binomial distribution and logarithmic link function was used. Secondary outcomes were analyzed using a linear model. In all models, group allocation and the minimization factors were the independent variables as well as the baseline value. For the analysis of the long-term efficacy, the random factor "patient" was included to account for the repetition of the measurements at T2 and T3. The results of the primary intention-to-treat analysis were compared with the results of a per-protocol analysis. Intervention pairs included in the per-protocol analysis had attended six or more sessions. The level of significance was set at a *P* value of less than 0.05 (two-sided). All statistical analyses were performed using SPSS statistical software version 16.0 (SPSS Inc., Chicago, Illinois).

Results

We evaluated 813 patients for eligibility and recruited 36 pairs of patients and caregivers, which is 13% of the 282 eligible patients. No falls in the previous six months (74%) and absence of a primary informal caregiver (21%) were the two major factors that resulted in noneligibility. The overburdening of patients (22%) and caregivers (11%), and patients' intercurrent diseases and associated hospital visits (19%), were major factors in the refusal of participation of eligible pairs. Immediately following randomization, three patients in the control group ended participation in the trial before baseline measurements were collected. These patients and their caregivers were not aware of the treatment allocation and were not included in the analyses.

Table 1 and table 2 show the characteristics and baseline outcome measure data of patients and caregivers, respectively. The mean age of the patients in the sample was 78.3 years, nearly 70% were female and 60% lived alone. Twenty-four percent had fallen once in the prior year (non-recurrent faller) and 76% had fallen multiple times (recurrent faller). Forty-eight percent suffered from MCI or dementia. The mean MMSE score was 25.8. The patients had a high level of multimorbidity (mean CIRS-G 13.8) and were moderately disabled in ADL and IADL (mean GARS 36.3). No relevant differences were found between the two groups with regard to baseline characteristics and outcome measures.

Table 1 Characteristics and baseline outcome measure data of patients.

	Intervention (n=18)	Control (n=15)
Age (years)	78.3 ± 6.9	78.3 ± 7.2
Gender (female)	14 (78)	9 (60)
Number of falls in the previous year	3.0 ± 1.75	5.07 ± 6.41
Non-recurrent fallers (1 fall in the previous year)	5 (28)	3 (20)
Recurrent fallers (>1 fall in the previous year)	13 (72)	12 (80)
Household composition	Living alone	8 (44)
	Living with other person	10 (56)
Use of a walking aid (yes)	8 (44)	10 (67)
CIRS-G (range 0-64^a)	14.0 [3]	13.0 [8]
MMSE (range 0-30^b)	26.1 ± 3.6	25.4 ± 3.4
Cognitive impairment	None	11 (61)
	MCI	6 (33)
	Dementia	1 (6)
Use of >4 different medications (yes)	11 (61)	10 (67)
Use of psychoactive medication (yes)	5 (28)	5 (33)
Handgrip strength (kgf)	28.9 ± 5.6	25.4 ± 5.7
Outcome measures at baseline		
FES-I (range 16-64^a)	32.8 ± 11.1	35.4 ± 11.0
HADS-A (range 0-21^a)	7.7 ± 4.8	6.57 ± 3.7
GDS (range 0-15^a)	4.7 ± 4.0	4.5 ± 3.4
Mastery (range 5-25^b)	13.5 ± 4.7	15.4 ± 2.4
GARS (range 18-72^a)	34.7 ± 11.5	38.3 ± 10.1
EQ-5D-VAS (range 0-100^b)	71.9 ± 16.7	64.9 ± 17.8
Gait and balance analysis	Velocity (cm/s)	81.0 ± 29.9
	Stride length CV (%) ^a	3.4 [3.3]
	Roll angle (deg) ^a	3.6 [2.3]
	Roll velocity (deg/s) ^a	23.5 [25.6]
TUG (sec)	14.9 [8.8]	14.8 [9.7]
LAPAQ (kcal/day)	529.0 [559.6]	193.1 [588.1]
Mean daily activity	54.2 ± 30.3	40.2 ± 21.6

Data are presented as mean ± SD for normally distributed variables, median [IQR] for skewed variables, and N (percentages) for categorical variables; ^aLower score is the more favorable score; ^bHigher score is the more favorable score; CIRS-G=Cumulative Illness Rating Scale for Geriatrics; MMSE=Mini-Mental State Examination; FES-I=Falls Efficacy Scale-International; HADS-A=Hospital Anxiety and Depression Scale, anxiety subscale; GDS=Geriatric Depression Scale-Short Form; GARS=Groningen Activity Restriction Scale; EQ-5D-VAS=European Quality of Life-5 Dimensions Questionnaire Visual Analogue Scale, 100 representing the 'best imaginable health state' and 0 representing the 'worst imaginable health state'; TUG=Timed Up and Go test, which was performed as quickly and safely as possible; LAPAQ=LASA Physical Activity Questionnaire.

Table 2 Characteristics and baseline outcome measure data of caregivers.

	Intervention (n=18)	Control (n=15)
Age (years)	67.3 ± 13.1	64.3 ± 14.3
Gender (female)	9 (50)	10 (67)
Living with the patient (yes)	10 (55)	7 (47)
Relationship to patient	Married/unmarried partners 10 (55) Child 5 (28) Other 3 (17)	9 (60) 6 (40) 0
Employed (yes)	5 (28)	5 (33)
Fear of the care recipient falling (yes)	18 (100)	12 (80)
Outcome measures at baseline		
ZBI (range 0-48 ^a)	5.2 [4.5]	6.0 [11.0]
CES-D (range 0-60 ^a)	3.0 [6.5]	3.0 [17.0]
HADS-A (range 0-21 ^a)	2.5 [3.8]	3.0 [8.8]
Total caregiving time (hours per week)	8.0 [13.1]	10.5 [8.0]
EQ-5D-VAS (range 0-100 ^b)	84.5 [15]	84.0 [18]

Data are presented as mean ± SD for normally distributed variables, median [IQR] for skewed variables, and N (percentages) for categorical variables; ^aLower score is the more favorable score; ^bHigher score is the more favorable score; ZBI=Zarit Burden Interview Short Form; CES-D=Center for Epidemiological Studies-Depression scale; HADS-A=Hospital Anxiety and Depression Scale, anxiety subscale; EQ-5D-VAS=European Quality of Life-5 Dimensions Questionnaire Visual Analogue Scale, 100 representing the 'best imaginable health state' and 0 representing the 'worst imaginable health state'.

None of the patients had missing values on the primary outcome measures before death (n=2) or being lost for follow-up (n=4). There was no relevant difference between the intervention and control groups in terms of number of days of follow-up (199 days versus 177 days, respectively).

At T1 and at the long-term evaluation, the rate of falls in the intervention group was higher than that in the control group, although these differences were not statistically significant (T1: 4.32 versus 0.52 falls per patient per year, relative risk [RR]=7.97, 95% confidence interval [CI]=0.86-73.4; p=0.07 and long-term: 4.94 versus 1.17 falls per patient per year, RR=2.12, 95% CI=0.6-7.56; p=0.25). During the seven months of follow-up, ten intervention patients (56%) and six control patients (40%) fell at least once, of whom, six (33%) and one (7%), respectively, fell at least twice.

Directly after the intervention, there were no statistically significant differences in any of the secondary outcome measures between the intervention and the control group (Table 3). At the long-term evaluation, the patients in the intervention group experienced

Table 3 Mixed linear regression analyses of secondary outcome measures in patients.

Instrument/Outcome measure	Direct follow-up			Long-term follow-up ^a		
	Intervention	Control	Regression Coefficient (95% CI)	Intervention	Control	Regression Coefficient (95% CI)
FES-I ^c	1.78 ± 8.51	-3.62 ± 8.59	4.81 (-2.11 – 11.72)	6.68 ± 6.98	-1.06 ± 8.73	7.69 (0.48 – 14.9) [*]
HADS-A ^c	-0.76 ± 3.42	-2.82 ± 2.93	2.34 (-0.32 – 4.99)	0.83 ± 2.70	-2.77 ± 2.2	3.41 (1.34 – 5.49) ^{**}
GDS ^c	-0.27 ± 1.91	-0.54 ± 1.68	0.10 (-1.46 – 1.67)	1.47 ± 2.23	-1.33 ± 1.97	2.36 (0.98 – 3.73) ^{**}
Mastery ^d	-0.27 ± 4.18	-2.00 ± 2.67	0.93 (-2.14 – 4.18)	1.14 ± 1.94	-2.05 ± 2.10	2.55 (1.07 – 4.02) ^{**}
GARS ^c	-0.90 ± 7.61	-1.27 ± 3.32	-0.41 (-4.85 – 4.03)	3.03 ± 11.01	-1.09 ± 6.96	1.24 (-6.81 – 9.28)
EQ-5D-VAS ^d	-4.07 ± 12.18	4.25 ± 16.38	-6.04 (-15.93 – 3.84)	-10.54 ± 17.19	9.19 ± 15.64	-12.86 (-28.30 – 2.58)
Velocity (cm/s) ^b	2.49 ± 18.84	3.23 ± 16.65	2.86 (-8.06 – 13.78)	-3.79 ± 21.46	5.64 ± 6.8	-4.80 (-20.77 – 11.16)
Stride length CV (%) ^{b,c}	-0.85 ± 4.22	-2.05 ± 4.42	0.70 (-1.28 – 2.68)	-0.31 ± 4.55	-0.27 ± 2.44	1.24 (-1.88 – 4.36)
Roll angle (deg) ^{b,c}	0.18 ± 0.76	-0.61 ± 0.98	0.80 (-0.01 – 1.60)	-0.24 ± 1.51	-0.01 ± 1.20	-0.57 (-2.61 – 1.48)
Roll velocity (deg/s) ^{b,c}	3.21 ± 11.81	-5.35 ± 10.55	4.7 (-3.53 – 12.93)	1.07 ± 9.42	-1.75 ± 4.19	1.03 (-8.64 – 10.71)
TUG (sec) ^b	-1.12 ± 3.1	-2.44 ± 7.15	0.14 (-2.73 – 3.01)	0.52 ± 5.3	-0.78 ± 5.0	0.06 (-4.56 – 4.68)
LAPAQ (kcal/day) ^b	66.23 ± 436.89	164.15 ± 316.34	-77.52 (-444.91 – 289.86)	223.20 ± 1008.47	115.46 ± 338.33	516.28 (-249.13 – 1281.69)
Daily activity ^b	-16.36 ± 16.66	-4.20 ± 12.03	-10.68 (-26.93 – 5.57)	-14.67 ± 17.61	-19.17 ± 19.10	5.99 (-8.69 – 20.68)

Data presented are the unadjusted changes over time (follow-up minus baseline) in the raw mean score ± SD, unless otherwise indicated. The crude regression coefficients and corresponding 95% confidence intervals (95% CI) present the difference between the intervention and control groups in change scores; ^aLong-term indicates T2 and T3 averaged, except for the variables only measured at T3; ^bThese variables were not measured on T2, long term change is calculated as T3 minus baseline; ^cNegative mean changes indicate a favorable change in the outcome measure; ^dPositive mean changes indicate a favorable change in the outcome measure; ^{*}p<0.05; ^{**}p<0.01.

Table 4 Mixed linear regression analyses of secondary outcome measures in caregivers.

Instrument/ Outcome measure	Direct follow-up			Long-term follow-up ^a		
	Intervention	Control	Regression Coefficient (95% CI)	Intervention	Control	Regression Coefficient (95% CI)
ZBI ^f	1.21 ± 3.41	-0.69 ± 2.25	1.42 (-1.02 – 3.86)	1.94 ± 2.97	0.14 ± 4.99	1.58 (-2.07 – 5.23)
CES-D ^c	-0.33 ± 3.31	-0.86 ± 3.53	0.06 (-2.39 – 2.50)	1.00 ± 2.87	-2.05 ± 6.40	2.73 (-0.32 – 5.78)
HADS-A ^c	0.33 ± 2.09	0.69 ± 1.65	-0.39 (-1.95 – 1.18)	0.53 ± 1.75	0.05 ± 1.38	0.52 (-0.85 – 1.92)
Total caregiving time	NA ^b	NA ^b	NA ^b	-2.07 ± 15.96	-3.37 ± 14.39	0.03 (-8.99 – 9.05)
EQ-5D-VAS ^d	-2.67 ± 11.16	-2.77 ± 9.79	-1.02 (-7.69 – 5.66)	-7.21 ± 11.27	-2.77 ± 11.91	-7.03 (-15.63 – 1.57)

Data presented are the unadjusted changes over time (follow-up minus baseline) in the raw mean score ± SD, unless otherwise indicated. The crude regression coefficients and corresponding 95% confidence intervals (95% CI) present the difference between the intervention and control groups in change scores; ^fLong-term indicates T2 and T3 averaged; ^bNA=not available. Total caregiving time is measured in hours a week. Total caregiving time was not measured at T1; ^cNegative mean changes indicate a favorable change in the outcome measure; ^dPositive mean changes indicate a favorable change in the outcome measure; *p<0.05; *p<0.01.

more fear of falling, anxiety, and depression than the patients in the control group (Table 3, p=0.038, p=0.003, p=0.002, respectively). Sense of mastery was higher in the intervention group compared with the control group (Table 3, p=0.002). There were no differences between the two groups in any of the gait and balance parameters measured at the long-term evaluation.

The analysis of secondary outcome measures in caregivers did not yield significant differences between the two groups, directly after the intervention or at the long-term evaluation (Table 4). For the per-protocol analysis, three intervention pairs group were excluded. Per-protocol results were similar to the results of the primary analysis (data not shown).

Discussion

This multi-factorial fall-prevention intervention for pairs of patients and their caregivers was not effective in decreasing falls in community-dwelling frail older fallers (of whom some had cognitive impairment). At long-term follow-up, the rate of falls in the intervention group even showed a tendency to be higher than that in the control group. The program was not effective in decreasing fear of falling in patients or subjective caregiver burden in caregivers. In fact, fear of falling was higher in the intervention patients, an effect that was accompanied by higher anxiety and depression scores in this group. In favor of the intervention, the participants of the fall-prevention intervention experienced a higher level of mastery.

To evaluate the lack of efficacy of this intervention, we examined three main factors that determine an intervention's effects: content, process, and choice of the target group.³⁴

The intensity and duration of the physical therapy in our intervention, may not have been sufficient to reduce the fall rate.³⁵ However, increasing intensity likely conflicts with the frailty of these patients. The intervention patients' increased awareness of their risk of falls and consequences of falls may have resulted in the increased feelings of fear of falling. The increased awareness may have also caused the increase in anxiety and depression in the intervention patients. Overall, 74% and 91% of patients had scores that were below the clinically relevant cut-off scores that are indicative of depression (GDS15 score ≥6)³⁶ and anxiety disorder (HADS-A score >10),²³ respectively. More importantly, the intervention patients developed a higher sense of mastery, which may help them actively address their fall problem. The lack of changes on outcome measures in the informal caregivers may indicate that the intervention was not optimally adjusted to their situation.

By evaluating the process, the way in which the intervention content was applied, we identified several strengths. The intervention was built on psychological theories,^{14, 37, 38}



We included mechanisms to maximize uptake and to facilitate habit formation, for example, with homework exercises. Furthermore, the intervention was advertised as a movement course with the aim of stimulating independence, because older adults are more likely to engage in fall prevention strategies when interventions are couched in terms of preserving independence.³⁹

Focusing the intervention on caregivers had a major drawback. The majority of the caregivers were unable to participate, as the course was provided during working hours. Former trials have suggested that introducing the caregiver as a co-therapist may result in the increased effectiveness of interventions in cognitively impaired subjects,^{40, 41} however, this trend was not confirmed in the current trial in the frailest fallers.

The choice of the target group is the third construct that must be considered. The preliminary analysis of the results of a questionnaire study among the nonparticipating pairs revealed that the intervention and assessments were likely too burdensome for patients due to numerous health problems and their dislike to leave their house. Furthermore, the instructors mentioned that the target group was quite heterogeneous, with patients who were afraid of falling and needed to be activated, as well as impulsive patients who needed to be controlled. In addition, the intervention group was also heterogeneous with regard to cognition, and this resulted in problems with holding the attention of cognitively impaired participants. Thus, a group format seems to be unsuitable in this population.

We conclude that this multi-factorial fall-prevention intervention is not suited for reducing falls and fear of falling in community-dwelling frail older fallers, including patients with cognitive impairments. Furthermore, one could conclude from our results that these type of interventions will not work, since they are overly intensive for frail, sometimes cognitively impaired, older persons.

The current study, although presenting negative results, has an important message for medical directors, funding agencies, and policy makers concerning the development and evaluation of fall-prevention interventions in frail older subjects, including the frailest with cognitive defects, and their caregivers. Developing even more complex and specialized fall-prevention interventions will probably not be effective or feasible for these patients and caregivers. Currently, the greatest added value can be reached by focusing on the implementation of basic geriatric practice principles, in other words, geriatric comprehensive fall assessment and drug review, for all fallers.

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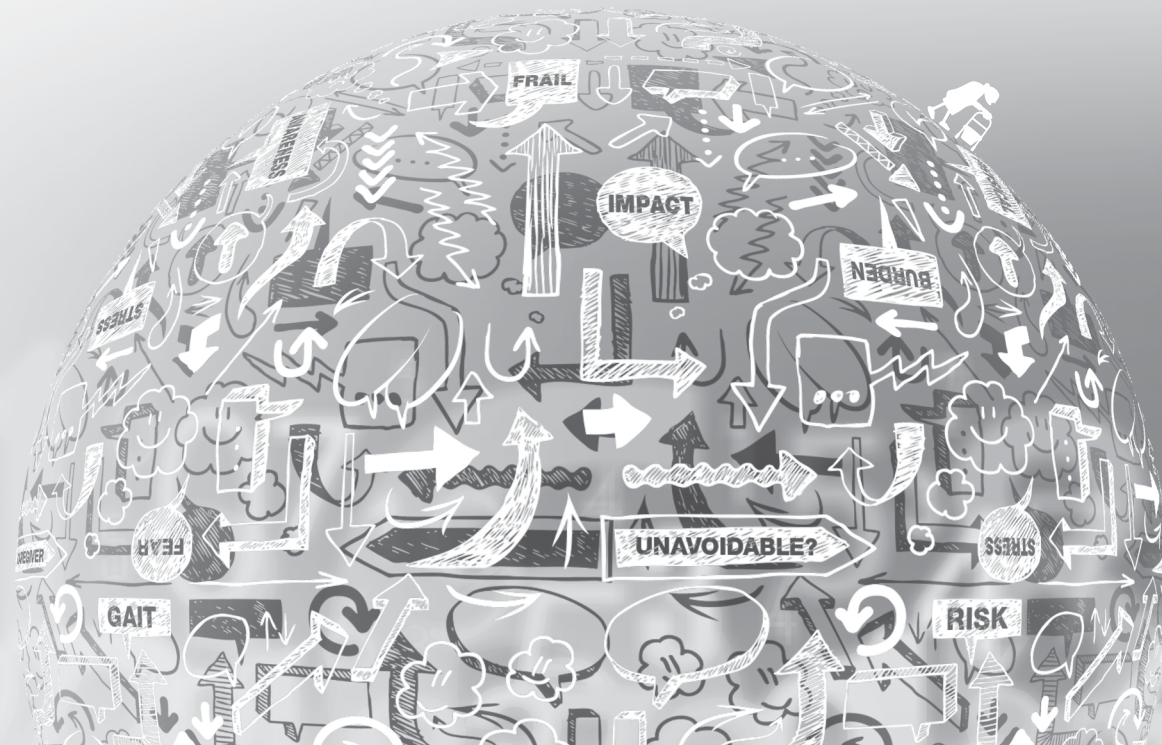
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Preplanned process evaluation of complex interventions

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How to perform a preplanned process evaluation for complex interventions in geriatric medicine: exemplified with the process evaluation of a complex fall-prevention program for community-dwelling frail older fallers. *Reelick M.F., *Faes M.C., Esselink R.A.J., Kessels R.P.C., Olde Rikkert M.G.M. *Journal of the American Medical Directors Association*: Feb 15 2011.

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Abstract

Complex interventions are difficult to develop, document, evaluate, and reproduce. Process evaluations aid the interpretation of outcome results by documenting and evaluating each process step in detail. Despite its importance, process evaluations are not embedded in all evaluations of complex interventions.

Based on literature, we structured the process evaluation for trials on complex interventions into three main components, namely the success rate of recruitment and selection of the study population, the quality of execution of the complex intervention, and the process of acquisition of the evaluation data.

To clarify these process evaluation components and measures, we exemplified them with the preplanned process evaluation of a complex fall-prevention intervention for community-dwelling frail older fallers and their informal caregivers. The three process evaluation components are operationalized, results are presented, and implications discussed. This process evaluation identified several limitations of the intervention and effect study, and resulted in multiple recommendations for improvement of both the intervention as well as the trial.

Thus, a good-quality process evaluation gives a detailed description of the most important components of a complex intervention, resulting in an in-depth insight in the actually performed intervention and effect analysis. This allows us to draw the appropriate conclusions on positive or negative trial results, and results in recommendations for implementation, or adjustment of the intervention or effect evaluation, respectively.

Introduction

Complex interventions are defined as interventions comprising multiple components acting independently or interdependently, and are therefore difficult to develop, document, evaluate, and reproduce. Such complex interventions are very often applied for treatment and prevention of geriatric syndromes, as these are mostly multi-factorial by cause.¹ The UK Medical Research Council (MRC) published a framework in which the development and evaluation of complex interventions is comprehensively guided.² This framework emphasizes the importance of performing a process evaluation alongside the effect evaluation; however, little information is provided on how to perform such a process evaluation.

Process evaluations aid the interpretation of outcome results by documenting and evaluating each process step in detail. This is of great value for both positive and negative trial results. A process evaluation may increase insight into why a successful intervention works, how it can be optimized, and provide insights to aid dissemination and implementation.² Next, it may also explain discrepancies between expected and observed outcomes, or explain lack of effectiveness, which is of great value for future studies. Process evaluations aid in making the distinction between 'failure to demonstrate underlying efficacy or effectiveness' (in other words, the evaluation failed) and 'good evidence of lack of efficacy and effectiveness' (in other words, the intervention failed).³ Both may have various causes, for example, failure of the evaluation may be due to inappropriate outcome measures or insufficient power, and failure of the intervention may be due to an incorrect intervention theory, or unsuccessful implementation. Without this information, accurate conclusions cannot be drawn on (lack of) efficacy or effectiveness of the intervention. Therefore, process evaluations should be conducted to the same high methodological standards and reported just as thoroughly as the clinical trial and its outcomes. However, currently process evaluations are not embedded in all evaluations of complex interventions, and when present, process evaluation components differ per study, or studies only assess a single aspect. Possible explanations are a lack of standardized measurement instruments for evaluating intervention processes, and that these evaluations may be time consuming and considered of less interest than effect analyses. Especially in geriatrics, the burden on frail older persons due to additional measurements is an important consideration which may hinder process evaluation planning. Although, for complex interventions in heterogeneous frail populations, in-depth insight in the process is highly relevant and has to be carefully planned before trials start.

This article presents a systematic and comprehensive guide for the development and application of a process evaluation for complex interventions in geriatrics, based on components used in previous studies on complex interventions. We then demonstrate and clarify this guide by applying it to the process evaluation of a complex fall-



prevention intervention for community-dwelling frail older fallers and their informal caregivers: the 'Carthage-Phoenix Study'.⁴

Process evaluation components for complex interventions

Previous process evaluations

We performed a literature search revealing previous studies performing process evaluations for complex interventions. Several studies performed a feasibility analysis of the intervention, studying barriers and facilitators to fine tune the intervention or improve implementation.^{5,6} Measures determining feasibility include performance of the program according to protocol (timing and duration of assessments, number and type of protocol deviations), nature of recommendations and referrals from assessments, participants' compliance with referrals and recommendations (self-reported compliance), and opinions about the program (benefit and satisfaction experienced by participants, acceptability of the program, recommendations for implementation).^{5,7,8} Barriers and facilitators may be assessed at different levels, for example, the intervention itself, the professional, the participant, or the social, organizational, economical, or political context.^{7,9} In some studies, the process evaluation includes identification of the characteristics of individuals attracted to the program.¹⁰ Often cited components follow the evaluation of fidelity, dose delivered, dose received, reach, recruitment, and context,^{9,11,12} or some of these components.¹³ These components provide a comprehensive evaluation of the intervention itself; however, this overlooks the importance of the evaluation of the research trial itself, which is of great influence on the assessed efficacy or effectiveness. A framework was proposed, to determine the strength of evidence, based on the study design, methodological quality and statistical precision, the magnitude of the measured effects, and the relevance of these effects measured in relation to the implementation context.³ Integration of the process and outcome evaluation also importantly aids in the explanation of the results, and thereby may improve knowledge on underlying pathways.⁷

Components of process evaluations for complex interventions

Based on these literature findings, we structured the process evaluation for trials on complex interventions into three main components, namely 1) the success rate of recruitment and selection of the study population, 2) the quality of execution of the complex intervention, and 3) the process of acquisition of the evaluation (Table 1). Each process component can be assessed by several measures and multiple variables.

Table 1 Process evaluation components and related process measures of a complex intervention.

Process components	Process measures
Study population	1. Recruitment and selection rate 2. Barriers and facilitators in recruitment and selection process 3. Follow-up: attrition rate 4. Barriers and facilitators for follow-up
Multiple components	1. Quality of delivery of the interventional components 2. Barriers and facilitators for delivery of interventional components 3. Adherence to interventional components 4. Barriers and facilitators for adherence to interventional components 5. Experience of participants and instructors with interventional components
Evaluation data	1. Outcome measures: coverage of interventional components 2. Completeness of data collection 3. Barriers and facilitators for data collection

The evaluation of the selection of the study population aims to determine the success rate of the selection process of this population, in other words, reach, generalizability of the sample, and barriers and facilitators for inclusion. This incorporates identifying characteristics of individuals participating in the intervention and refusing participation, and assessing motivations for (refusal of) participation and (lack of) adherence. Especially in a heterogeneous population, insight into the quality of the recruitment, presence of selection bias, and barriers and facilitators for recruitment, are highly valuable and can be used to improve recruitment in next stages of the cycle of development and implementation of a new complex intervention. The evaluation of the intervention itself aims to determine whether the intervention was delivered as intended (fidelity) and was feasible, to identify successful components of the intervention and recommendations. Especially for complex interventions this is an important but difficult part of the process evaluation. The intervention may be intended to be delivered tailor-made, therefore successful delivery cannot simply be assessed with 'performance according to protocol'. In addition, participants may mention contradictory strengths and weaknesses, and reveal different beneficial

components. Conclusions on revisions should therefore should be prepared carefully. Adherence, motivation to participate, or reasons for dropout may be divers, and should be closely assessed, to be able to approach each (category of) participant appropriately.

Investigation of the process of acquiring the evaluation data aims at determining whether the appropriate outcome measures were selected to measure the effect of the intervention, and whether they were sufficiently sensitive to change and close enough to the intervention. This part also assesses completeness of the data collection. The characteristics of missing data often reveal important characteristics of the intervention and the trial. Missing data can bias results, when persons with and without outcome data are different, can reduce generalizability, and limit power.¹⁴ So it is highly relevant to identify how much data is missing, characterize missing data, and to assess why data are missing.

Methods of process evaluations

Process evaluations can use both quantitative and qualitative methods. Quantitative methods may be easier to apply, and require relatively straightforward analyses and interpretation. Qualitative methods may be more difficult to obtain and use, though it gives insight in underlying mechanism by answering ‘why’ and ‘how’ questions, as well as collecting diverse perspectives of participants. By triangulation of the data collected from different sources, an accurate image of all aspects of the process can be derived. In designing the process evaluation plan, the choice of methods is strongly influenced by considerations of feasibility, including the limitations of available resources, burden and acceptability of methods, and the likelihood of obtaining information of the same quality through alternative methods. Especially in a geriatric population, benefit-to-burden ratio must be carefully weighed and when cognitive impairment is present, outcome measures may require verification by caregivers.

Example: the process evaluation of a complex fall-prevention intervention

We preplanned a process evaluation for our newly developed fall-prevention intervention, based on the components described previously. Table 2 shows the variables operationalizing the process components for our study. Because of the frailty of our population, we tried to assess as many variables as possible with simple questionnaires or registration forms. In addition, we performed short semi-structured interviews among participants and instructors to gather information about their experiences and thoughts.

Table 2 Preplanned process variables collected for the process evaluation of a complex fall-prevention intervention study in frail older persons.

Process measures	Process variables
1. Recruitment and selection rate	1. a. Number of eligible persons in screened population; b. Number of participants from the sample of eligible persons; c. Number of participants versus aimed number
2. Barriers and facilitators in recruitment and selection process	2. a. Difference in baseline characteristics between nonparticipating and participating eligible persons; b. Motivation of nonparticipating and participating eligible persons; c. Experience with recruitment and selection
3. Follow-up: attrition rate	3. Number of participants completing follow-up versus number started
4. Barriers and facilitators for follow-up	4. Reasons for dropout and motivation for continued participation
1. Quality of delivery of the interventional components	1. a. The part of each component and the complete intervention delivered by instructors; b. Satisfaction with delivery
2. Barriers and facilitators for delivery of interventional components	2. Reasons for diverging from, or applying (planned) components
3. Adherence to interventional components	3. a. Number of sessions followed; b. intervention components (partly) followed; c. Compliance to individual recommendations; d. Homework adherence
4. Barriers and facilitators for adherence to interventional components	4. Motivation for (lack of) attendance and compliance
5. Experience of participants and instructors with interventional components	5. a. Perceived benefit; b. Strong and weak aspects of the interventional components (structure and content), and the total intervention
1. Outcome measures: coverage of interventional components	1. Average number of outcomes per component
2. Completeness of data collection	2. Number and characteristics of missing data
3. Barriers and facilitators for data collection	3. a. Feasibility of outcome measures; b. Reasons why data were missing; c. Reasons why participants were excluded from analysis
	4. Comparison of qualitative and quantitative effectiveness data

Table 3 Most important findings from the preplanned process evaluation of a complex fall-prevention intervention study in frail older fallers.

Process components	Findings per process variable <i>(The numbers in this column refer to numbers in table 2.)</i>
Study population	<ol style="list-style-type: none"> 1. a. A total of 813 patients were screened; b. Of the 282 eligible patients, 241 participants (85.5%) declined participation; c. Recruitment objective was not reached (22.5%). 2. a. Compared to nonparticipating eligible patients, participants were younger, experienced fewer falls, had a higher co-morbidity score, showed a lower frequency of dementia, attributed falling more to extrinsic causes, had less frequent employed caregivers, and less frequent caregivers who experienced fear that the patient would fall; b. Most important barrier for participation was the burden of participation, due to the frequency and timing of the sessions, distance to facility, co-morbidity or other obligations. In addition, caregiver participation was an important barrier; c. Recruitment was complicated and time consuming. None of the participants could express their expectations or give a clear description of the content of the intervention before the start. 3. Dropout was 27.7% and 55.6% in the intervention and usual care group respectively. 4. Dropout was due to co-morbidity and mortality.
Complex intervention	<ol style="list-style-type: none"> 1. a. All components were applied, and the program could be delivered tailor-made; b. The intervention components were feasible and satisfactory. 2. Barriers for delivery were absence of one or more of the pairs, or moderate cognitive or severe physical impairment of one of the participants in a group. 3. a. Five pairs (21.7%) followed less than five session (out of ten); b. All participants received all components that were applicable for them; c. Most patients (90%) followed personalized recommendations, though some only at the end of the intervention; d. Most patients (90%) continued to exercise at home, though at moderate frequency (mean: six times a week, 15 minutes a time) 4. Reasons for low attendance of pairs were unavailability of the caregiver on a specific day, previously planned obligations, and health issues (severe illness, too severe hearing impairment for group participation, and hip fracture of the caregiver). Barriers for homework exercise performance were physical impairment, fatigue, or not recalling homework exercise.
	<ol style="list-style-type: none"> 5. a. All participants indicated to have benefitted from the intervention, which was in line with the judgment of the instructors. Perceived benefits were diverse, including increased insight in fall risk and limitations, increased coping, decreased fear of falling, and increased physical activity; b. Both training in pairs and training in a group were considered very valuable; it was enjoyable and educational, learning from other pairs, sharing experiences, feeling supported, and being able to practice together. Participants desired to receive a higher number of sessions, up to 30 sessions, and/or a longer follow-up, to be able to practice more, receive more information, and achieve behavioral change. Insight into personal limitations and capacities was increased in all participants. However, increased insight was confronting for participants, resulting in negative feelings or rejection of the intervention content. For some caregivers, increased insight led to an increase in time and load invested. Information and training were considered very useful, though, when a fall did occur, it proved difficult to stay calm and implement intervention. Some participants refused to use aids to decrease fall risk, afraid people might condemn them, or because of the wish to stay independent. Some caregivers refused to act as trainer, to avoid conflict or because they believed the patient would not change.
Collecting evaluation data	<ol style="list-style-type: none"> 1. Participants could roughly be divided into two groups: the 'fearful' and 'high-risk behavior/denial' group. The heterogeneous nature of the group resulted in different aims and thus different results for each individual. Not all goals that were listed by the participants were assessed in the measurements, for example level of acceptance, insight in limitations, and the ability to get up after a fall. 2. None of the patients had intercurrent missing values on the primary outcomes measure before death or loss to follow-up otherwise. The frequency or causes of dropout or missing data on secondary outcome measures did not differ between the treatment groups. 3. a. Measurements were considered long, but not too burdensome. Questionnaires were easy to understand and measurements easy to follow; b. Visiting the hospital for measurements was considered burdensome, in most cases due to intercurrent disease or lack of transportation; c. Reasons for exclusion from analysis were missing data owing to disease. 4. Perceived benefit was not in accordance with quantitative benefit. Participants indicated more effects of the intervention than were assessed quantitatively. Some changes only became apparent after questioning in interviews, probably because participants had adjusted their standard and were no longer aware of the achieved change.

The fall-prevention intervention

The fall-prevention intervention is a group program developed for pairs of frail older fallers and their informal caregivers, primarily aimed at fall risk reduction and reduction of fear of falling. The intervention has both physical and psychological components, specifically tailored to this frail patient group. Physical training took place in an 'activities of daily living'-based circuit that simulates daily living conditions, and aimed at training of balance, strength, coordination, and functionality. Psychological training handled fear of falling, impulsiveness, and uncovering and accepting limitations and abilities. The intervention is described in detail in a previous publication.¹⁵

Table 3 shows the most important findings of the process evaluation per process measure. Following we describe the implications of these findings, and how the process evaluation facilitates adaptation of the intervention and study.

Implications: study population

Results from the process analysis of the study population indicate that the information supply for potential participants needs adaptation, to ensure and increase understanding of the intervention content and structure of the program. This will increase insight into potential benefits of the program, and therefore acceptance of the burden of the program, which may increase successful recruitment. Moreover, the group actually selected may have been too frail to participate and benefit. The current intervention seems more appropriate for a less frail group of older persons with a high risk of falls. For this frail population, adaptations of the program should reconsider location, timing, and duration, with a special consideration to caregiver availability.

Implications: complex intervention

Process data on the complex intervention show that adherence and compliance were moderate. Inclusion of participants should specifically address appropriateness for group participation, including physical and cognitive aspects, and availability. In addition, more emphasis should be placed on the importance and benefit of homework exercise. The intervention should be prolonged to ensure that the increased insight results in behavioral change, and to overcome negative effects of the increase in insight.

Implications: outcome measures

The process analysis of the outcome measures indicate that these measurements did not fully match the intervention. Heterogeneous effects could be expected, and even contradictory findings between different persons might be expected, such as both increased and decreased activity, which would result in lack of change in overall group analysis. Effectiveness ultimately may be assessed at individual level, for example, goal attainment scaling may be of high value for tailor-made complex

interventions. In addition, some of the goals were not assessed at all, such as being able to get up after a fall, or acceptance or increased insight in limitations and abilities, although the intervention trained specifically on these aims. Thus, all possible goals should be reviewed before start of the intervention, adjusting outcome measures to anticipated goals. Perceived benefit assessment should consider an individual frame shift, which may result in no longer acknowledging improvement since one adapted to the new situation. Socially desirable answers should also be identified, since these may result in a too positive intervention evaluation.

Conclusion

In conclusion, the process evaluation identified limitations of the intervention and effect study, and resulted in multiple recommendations for improvement of our fall-prevention intervention. Therefore, the intervention was not implemented in its present form. We both adapted the program to an individual, home-based program for the group of frail older fallers, who could not participate in the group intervention, and we adapted the recruitment, so a less frail group could be selected for the ongoing group intervention. Outcome measures will be adapted to more closely represent the individual aims in this heterogeneous population. Pilot studies with these adaptations included are currently being performed.

In general, future complex intervention studies, especially in heterogeneous groups, should perform a preplanned process evaluation alongside the effect evaluation. The study population, the intervention itself, but also the data collected for the evaluation should be conscientiously evaluated, resulting in an in-depth insight in the actually performed intervention and effect analysis. This prevents inappropriate conclusions from being drawn on efficacy or effectiveness, and results in comprehensive recommendations for appropriate adjustment of the intervention or effect evaluation. It gives detailed information on the barriers and facilitators for this and similar interventions, and experiences from participants and instructors, which would otherwise remain unidentified. This results in more efficient adaptation and development of complex interventions, and aids implementation.

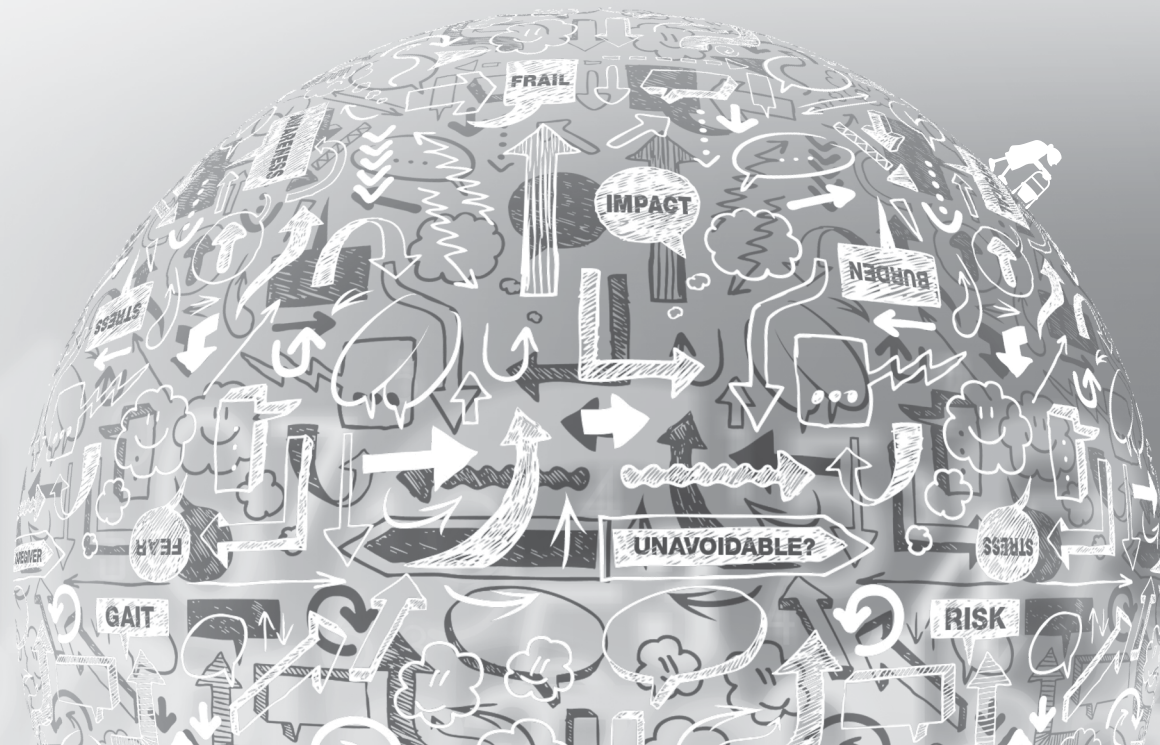
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PART III

Adaptations for fall prevention in frail older fallers





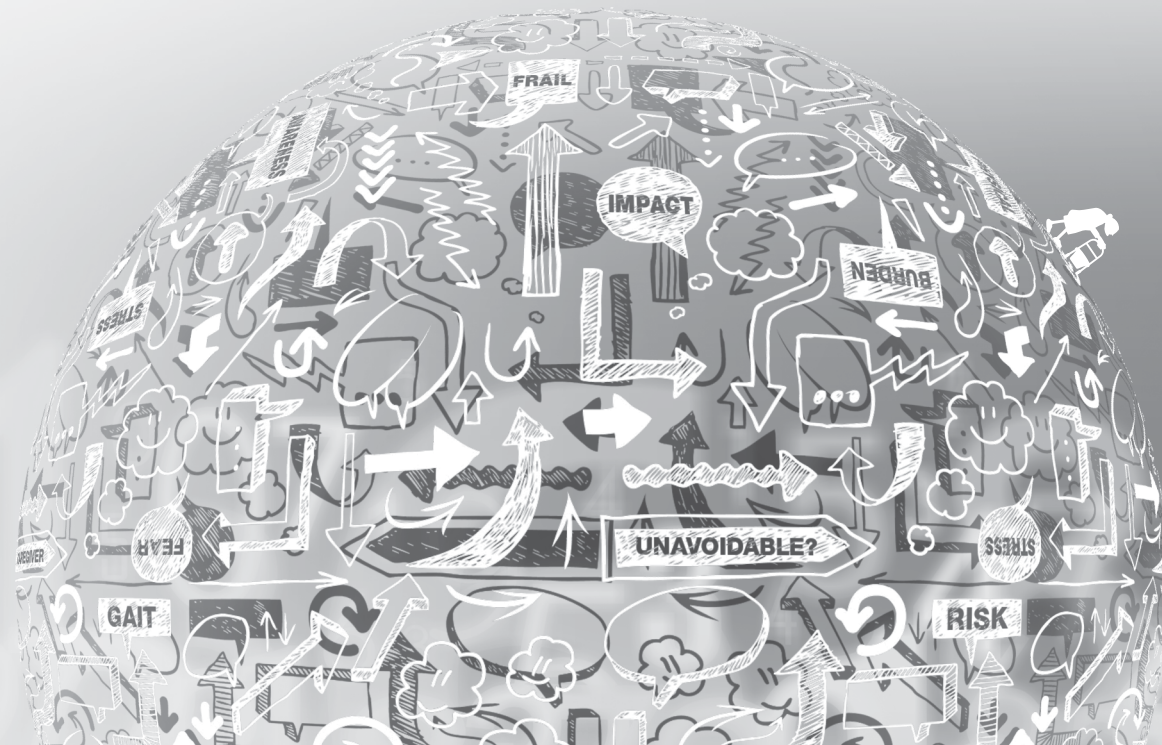
The fall telephone: a new method to assess falls in frail older persons

Published as:

The fall telephone for falls assessment in frail older persons; feasibility, reliability and validity.

Reelick M.F., Faes M.C., Lenferink A., Esselink R.A.J., Olde Rikkert M.G.M.

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To the Editor: There is an ongoing discussion on methods used to assess falls in older persons for research purposes. Retrospective methods probably result in underreporting of falls, especially in cognitively impaired older persons.^{1,2} Prospective methods such as fall calendars (FCs) provide more-valid data but are burdensome, and the response rate is often low. Automated calls using Touch Tone Data Entry (TTDE) have successfully been used for screening or monitoring in older persons,^{3,4} although cognitive and physical impairments might hinder the use of TTDE.

Therefore, the feasibility, reliability, and validity of a TTDE system (the Fall Telephone [FT] ASK Community Systems, Rotterdam, The Netherlands) was qualitatively studied. Fifteen frail older persons (10 female, age 69-86 years) with a wide range of cognitive and physical impairments (Mini-Mental State Examination score: range 21-30,⁵ Cumulative Illness Rating Scale-Geriatrics score: range 5-18⁶) used both the FT and FCs for three months. The FT automatically telephoned participants once a week on their day of preference, and they reported the number of falls in the past week twice. In case of no response, the system retried to a maximum of four times a day and again the next days. FCs had to be filled in daily and mailed, free of charge, every two weeks. The researcher called participants to check registered falls and randomly called participants with no falls registered. In addition, we conducted a semi-structured interview to gain insight into participants' experiences with both methods and analyzed the data using content analysis.

Participants found both methods easy in use, although some discrepancy arose; some participants declared that a calendar was easy, but had not completed it. Besides, in some cases their caregiver registered the falls because of cognitive or hearing impairment. Participants preferred the use of FT over FCs, primarily because they had to perform only one reactive act, that was finished after the telephone call. Filling in or mailing FCs was easy to forget, and mailing FCs was a barrier for some participants. Only a few participants filled in their FCs daily, and one participant had difficulty with writing due to his illness. Nevertheless, two participants preferred FCs, because they preferred having the registration on paper, since this made them more aware of their falls. Besides, they felt more in control, since they could decide when they completed the registration.

Some of the cognitively impaired participants were confused about the frequency of calls and some had the impression they had to call the system themselves after experiencing a fall. Some participants were restless, knowing that FT would call, although after the first calls, they became used to it. Participants did not experience the fact that they could not reply as a problem, although they sometimes missed the option to report the circumstances of the fall.

The FCs appears less reliable, because approximately 25% of FCs were lost or returned incomplete, in contrast to one missed call due to a technical problem. One participant was unable to use FT because of her house telephone system.



Results from the calls by the researcher showed that all registered falls were actual falls. Participants were well aware what occurrences to report and which not to report, suggesting the registered numbers are valid and reliable.

This qualitative study showed FT to be a feasible, reliable, and valid method of assessing falls in frail older persons. FT will be used in a future trial, replacing resource-intensive FCs. We recommend that the researcher calls the participants after the first two FT calls to address any questions and after every recorded fall to ask about the circumstances. Persons with a cognitive or hearing impairment and their caregivers should receive extra instructions, and in general, instructions should emphasize that participants do not have to call the system themselves.

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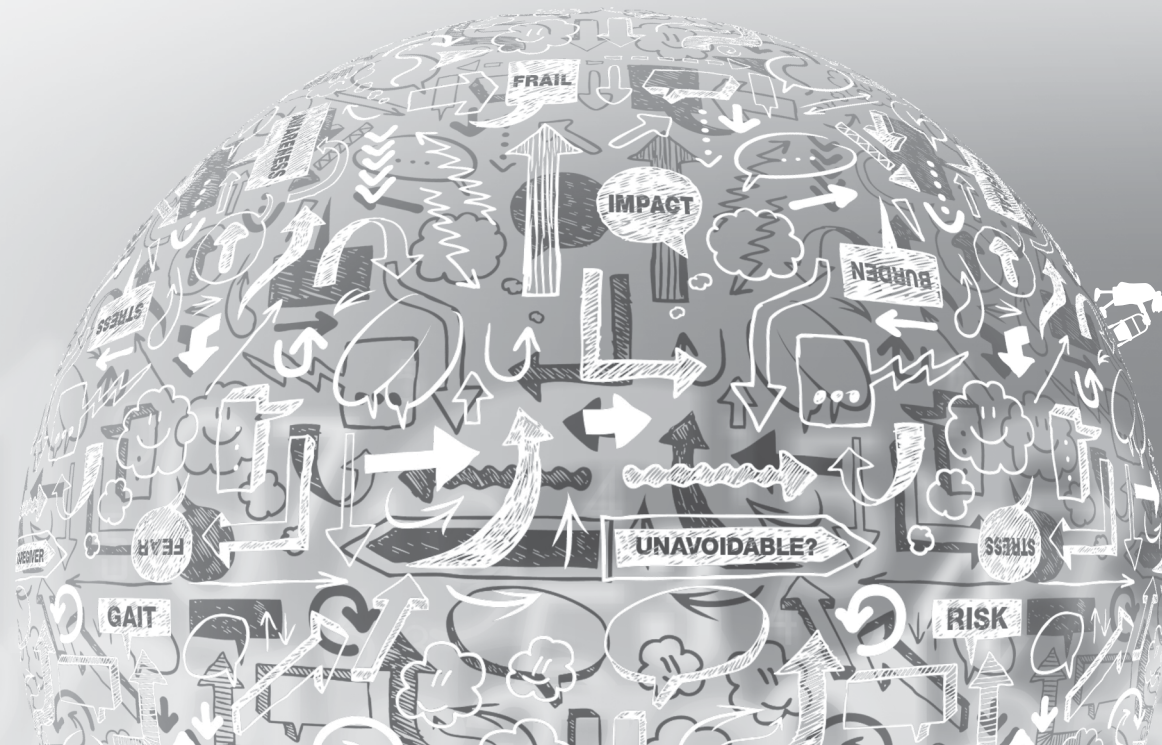
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Biofeedback as single intervention to improve balance performance

Submitted as:

Supportive evidence for the concept of biofeedback training in geriatric patients with impaired balance ability. Reelick M.F.,

Van der Doelen D., Scholten M., Nanhoe-Mahabier W., Olde Rikkert M.G.M.



Abstract

Background and aims In different populations balance was improved with an artificial biofeedback system. The purpose of this study was to assess feasibility and effect of a multi-modal biofeedback (balance) training (BT) in vulnerable older persons with impaired balance ability.

Methods Eight geriatric outpatients (median age 81.5 years; five women) received BT of sway angle using vibrotactile and auditory signals during three visits. Balance was assessed as trunk sway angle and velocity in the medio-lateral (roll) and anterior-posterior (pitch) direction, before, directly after and approximately three days after BT.

Results After the training, roll and pitch angle decreased when walking eyes closed and pitching head, -0.56 deg and -1.3 deg respectively. Pitch velocity decreased when standing eyes open and eyes closed on foam, -1.3 deg/s and -1.1 deg/s respectively. Pitch and roll velocity increased when walking while performing a dual task; +3.5 deg/s and +3.0 deg/s respectively.

Conclusions We showed that low intensity BT was well tolerated and may improve balance in vulnerable older persons with impaired balance ability. However, for the cognitive dual-task, pitch and roll velocity increased significantly. This may indicate deteriorated balance during dual tasking. Since it took participants multiple BT protocols to understand the use of the biofeedback system, it is recommended that a longer, higher-intensity BT is tested in this population to optimize training effects, with special attention for the prevention of undesired effects on dual-task performance.

Introduction

Balance control requires input from the visual, vestibular, proprioceptive, and somatosensory system, and is not a fully automatic process.¹ Since the capacity of central processing is limited, performance of a dual task may affect postural stability,¹ especially in older persons, because of age-related decline in cognitive and sensorimotor processing.² Balance impairment may have serious consequences, such as falls.³⁻⁵ To improve balance during stance and gait, an artificial biofeedback system can be used as supplement to natural sensory inputs, providing additional information about trunk sway to the brain.⁶ In healthy young (approximately 25 years old) and healthy older (approximately 70 years old) persons, multi-modal biofeedback training showed promising results.⁷⁻¹⁰ Sway angle decreased regardless of biofeedback direction, indicative of a general increase in balance awareness.⁸ Multi-modal biofeedback training has also been successfully used in patients with vestibular or proprioceptive loss.¹¹ To our knowledge, the effect of a multi-modal biofeedback system was not yet examined in a geriatric population. Possible cognitive and physical impairment might decrease effectiveness of biofeedback (balance) training (BT). In addition, none of these studies re-assessed balance a few days after BT. We aimed to determine the feasibility and effect of a multi-modal (vibrotactile and auditory) BT on balance performance of vulnerable older persons with impaired balance ability, directly and three days after BT.

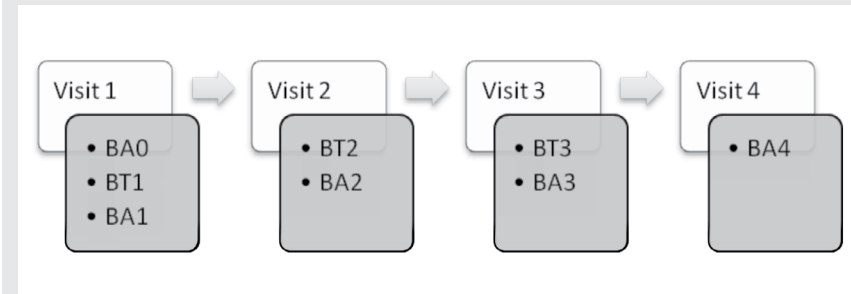
Methods

We recruited outpatients from the geriatrics department (Radboud University Nijmegen Medical Centre (RUNMC), the Netherlands). Patients were eligible if they were ≥ 70 years, able to walk ≥ 15 meters independently, and scored ≤ 24 on the Tinetti gait and balance scale.¹² Patients with a score of ≤ 24 on the Mini-Mental State Examination (MMSE)¹³ or with co-morbidities contraindicating physical training were excluded. All participants signed informed consent. This study was approved by the medical ethics committee (CMO Arnhem-Nijmegen).

We recorded participants' characteristics, assessed fall history of the past six months, fear of falling (yes/no question), falls efficacy (Falls Efficacy Scale-International; FES-I)¹⁴ and (instrumented) activities of daily living (Groningen Activity Restriction Scale; GARS).¹⁵

Participants received BT during three visits within two weeks, scheduled at the convenience of the participant (Figure 1). Balance was assessed using the SwayStar™ device (Balance Int. Innovations GmbH, Switzerland), as trunk sway angle and velocity in the medio-lateral (roll) and anterior-posterior (pitch) direction. During the measurement, a researcher always stood or walked besides the participant, to ensure



Figure 1 Balance assessment and training protocol.

BA=balance assessment, consisting of stance tasks (eyes open and eyes closed on regular floor or foam) and gait tasks (walking eight meters eyes open, eyes closed, while pitching head, while performing a cognitive dual-task and while performing a motor dual-task). BT=Biofeedback (balance) Training, consisting of stance tasks (stance eyes closed, eyes open and closed on foam) and one gait task (walking eight meters eyes open).

the participant's safety. The head-mounted Balance Freedom™ device provided position feedback on trunk sway, when sway passed a set threshold. Thresholds were task-specific and were set for both roll and pitch directions, based on the individual's sway (90% range) in the previous balance assessment. Vibrotactile and auditory signals responded to a 40%-threshold and 80%-threshold respectively. For example, a 90% peak-to-peak roll angle of 1 deg would correspond to a vibrotactile peak-to-peak threshold value of 0.4deg divided equally left 0.2 deg, right 0.2 deg, and an auditory threshold of 0.8 deg.⁸ Participants were instructed to reduce trunk sway so that feedback was not activated. A fourth visit reassessed balance approximately three days after BT. The BT protocol consisted of three stance tasks (eyes closed, eyes open on foam, eyes closed on foam) and one gait task (8 meters walking at preferred speed), performed four times consecutively. The balance assessment tasks consisted of stance and gait tasks (8 meters) with and without suboptimal sensory conditions (eyes closed, foam, head pitching), and of walking (8 meters) with and without performance of a cognitive and motor dual-task. The cognitive dual-task consisted of naming as many words starting with a specific letter as possible (verbal fluency). Each time, participants received a different starting letter with comparable level of difficulty.¹⁶ For the functional motor dual-task, participants held a mug with water (filled up to 1 cm below the rim) with their dominant hand while walking at preferred speed. Trunk sway angle and velocity before and after BT was compared with use of the Wilcoxon signed-ranked test for paired samples. Data are presented as median with ranges (between []) or means \pm standard deviation.

Results

We screened 36 patients visiting the geriatric department, of which 21 patients were not eligible because of age and/or Tinetti score. Seven patients declined participation because they expected the burden to be too high. We included eight older persons (age 81.5 years [range 70.0-86.0]; 5 women). Participants had a body mass index of 27.6 [range 21.8-30.1], an MMSE score of 29 [range 26-30], scored 8.5 on the Tinetti gait subscale [range 8-10], 12.0 on the Tinetti balance subscale [range 7-14], 33.5 on the FES-I [range 26-51], and 35.5 on the GARS [range 20-47]. Three participants experienced

Table 1 Effect of biofeedback training: changes between the initial balance assessment (BA0) and the balance assessment directly after training (BA3) and three days after training (BA4).

Tasks		RA (deg)	PA (deg)	RV (deg/s)	PV (deg/s)
1.sEC	Δ BA0-BA3	0.093 (0.20)	-0.40 (0.94)	0.047 (0.36)	-0.19 (0.70)
	Δ BA0-BA4	0.089 (0.51)	-0.23 (1.0)	-0.012 (0.37)	-0.26 (1.3)
2.sEOf	Δ BA0-BA3	0.035 (0.21)	-0.25 (1.2)	-0.56 (0.72)	-1.3 (1.4)*
	Δ BA0-BA4	0.073 (0.22)	-0.23 (1.2)	-0.27 (0.83)	-1.1 (0.93)*
3.sECf	Δ BA0-BA3	0.14 (0.45)	-0.51 (1.4)	-0.61 (1.32)	-0.91 (2.0)
	Δ BA0-BA4	-0.081 (0.49)	-0.52 (0.78)	-0.32 (1.8)	-1.1 (1.8)**
4.wEO	Δ BA0-BA3	0.23 (0.73)	1.6 (2.3)	4.1 (6.1)**	5.4 (12.7)
	Δ BA0-BA4	-0.0030 (0.75)	0.45 (1.8)	2.0 (6.5)	0.33 (12.6)
5.wEC	Δ BA0-BA3	-0.56 (0.73)**	-0.10 (1.6)	1.5 (6.2)	1.3 (8.8)
	Δ BA0-BA4	-0.054 (0.77)	0.079 (2.2)	4.0 (9.7)	2.5 (11.7)
6.wPH	Δ BA0-BA3	-0.043 (1.1)	-0.51 (1.7)	3.2 (6.8)	1.8 (9.2)
	Δ BA0-BA4	-0.23 (0.83)	-1.3 (1.7)**	1.7 (6.9)	2.3 (7.9)
7.wDTc	Δ BA0-BA3	-0.095 (1.2)	-0.25 (1.3)	3.5 (4.1)*	3.0 (4.6)**
	Δ BA0-BA4	-0.27 (1.5)	-0.56 (1.6)	2.4 (2.7)**	2.1 (4.1)**
8.wDTm	Δ BA0-BA3	0.30 (0.65)	0.35 (1.1)	6.8 (7.9)**	1.8 (8.7)
	Δ BA0-BA4	-0.046 (0.39)	0.70 (1.6)	4.5 (5.9)	0.39 (7.4)

Data presented as mean (standard deviation). Negative mean change indicates biofeedback training reduced trunk sway angle or velocity. * $p < 0.05$, ** $p < 0.1$ by Wilcoxon signed-rank test for paired samples. Abbreviations: sEC=stance eyes closed, sEOf=stance eyes open foam, sECf=stance eyes closed foam, wEO=walking eight meters eyes open, wEC=walking eight meters eyes closed, wPH=walking eight meters pitching head, wDTc=walking eight meters while performing the cognitive dual task, wDTm=walking eight meters while performing the motor dual task. BA=balance assessment, RA=roll angle, PA=pitch angle, RV=roll velocity, PV=pitch velocity.

a fall in the past six months, five participants acknowledged fear of falling, and seven participants used fall-risk related drugs (median number of fall risk related drugs used: 1 [range 0-4]). The three BT visits were scheduled within 10.5 days [range 7-16], visit four was scheduled 2.5 days [range 2-5] after visit three.

Table 1 shows the change in trunk sway, directly and approximately three days after BT. Pitch velocity was reduced when standing with eyes open and eyes closed on foam ($\Delta -1.3 \pm 1.4$ and $\Delta -0.91 \pm 2.0$ deg/s respectively), even several days after BT ($\Delta -1.1 \pm 0.93$ and $\Delta -1.1 \pm 1.8$ deg/s respectively). Roll angle decreased in the walking with eyes closed condition ($\Delta -0.56 \pm 0.73$ deg), and pitch angle decreased when walking while pitching head ($\Delta -1.3 \pm 1.7$ deg). Pitch and roll velocity increased significantly when walking while performing the cognitive dual-task ($\Delta 3.0 \pm 4.6$ and $\Delta 3.5 \pm 4.1$ deg/s respectively).

Discussion

To our knowledge, this is the first study among geriatric patients with impaired balance ability aimed at determining the feasibility and effect of a multi-modal biofeedback (balance) training (BT). We showed that low intensity BT may improve balance in this population, in other words, reduced sway angle and velocity directly and approximately three days after BT.

However, for the cognitive dual-task, pitch and roll velocity increased significantly, which may indicate deteriorated balance during dual tasking. Difficulty with dual-task performance is associated with increased fall risk.^{17,18} Dual tasking requires a person to divide his/her attention over different tasks. When the attentional capacity is diminished, or a process requires more attention because of deteriorated function, one or both of the tasks cannot be performed optimally.¹⁹ With the BT, even a third task requires attention, namely responding to the feedback signals. Easier tasks may require less attention, and the added attention required for the BT response may therefore not result in exceeding the attentional capacity and the consequential deterioration of balance performance. Secondly, the increase in roll and pitch velocity may also be a result of increased gait velocity after BT. Studies have shown that sway velocity is related to gait velocity.^{10, 20} Repeated performance of the dual tasks may have resulted in a learning curve, increasing the gait velocity while dual tasking, over time. Future studies should also include gait velocity to disentangle the underlying cause of the increased pitch and roll velocity while dual tasking.

The BT did not affect all balance measures. This could be due to our small sample size and large variance of sway in this sample.²¹ Also, it may be due to our choice of training tasks, since not all tasks were included in de BT. However, previous studies have shown reduced sway angles in tasks that were not practiced, suggesting that training with

biofeedback may result in a carry-over effect leading to general balance changes, probably due to increased awareness.^{7,9} In addition, a certain amount of initial sway seemed necessary to enable a beneficial effect of biofeedback, which may clarify the results for the less demanding tasks. Horlings et al. noted that change in sway with biofeedback was proportional to initial balance performance of participants, thus participants with the largest initial sway were most aided by having biofeedback of their postural sway available to them.¹¹

Although we excluded patients with an MMSE score ≤ 24 , participants initially experienced difficulties with responding to the biofeedback signals; participants responded with head movement instead of trunk movement, or overcompensated. Therefore, optimal training effects may not have been reached. After several BT protocols, all participants were able to respond to the biofeedback adequately.

A limitation of this study is the lack of a control group. Consequently, our study cannot be conclusive about the cause of the change in balance, which, in part, may be caused by other factors such as familiarization with the tests after being repeatedly tested. However, previous studies showed that BT effects are more than practice effects alone.⁷

Conclusion

It took participants several BT protocols to understand the use of the biofeedback system, but results are promising and provide evidence that the concept may work even in vulnerable older persons with impaired balance by multiple causality. Since our sample tolerated the tasks and the duration of the training well, it is recommended that a longer, higher-intensity training is tested, which would probably optimize training effects.



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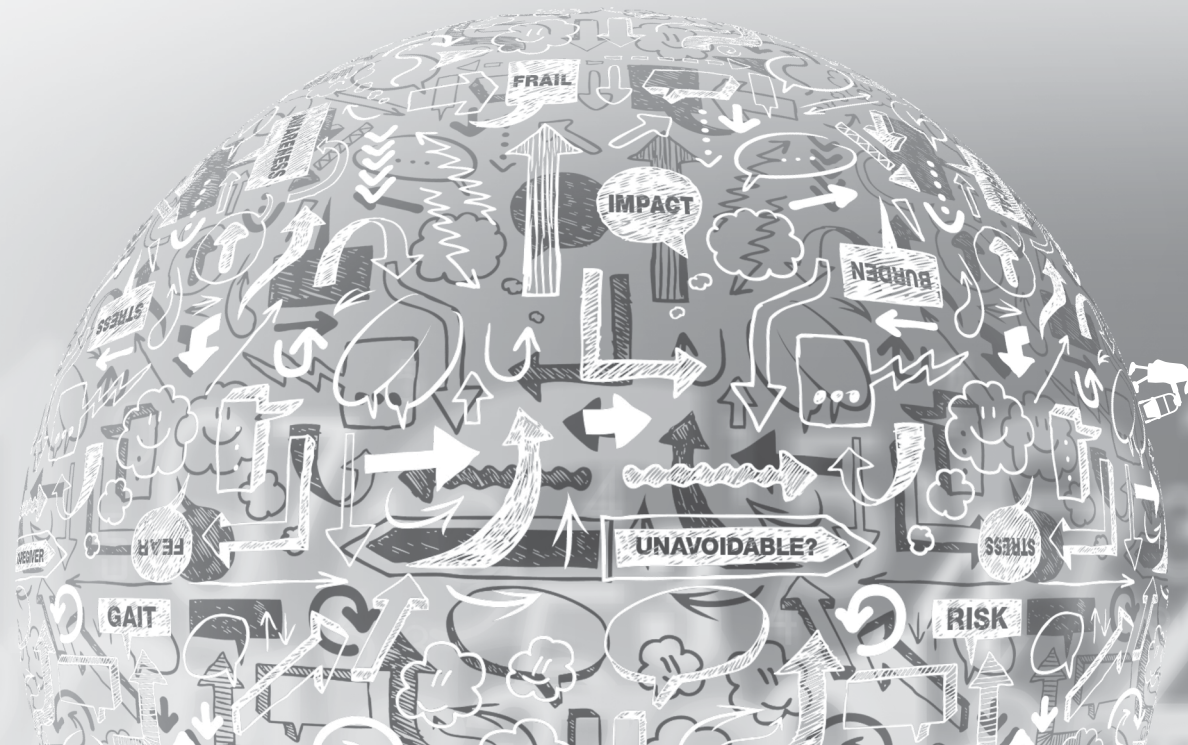


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Identifying older persons at risk of falls: within-task variability in stride length and reaction time

Published as:

Increased intra-individual variability in stride length and reaction time in recurrent older fallers. Reelick M.F., Kessels R.P.C., Faes M.C., Weerdesteyn V., Esselink R.A.J., Olde Rikkert M.G.M. *Aging Clinical and Experimental Research*: Nov 2 2010.



Abstract

Aims To study and compare both the mean performance measures as well as the intra-individual variability measures of stride length and decision time in vulnerable recurrent and non-recurrent older fallers.

Methods Stride length during walking, and walking while dual-tasking (GAITrite™), and choice decision time (CANTAB™) were assessed in geriatric outpatients and their informal caregivers (N=60, ≥60 years). Using logistic regression and Receiver Operating Characteristic (ROC) analysis, models were obtained with mean performance measures and with intra-individual variability measures (coefficients of variation; $CV = [Standard\ deviation / Mean] \times 100$), as risk factors for recurrent falls.

Results Decision-time CV was higher in recurrent fallers compared to non-recurrent fallers: 21.3% [range 9.3-47.7] versus 15.8% [range 8.3-34.9] ($p=0.04$). Also, stride-length CV was higher in recurrent fallers during performance of the verbal fluency dual-task: 4.5% [range 1.2-31.4] versus 3.5% [range 0.9-9.7] ($p=0.017$). The model with CVs provided an explained variance of 23.7%, and an area under the curve (AUC) of 0.73, which was higher than the model including the mean performance measures (8.6% and 0.65 respectively).

Conclusions Older recurrent fallers are characterized by increased within-task variability in decision time and stride length while dual-tasking. Moreover, variability in performance is a more sensitive measure in discrimination of recurrent falls than the mean performance itself, suggesting deterioration in neurocognitive regulation mechanisms as part of the causal pathway for recurrent falls.

Introduction

Falls in older persons have a high impact on mortality, functional performance, and quality of life.^{1,2} Therefore, identifying risk factors for falls remains an important research objective, as this may improve prediction of falls and elucidate the causal pathways. Gait and balance disorders have proven to be important risk factors for falls.³ For example, stride-time variability was found to be associated with fall status, independent of age, medication use, sex, height, and weight.⁴ Quantitative gait studies have shown that measures of gait variability may be more sensitive in predicting functional decline and falls than mean values of gait measures.⁵⁻⁷ Previous results demonstrated that stride-length variability predicted falls in patients with dementia, and in another study, increased gait variability was associated with an increased risk of future falls in community-living older adults attending an outpatient geriatric clinic, while mean value gait measures did not.^{5,7} Maki et al. observed that gait speed and other stride variables were associated with fear of falling, while stride variability was predictive of future falls among older residents of an assisted-living facility.⁶ An explanation for this may be that mean performance is more susceptible to environmental factors, while gait variability reflects inconsistency in the central neuromuscular control system's ability to regulate gait and maintain a steady walking pattern.⁸

Specifically dual-task walking ability is related to future falls.⁹ Due to the limited nature of attention capacity, if two tasks are performed together, competition between the two tasks may occur, resulting in a deterioration of the performance on one or both tasks.¹⁰ With respect to falls in older persons, a strong relationship exists between dual-task related gait changes and the risk of falling.¹¹⁻¹³ Falls risk is higher in persons who slow their walking while performing a verbal cognitive task, and especially in persons who stop walking while talking.¹⁴⁻¹⁶

Recent studies have shown that executive function measures are strongly related to gait, and are associated with fall risk in older persons with, but also without, cognitive impairment.^{14, 17} Older fallers show decrements in executive functions and especially an increased variability in decision time compared to non-fallers, probably due to a diminished attention capacity.¹⁸ Again, intra-individual variability in decision times was a more sensitive predictor of cognitive changes than the mean decision time itself.¹⁹ Herman et al. found that gait variability during dual tasking and measures of executive function predicted future falls in a large prospective study among older persons without falls in the year prior to the study.⁹

Overall, increased intra-individual variability, both in gait parameters and in decision time, could well reflect deterioration in neurocognitive regulation mechanisms resulting in falls, especially in an older population. Therefore, these variability measures are potentially useful in early detection of particularly recurrent fallers, since recurrent falls are more often related to intrinsic risk factors for falling than isolated falls.^{2, 20} Early

detection of recurrent fallers may result in early application of preventive measures and thus result in prevention of falls, falls-associated injuries and other serious consequences.²

However, we are unaware of a study with a specific focus on this combination of variability measures in relation to fall status in a group of vulnerable older persons. In the current study, we hypothesized that intra-individual variability of stride length and decision time are useful for the identification of recurrent fallers. In addition, we hypothesized that these variability measures are more discriminative compared to the mean values of these variables.

Methods

Participants

We recruited outpatients of the Geriatric department of the Radboud University Nijmegen Medical Centre (RUNMC) and their informal caregivers from January 2008 to September 2009. Inclusion criteria were age ≥ 60 years, being able to walk 15 meters independently (use of a walking aid allowed), and to understand and follow short instructions. Participants were excluded if their vision was insufficient to read instructions, when they had a Mini-Mental State Examination score < 15 (MMSE; 0-30), or a neurologic impairment with upper limb motor loss. The study was approved by the medical ethics committee (CMO Arnhem-Nijmegen). We obtained written informed consents from all participants.

Design and outcome measures

This study was conducted in a cross-sectional design.

Baseline characteristics

At inclusion, we assessed relevant demographical characteristics and the medical history. Co-morbidity was calculated as severity index based on the Cumulative Illness Rating Scale – Geriatrics (CIRS-G; severity index = total score/number of scored categories). Participants' premorbid intelligence levels were estimated using the Dutch Adult Reading Test (DART), and global cognitive function was assessed using the MMSE. Participants completed the Groningen Activity Restriction Scale (GARS), which is a validated scale for the assessment of (instrumental) activities of daily living.²¹ In addition, as a measure for general mobility, participants performed the Timed Up and Go test (TUG). The number of falls during the past six months was assessed by detailed medical history taking of both the patients and their informal caregiver. Based on this, participants were classified as recurrent faller or non-recurrent faller (zero or one fall).

Decision time

We used the Choice Reaction Time (CRT) subtest of the Cambridge Neuropsychological Test Automated Battery (CANTAB™) as a compound measure of processing speed and attentional capacity.²² Participants held down a press pad button until a stimulus appeared for a moment at random at one of five possible locations on a touch screen, then released the press pad button and touched the position of the stimulus as fast as possible. The task was practiced and then assessed with 15 stimuli. The instructions by the researcher emphasized speed of performance. Task outcome was decision time, in other words, the time necessary to initiate a response. We calculated the individual within-task variability (dispersion) as coefficient of variation ($CV = [\text{Standard deviation}/\text{Mean}] \times 100$) for all accurate responses. The number of inaccurate, premature and missed responses was registered.

Gait

Participants walked at preferred velocity, with and without performance of a cognitive dual-task. The two subsequent dual-tasks consisted of continuously subtracting 7 starting from 100, and naming words starting with a given letter. We continuously assessed gait velocity, stride length, stride time and stride width during steady state walking on a 6.1m long electronic walkway (GAITRite™).²³ We calculated CVs for stride length, stride time and stride width based on one GAITRite™ pass per task. Use of a walking aid was allowed during the measurements if necessary. Walking aid prints were manually erased from the raw GAITRite™ data files to derive the gait variables. The numbers of correct and incorrect responses to the cognitive dual-tasks were registered.

Statistical analysis

We performed outlier evaluation with use of scatter plots on falls and stride-length and decision-time variability, to verify that overall observed results were not driven by single outcomes. Continuous, normally distributed data were expressed as mean \pm standard deviation, and were compared with the independent-samples t-test. Data with non-normal distribution were expressed as median and range and compared with the Mann-Whitney U test. Categorical variables were expressed as percentage (%) and were compared with the chi-square test.

We performed a binary logistic regression analysis with decision-time CV and stride-length CV as primary risk factors for recurrent falls. The number of drugs used, use of a walking aid and MMSE score were considered as potential confounders. In addition, we performed the logistic regression analysis with the mean values of decision time and stride length. Based on the logistic regression model, we calculated a 'falls score' for each participant, for both the model with the CVs and the model with the mean values. We used Receiver Operating Characteristic (ROC) analysis and

calculated areas under the ROC curves (AUC) to determine the sensitivity and specificity of this composite score in discriminating non-recurrent and recurrent fallers. Comparison between the two ROC curves were made using the method of DeLong et al.²⁴

As secondary analysis, the other gait variability measures, e.g. stride-time and stride-width variability, were used in the logistic regression model. Analyses were performed with SPSS statistical software (version 16.0) and MedCalc statistical software.

Results

We included 62 consecutive patients and caregivers fulfilling the in- and exclusion criteria. Data of two females (age 82 and 86 years) were excluded from further analyses following outlier evaluation, based on their number of falls (they experienced more than 40 falls in the past six months). Data of the 60 remaining participants (75.8±6.6 years, 63.3% female, 0-10 falls in the past six months) were used for analysis. Baseline characteristics are shown in table 1, in which participants are subdivided into recurrent fallers and non-recurrent fallers. Of the non-recurrent fallers, 16 participants (42%) experienced one fall in the past six months. Groups were comparable except for the number of drugs used; participants with recurrent falls used significantly more drugs, but there was no difference in the percentage of participants using psychotropic drugs (31.8% versus 21.1%; p=0.37).

Table 2 shows the decision-time CV, and the gait velocity, number of strides, stride-length CV, stride-width CV and stride-time CV for walking at preferred velocity, and during dual-tasking. Decision-time CV was higher in the recurrent falls group: 21.3% [range 9.3-47.7] versus 15.8% [range 8.3-34.9] (p=0.04). The number of incorrect responses in the decision time task was comparable, namely 0 [range 0-3] in the non-recurrent fallers and 0 [range 0-7] in the recurrent fallers (p=0.81).

Stride-length CV was higher when participants performed a dual-task compared to walking at preferred velocity, and higher in the recurrent fallers compared to the non-recurrent fallers, although this difference was only significant during performance of the verbal fluency task (4.5% [range 1.2-31.4] versus 3.5% [range 0.9-9.7]; p=0.017). Stride-width and stride-time CV were comparable for all tasks. The number and quality of responses in the calculation dual-task was comparable between groups. The numbers of correct responses were 1 [range 0-3] and 1 [range 0-5] in non-recurrent fallers and recurrent fallers respectively (p=0.23), and the numbers of errors were 0 [range 0-2] in the non-recurrent fallers, and 0 [range 0-2] in the recurrent fallers (p=0.44). For the verbal fluency task the number of correct responses was comparable, namely 3 [range 0-5] in the non-recurrent fallers and 3 [range 0-5] and in the recurrent

Table 1 Baseline characteristics of the participants.

Characteristics	Non-recurrent fallers (n=38)	Recurrent fallers (n=22)
Age (years)	75.8 ± 7.2	75.7 ± 5.6
Age ≥ 70 years (%)	81.6	83.3
Gender (% female)	63.2	63.6
Number of falls in the past 6 months	0 (0-1)	3 (2-10)*
CIRS-G severity index	1.7 ± 3.1	1.9 ± 3.2
Drugs		
Number of drug used	4.3 ± 3.3	6.0 ± 2.4*
Psychotropic drugs (%)	21.1	31.8
GARS score	29.5 ± 11.4	31.80 ± 11.5
Use of a walking aid (%)	31.6	31.8
TUG preferred speed (s)	15.4 ± 8.4	15.4 ± 5.0
Estimated verbal IQ	99.0 ± 14.6	100.7 ± 12.9
MMSE score	28 (18-30)	27 (18-30)
MMSE score <26 (%)	26.3	27.3

*p<0.05; Data presented as means ± SD in case of normally distributed variables or as median with (range), for non-normal distribution. CIRS-G=Cumulative Illness Rating Scale - Geriatrics, severity index=total score/number of scored categories. GARS=Groningen Activity Restriction Scale; a higher score indicates a higher level of (I)ADL dependence (range 18-72). TUG=Timed Up and Go; a higher time indicates a lower level of physical mobility. MMSE=Mini-Mental State Examination; a higher score indicates a higher level of cognitive performance (range 0-30).

fallers (p=0.45), but recurrent fallers produced more errors than non-recurrent fallers (0 [range 0-2] versus 0 [range 0-1]; (p=0.01). The total number of responses to the verbal fluency task, however, did not differ between the two groups (p=0.15).

Table 3 shows the results of the regression analysis. The suggested confounders and other stride measures did not significantly contribute to the model, and were not included in the final models. The model with only decision-time CV provided an explained variance of 18.0% (p=0.042), and adding stride-length CV to the model increased the explained variance to 23.7% (p=0.111, p=0.038 for response-time CV and stride-length CV respectively). The model including the mean values of response time and stride length provided an explained variance of 8.6%, though none of the B-coefficients of these risk factors were statistically significant (p=0.466, p=0.220 for mean response time and mean stride length respectively).



Table 2 Comparison of decision time and gait measures between non-recurrent and recurrent fallers.

Variable		Non-recurrent fallers (n=38)	Recurrent fallers (n=22)	P-value
Decision time	Mean value	435.8 (316.6-857.0)	457.4 (291.4-783.1)	0.244
	(ms)	15.8 (8.3-34.9)	21.3 (9.3-47.7)*	0.040
	CV (%)			
Velocity 1 (cm/s)		94.7 ± 27.4	87.7 ± 26.3	0.342
Number of strides 1		8.4 ± 2.3	8.9 ± 2.2	0.160
Stride length 1	Mean (cm)	113.9 (75.2-151.5)	106.6 (70.8-136.4)	0.125
	CV (%)	2.3 (0.4-7.8)	2.8 (0.8-22.0)	0.133
Stride width 1	Mean (cm)	10.8 (4.1-19.0)	11.6 (6.1-24.0)	0.794
	CV (%)	12.0 (1.8-63.0)	15.5 (4.1-32.3)	0.591
Stride time 1	Mean (cm)	1.2 (1.0-1.8)	1.2 (1.0-1.7)	0.866
	CV (%)	2.2 (0.6-9.2)	1.7 (0.9-8.6)	0.645
Velocity DT1 (cm/s)		82.9 ± 28.2	74.2 ± 28.4	0.263
Number of strides DT1		9.2 ± 2.9	9.9 ± 2.0	0.296
Stride length DT1	Mean (cm)	107.9 (53.9-151.0)	94.0 (70.2-137.1)	0.141
	CV (%)	3.2 (0.5-16.2)	4.7 (1.1-8.0)	0.194
Stride width DT1	Mean (cm)	10.8 (2.5-25.7)	12.3 (6.5-23.7)	0.334
	CV (%)	15.7 (3.2-70.3)	12.3 (4.8-43.6)	0.591
Stride time DT1	Mean (cm)	1.3 (1.0-2.2)	1.4 (1.0-2.5)	0.419
	CV (%)	3.1 (0.7-26.7)	3.2 (0.7-97.8)	0.646
Velocity DT2 (cm/s)		82.4 ± 29.3	71.5 ± 27.7	0.161
Number of strides DT2		9.1 ± 2.8	9.7 ± 2.1	0.122
Stride length DT2	Mean (cm)	108.2 (54.2-151.7)	100.6 (59.8-140.4)	0.050
	CV (%)	3.5 (0.9-9.7)	4.5 (1.2-31.4)*	0.017
Stride width DT2	Mean (cm)	10.8 (5.4-25.0)	12.4 (4.7-23.4)	0.390
	CV (%)	14.6 (2.7-51.5)	14.7 (4.5-52.4)	0.842
Stride time DT2	Mean (cm)	1.3 (1.0-2.3)	1.4 (1.0-4.3)	0.581
	CV (%)	3.4 (0.5-39.3)	4.2 (1.2-197.3)	0.073

*P<0.05; Data presented as means ± SD in case of normally distributed variables or median with (range), for non-normal distribution.
CV=Coefficient of variation ([SD/mean]x100). Stride length 1=during walking at preferred gait velocity (velocity 1); DT1=performance of the arithmetic dual-task, at gait velocity DT1; DT2=performance of the verbal fluency dual-task, at gait velocity DT2.

Table 3 Logistic regression models for recurrent falling (versus non-recurrent falling) with variability (CV) and mean values (M) of decision time and stride length as independent variables.

Model	B	S.E.	P	Exp (B)
Model 1				
Constant	-2.746	0.890	0.002	0.064
Decision-time CV	0.061	0.038	0.111	1.063
Stride-length CV	0.194	0.093	0.038	1.214
Model 2				
Constant	0.311	2.344	0.895	1.364
Decision-time M	0.002	0.003	0.466	1.002
Stride-length M	-0.018	0.014	0.220	0.983

Model 1: $R^2_{\text{nagelkerke}}=0.237$; **Model 2:** $R^2_{\text{nagelkerke}}=0.086$
B=estimated regression coefficient, S.E.=standard error, P=significance level of B-coefficient, Exp(B)=an indicator of the change in odds (=probability of an event occurring divided by the probability of an event not occurring) resulting from change of the predictor.

The ROC analysis showed that a combined measure of response-time CV and stride-length CV had moderate power to differentiate; the area under the curve was 0.736 (95% CI 0.602-0.869). The combined score of the mean values of these measures had lower power to differentiate, AUC of 0.654 (95% CI 0.511-0.797), though the difference was not significant (p=0.292) (Figure 1).

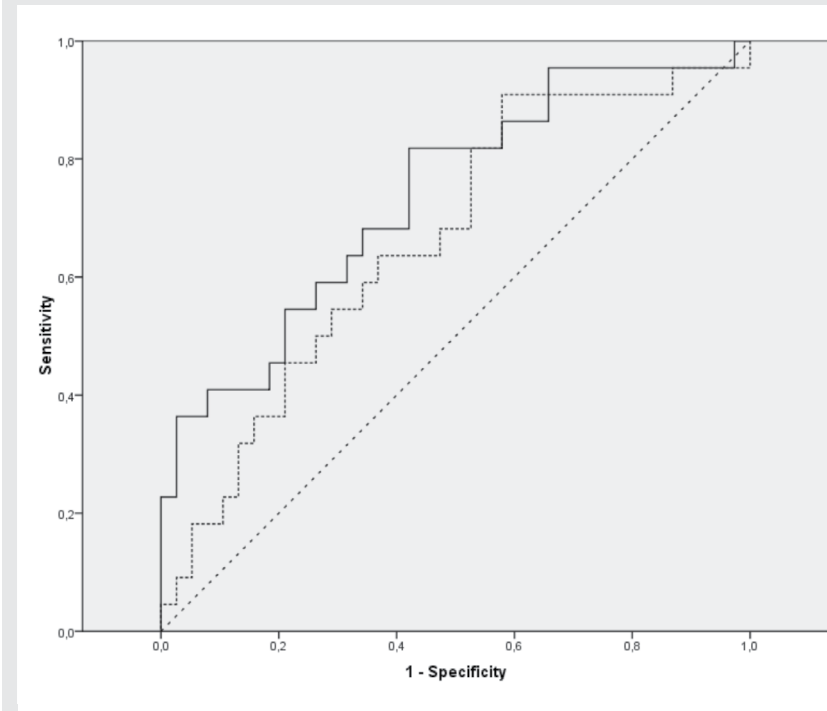
Discussion

We assessed both cognitive and gait measures in vulnerable older persons in relation to fall status. We showed that response-time variability was significantly higher in recurrent fallers compared to non-recurrent fallers. Furthermore, stride-length variability during walking while dual tasking was also higher in recurrent fallers. Overall, variability in performance was a more sensitive measure in discriminating recurrent fallers than mean performance itself.

Surprisingly, the non-recurrent fallers and recurrent fallers were highly comparable regarding the baseline characteristics. In previous studies, for example, the Timed Up and Go test has been able to discriminate between (recurrent) fallers and non-fallers.²⁵ However, in our sample, this mobility measure, use of a walking aid, cognition or



Figure 1 ROC curve comparison of variability and mean value measure of decision time and stride length for the prediction of falls (N=60).



BA=balance assessment, consisting of stance tasks (eyes open and eyes closed on regular floor or foam) and gait tasks (walking eight meters eyes open, eyes closed, while pitching head, while performing a cognitive dual-task and while performing a motor dual-task). BT=Biofeedback (balance) Training, consisting of stance tasks (stance eyes closed, eyes open and closed on foam) and one gait task (walking eight meters eyes open).

performance of activities of daily living did not discriminate recurrent fallers from non-recurrent fallers. An explanation may be that of the non-recurrent fallers, 42% experienced one fall in the past six months. As a result of the high number of participants who experienced one fall, the difference between the two groups may be smaller than when comparing non-fallers and recurrent fallers. This may explain the lack of difference in measures as TUG and gait velocity. Only the number of drugs used was significantly higher in the recurrent faller group. Corresponding to this difference, the co-morbidity level was expected to be higher in the recurrent fallers. However, the co-morbidity-severity index was comparable. Post hoc evaluation of the

co-morbidity scale showed that recurrent fallers scored on more categories, though with low severity in those categories, thus resulting in an equal severity score for both groups. The fact that recurrent fallers scored on more categories, may explain the difference in number of drugs used. In the regression analysis, the number of drugs showed not to be a confounder in the discrimination of the two groups, though in particular psychotropic drugs are associated with fall risk.¹ In our study, no difference was found between the recurrent and non-recurrent fallers in the use of this specific group of drugs.

Our study confirmed that the within-task variability was more sensitive than the mean performance in discriminating between recurrent and non-recurrent fallers. Mean values were similar for both groups, while the CVs were able to distinguish the two groups. Variability measures may provide a more sensitive measure, revealing increased variability even when the multiple components that contribute to variability in balance only show more subtle changes.

Response-time CV was able to differentiate between non-recurrent and recurrent fallers, with a higher response-time CV in recurrent fallers. Previous studies have shown that increased response-time CV is a marker for pre-frontal and frontal lobe dysfunction.^{26, 27} For example older recurrent fallers may have increased frontal activation, which possibly reflects a higher demand for executive control in order to maintain task performance.²⁷

Stride-length CV was higher in the recurrent faller group, but surprisingly, only significantly higher while performing the verbal fluency dual-task. We expected the effect of the arithmetic task on gait to be higher than the effect of the verbal fluency task. Verbal fluency relies on semantic memory, whereas counting backwards relies directly on working memory, a concept that is closely related to executive functioning and that can be expected to recruit more attentional resources.²⁸ Bloem et al. suggested that regardless of the type of the walking associated task, gait quality in the dual-task condition is equally affected.² However, other studies provide evidence for task-specific dual-task effects.²⁹ An explanation for this contradictory finding could be that participants used a different strategy for the different cognitive dual-tasks. Verghese et al. showed differences in dual-task effect depending on task prioritization.³⁰ In our study, participants gave a significantly lower number of responses for the arithmetic task than for the verbal fluency task, which suggests that participants focused more on the walking task while performing the arithmetic task, than while performing the verbal fluency task. This is confirmed by our observation that participants often gave their only answer to the arithmetic task at the start of the walk.

In contrast to the higher stride-length variability in recurrent fallers, stride-width CV and stride-time CV were comparable between the two groups. An explanation for this difference may be that stride-time variability is highly influenced by gait velocity,

which was comparable for the two groups, suggesting that gait timing mechanisms are similar. Step-width variability more closely reflects inconsistency in balance control, whereas stride-length variability is a reflection of the pattern generator of gait. Zimmerman et al. found an association between increased stride-length variability and lower levels of hippocampal neuronal metabolism, without an association with hippocampal volume in non-demented older adults.³¹

Lack of significant difference on stride-width and stride-time CV may also be due to the limited number of strides used, some studies suggest that hundreds of strides are necessary to accurately calculate variability measures. However, the short measurement we used has acceptable feasibility and thus clinical applicability in a vulnerable group of older fallers, and showed significant difference in stride-length CV. An other quantitative study showed a tendency towards increased step-length variability during a six-meter walk (several strides) in a small number (N=7) of community-dwelling older fallers.³²

The model containing both dispersion measures showed moderate discriminative power with an area under the curve of 0.736 (95%CI 0.602-0.869). Interestingly, this model with only two variability measures has a similar discriminative power compared to the LASA risk profile, which included a score based on eleven items (AUC=0.71 95%CI 0.67-0.74).³³ Though our model seems to be able to discriminate non-recurrent fallers and recurrent fallers, it may be that other factors increase the sensitivity and specificity of the model. Researchers should continue to explore and report risk factors and models predicting recurrent falls, to add to the ability to develop a highly sensitive and specific prediction model. Perhaps inconsistency measures of performance (intra-individual day-to-day variability in performance), instead of dispersion (within-task variability), are more sensitive in detecting the first signs of deterioration in neurocognitive control, and will further improve predictive power of variability measures in gait and response time.^{34, 35}

A limitation of this study is the cross-sectional nature of this study. As a consequence, data on falls was collected retrospectively. Retrospective data are known to be less reliable than prospective data collection methods,^{36, 37} which may have lead to an underestimation of the number of falls, and consequently, the number of multiple fallers. Meticulous medical history-taking of participants, also including their relatives, was used to make data on fall history of participants as reliable as possible. Additionally, due to the cross-sectional nature of this study, it is not possible to be conclusive on causality. Fallers may change their gait after the fall, in order to try and reduce the risk of future falls and out of fear of falling.⁶ This potentially enforces the discriminative power of retrospective risk factor studies. However, previous prospective studies in community-dwelling older persons showed that gait variability predicts (in other words, precedes) future falls.⁹

Conclusion

We conclude that the increase in within-task variability in response time and stride length characterize older recurrent fallers, indicating deterioration in neurocognitive regulation mechanisms as cause for recurrent falls. However, underlying mechanisms remain to be identified, as this cross-sectional study cannot elucidate causality.

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10

Within-task variability and day-to-day variability in gait, balance, and cognition and future falls

Submitted as:

Dispersion and inconsistency in gait, balance, and cognition are not associated with falls at follow-up. Reelick M.F., Kessels R.P.C., Faes M.C., Esselink R.A.J., Van Beek A.H.E.A., Studenski S.A., Olde Rikkert M.G.M.



Abstract

Background Variability in gait, balance, and cognition is suggested to be a useful predictor for falls in older persons. This prospective study describes and compares variability in repeated performances of gait, balance and cognition within one task, *dispersion*, and over time between different sessions on different days, *inconsistency*, between participants with and without a fall at follow-up.

Methods We included 40 community-dwelling older persons (76.3±7.5 years). Stride length, mediolateral sway (roll angle), choice decision time, and spatial working memory were assessed during three consecutive measurements within two weeks. Stride length and roll angle were assessed during walking at preferred velocity and while performing a cognitive dual-task. Both dispersion and inconsistency were calculated as coefficients of variation ($CV = [\text{Standard deviation}/\text{Mean}] \times 100$). Falls were continuously registered for six months with fall calendars. Dispersion and inconsistency measures were compared between older persons with and without falls at follow-up. In addition, groups were subdivided based on fall history and global cognitive function.

Results Stride length and roll angle change due to dual tasking showed large inconsistency (104% and 45%, respectively). Choice decision time showed moderate dispersion (17%), and spatial working memory performance showed both high dispersion and consistency (57% and 50%, respectively). Only inconsistency in the spatial working memory task was significantly lower in fallers, when subdivided for cognition.

Conclusions Gait, balance, and cognitive measures showed both dispersion and inconsistency, though these variability measures were not directly related to falls at follow-up. In gait and balance measures, inconsistency may reflect lack of test-retest reliability, questioning the use of repeated assessments to monitor patients. The large inconsistency in the spatial working memory task in non-fallers may reflect a better ability to learn, and thus to adapt to an unknown environment. The value and interpretation of inconsistency should be studied next.

Background

In our ageing society the prevalence of impairments in gait, balance, and cognition is rapidly increasing.^{1,2} These impairments interact and in combination may often result in falls.^{3,4} Falling is common among older persons and has a great impact on functioning and quality of life of older persons and their caregivers.⁵⁻⁷ Consequently, the prevention of falls is highly desirable. A better understanding of the relation between falls and gait, balance, and cognitive performance will probably provide new opportunities for early prevention of falls. Especially variability in performance may be used as sensitive predictor for falls. Intra-individual variability in performance may reflect loss in neurobiological homeostasis,⁸ which results in a greater instability of physiological resting state.

Variability can exist in repeated task performance within one session, also called: *dispersion*. For example, persons may demonstrate variation in stride length from stride-to-stride within a single walk. Variability may also be present over time, across different sessions on different days, within a short episode, which is called: *inconsistency*. For example, persons may show a different mean stride length from day-to-day, performing better or worse one day in comparison to another.

Previous studies have shown that higher dispersion of gait variables is associated with falls in older adults⁹⁻¹¹ In community-dwelling older adults (aged over 70 years), higher dispersion of stride time predicts falls during one-year follow-up.¹⁰ Especially the change in dispersion seems associated with falls. An increase in stride time dispersion as a result of performing another task while walking (dual tasking).¹²⁻¹⁴ In line with this, cognitively impaired older adults show a larger increase in gait dispersion¹³ and larger sway due to dual tasking.¹⁵ However, whether dispersion of cognitive function is associated with falls is, to date, unknown.

Little is known about the relation of inconsistency of gait, balance, and cognition with falls. A few studies have reported relatively high consistency of gait velocity, stride length and stride-length variability in older adults, even under dual task conditions.^{16,17} Whether this consistency of gait performance applies to variables other than velocity and to balance variables, or extends to other populations of older adults has not been studied.

In contrast to the consistency of gait, various studies have shown inconsistency in cognitive performance.¹⁸⁻²¹ Inconsistency in cognition is higher in older adults compared to younger adults.²²⁻²⁴ The relationship between inconsistency in cognition and falls in older persons is yet unclear.

Dispersion and inconsistency, when explained by decreased homeostasis, could be predictors of falls events. Consequently, persons with low inconsistency may have a lower risk of experiencing a fall. However, inconsistency may also reflect learning ability. Though many tests have parallel versions to reduce learning of specific test

items, it can be expected that item-nonspecific learning is still present. In other words, persons become 'test wise', which may also result in inconsistency. Whether the assessment of inconsistency within a short period of time represents a higher risk of falls, or a lower risk through higher learning capacity should be examined.

This study aimed to explore and describe dispersion and inconsistency measures of gait, balance, and cognition for fallers and non-fallers. We hypothesized that both dispersion and inconsistency of gait, balance and cognition would be higher in fallers, since these measures are most likely to reflect loss of control of the complex regulation mechanisms of gait, balance, and cognition. These factors may importantly increase the risk of recurrent falls.

Method

Participants

We recruited patients of the outpatient clinic of the department of Geriatric Medicine (Radboud University Nijmegen Medical Centre, the Netherlands) and their informal caregivers. Persons were eligible if they were ≥ 60 years, lived in their own home or in a home for the aged, were able to walk 15 meters independently (use of a cane or walker was permitted) and were able to read (vision), and follow instructions (cognition). Persons with severe cognitive impairment (Mini-Mental State Examination score < 15) and with a life expectancy of less than six months (as assessed by a geriatrician) were excluded.

Measurements

The study consisted of three consecutive measurements within two weeks, all at the same time of the day. Dispersion measures were calculated for the first visit and inconsistency was calculated over the performance on the three visits. Both dispersion and inconsistency were calculated as coefficient of variation ($CV = [\text{Standard deviation} / \text{Mean}] \times 100$).

Baseline assessment

During the first visit, we recorded age, sex, number of falls in the past six months, use of a walking aid, number and type of drugs used, gait and balance score (Performance Oriented Mobility Assessment; POMA),²⁵ mobility (Timed Up and Go; TUG),²⁶ (instrumental) activities of daily living; IADL (Groningen Activity and Restriction Scale; GARS),²⁷ physical activity performance (LASA physical activity questionnaire; LAPAQ),²⁸ falls efficacy (Falls Efficacy Scale-International; FES-I)²⁹ and fear of falling (yes/no). We used the Mini-Mental State Examination (MMSE)³⁰ to assess a global cognition score and we estimated IQ with the 'Dutch version of the National Adult Reading Test' (NART).³¹

Falls

The number of falls were also prospectively collected for six months using a daily fall calendar. We performed active falls monitoring with structured phone calls to ensure reliable fall reporting.

Gait and dynamic balance

Quantitative gait analysis was performed with an electronic walkway (GAITRite™)³² and balance was measured with a device containing two angular velocity transducers (mediolateral en anteroposterior direction) attached to the trunk (SwayStar™).³³ Participants walked at preferred velocity, with and without performance of a cognitive dual task (verbal fluency task; naming words starting with a given letter). Outcomes were stride length and mediolateral sway during walking at preferred velocity, and the change in stride length and mediolateral sway (roll) due to performance of the dual task.

Cognition

We assessed processing speed and attentional capacity with the Choice Reaction Time (CRT) subtest of the Cambridge Neuropsychological Test Automated Battery (CANTAB™).³⁴ This system used a press pad and a touch-sensitive screen and assesses the reaction time of participants to the appearance of a stimulus at random at one of five possible locations. The task was practiced and then assessed with 15 trials. The instructions provided by the researcher emphasized speed of performance. Task outcome was decision time, in other words the time needed to release the press pad button in response to the onset of a stimulus.

In addition, we assessed spatial working memory and updating with the Box task.³⁵ This task requires participants to search through a number of completely identical boxes shown at different locations on a touch-sensitive computer screen to find a hidden target object. In subsequent trials, new objects were hidden in boxes that were previously empty. Task outcome was the number of between-search errors, in other words the number of times a participant returned to a box that already contained a target item, for the cluster of eight boxes.

Both tests have several parallel tests to minimize practice effects and have been validated in older persons.³⁴⁻³⁶

Statistics

Baseline characteristics are presented for participants with and without fall history separately. Data are presented as mean with standard deviation or as median with range for non-normally distributed data, and frequencies for categorical data.

We examined differences in mean performance, dispersion, and inconsistency between participants with and without falls at follow-up for the following variables:

stride length and mediolateral sway angle during walking at preferred velocity, stride length and mediolateral sway angle change due to dual tasking, choice decision time, and the number of between-search errors. To test the relation of dispersion and inconsistency with fall risk and cognitive decline, the difference between persons with and without prospectively confirmed falls were tested, also subdivided for fall history, and for high and low MMSE score (cut-off score 24). All analyses were performed in SPSS 16.0 for Windows.

Results

Recruitment and baseline characteristics

Of the 138 persons screened for eligibility, 127 persons were eligible for participation (Figure 1). Forty-six persons gave written informed consent (36%), six of whom withdrew their consent before the first measurement. Finally, 40 persons participated in the study (31%). Table 1 presents the baseline characteristics for fallers and non-fallers

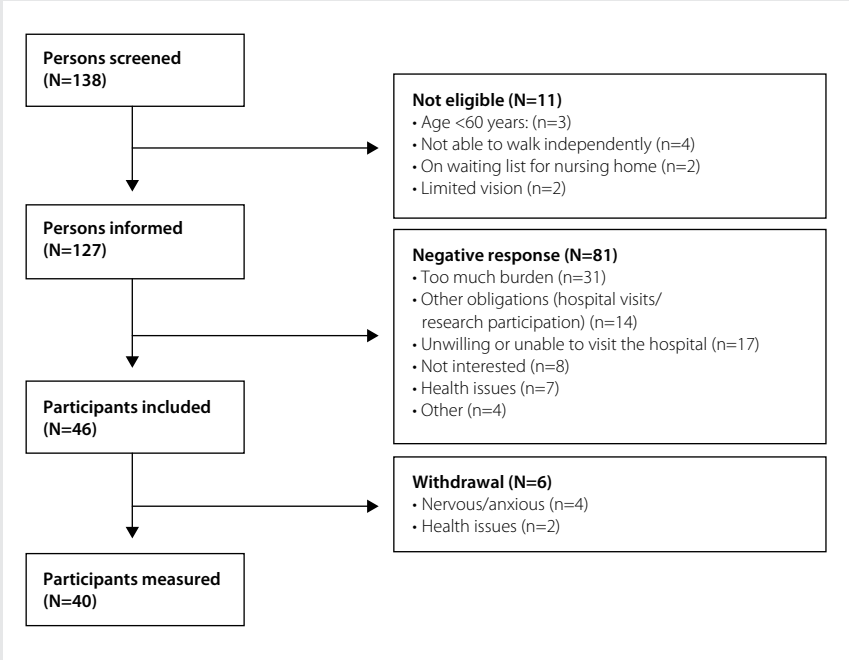
separately, based on fall history. Nineteen persons had experienced at least one fall during the six months prior to the visits. Fallers and non-fallers were comparable for all baseline characteristics.

Table 1 Baseline characteristics of participants together, and divided based on the occurrence of falls in the six months prior to the first visit.

	All participants (N=40)	No falls in history (n=21)	Falls in history (n=19)
Age (years)	76.3 ± 7.5	78.2 ± 6.4	74.0 ± 8.2
Sex (female)	27 (67.5%)	12 (57.1%)	15 (78.9%)
Use of a walking aid (yes)	9 (22.5%)	6 (28.6%)	3 (15.8%)
Medications (total number)	4 [0-23]	5 [1-23]	3 [0-16]
MMSE (score)	26.9 ± 3.3	27.3 ± 2.4	26.5 ± 4.2
NART (score)	78.3 ± 19.0	78.0 ± 18.9	78.0 ± 19.8
Tinetti	Total	24.1 ± 3.9	24.6 ± 3.8
	Gait subscale	10.3 ± 1.9	10.5 ± 1.8
	Balance subscale	13.8 ± 2.4	14.1 ± 2.3
TUG (sec)	14.4 ± 8.0	14.4 ± 8.9	14.5 ± 7.5
GARS (score)	27 [18-65]	28 [18-65]	25 [18-51]
LAPAQ (total kcals/day)	544.5 [0-3935]	546.1 [87-3935]	383.2 [0-1546]
FES-I (score)	27.9 ± 8.3	27.3 ± 7.3	28.6 ± 9.4
Fear of falling (yes)	20 (50%)	8 (38.1%)	12 (63.2%)
Gait velocity (cm/sec)	95.3 ± 27.2	95.3 ± 25.3	95.4 ± 29.8

MMSE=Mini-Mental State Examination (range 0-30, a higher score represents better cognitive performance. Depending on the level of education, a score of ≤27 is indicative for cognitive impairment); NART=Dutch version of the National Adult Reading Test (range 0-100, a higher score represents a higher pre-morbid verbal intelligence); Tinetti (total range 0-28, gait subscale 0-12, balance subscale 0-16, a higher score indicates better performance) TUG=Timed Up and Go (a higher score represents a poorer mobility; a score ≥14 seconds is associated with increased risk of falls); GARS=Groningen Activity Restriction Scale (range from 18 to 72 (total scale), from 11 to 44 (ADL subscale) and from 7 to 28 (IADL subscale), a higher score indicates higher dependence in (i)ADL); LAPAQ=LASA physical activity questionnaire (a higher score represents a higher physical activity level) FES-I= Falls Efficacy Scale (range 16-64, a higher score indicates a higher concern of falls).

Figure 1 Flowchart of the recruitment and selection procedure.



Comparison fallers and non-fallers at six months follow-up

During the six months follow-up, 18 participants (45%) experienced a fall during follow-up, of whom six (15%) had repeated falls. Baseline characteristics were comparable between participants with and without falls during the six months follow-up, except for LAPAQ activity score and fall history. Fallers were significantly less active than non-fallers (321.4 [range 0-1244] and 631.7 [range 87-3935] kcal/day, respectively). In this group, more participants had experienced a fall in previous six months (12 (66.6%) and 7 (31.8%), respectively).

Table 2 presents the outcome measures for all participants together, and divided into two groups based on prospective falls. Mean stride length during walking at preferred velocity was 112.3 cm (SD 21.1) and showed low dispersion (3.6%) and inconsistency (4.0%). The stride-length dual-task change showed little dispersion (1.2%), but high inconsistency (104.3%) with a large range. Mean roll angle during walking at preferred velocity was 5.7 (SD 2.1) degrees, with an inconsistency of 16.7%. Roll angle decreased 1.1 degrees when dual tasking. Roll-angle change showed large inconsistency (45%), with a large range. Choice decision time was 415.3 (SD 69.2) ms, with moderate dispersion (17.3%) and small inconsistency (7.2%). Mean number of spatial working memory between-search errors was 7.2 (SD 4.4). The number of between-search errors showed high dispersion and consistency (56.8% and 49.9%, respectively). There were no significant differences in these measures of dispersion and inconsistency between participants without and participants with falls at follow-up.

As a secondary descriptive analysis, we examined the outcome measures subdivided based on fall history and overall cognitive function (MMSE cut-off 24). When comparing participants with and without fall history separately, participants without falls at follow-up had a larger inconsistency of the dual task effect on roll angle (-342.4 (SD 458.7) and 501.0 (SD 747.7) for no fall history and falls in history respectively), than participants with falls at follow-up (9.0 (SD 346.9) and 26.4 (SD 275.2) no fall history and falls in history respectively). Participants with an MMSE \leq 24 and falls at follow-up, had a higher number of between-search errors and lower inconsistency in between-search errors (13.8 (SD 0.6) and 5.7 (SD 4.1), and 15.2 (SD 6.4) and 61.1 (SD 50.4) respectively).

Table 2 Baseline characteristics of participants together, and divided based on the occurrence of falls during the six months follow-up.

	All participants (N=40)	Participants without falls at follow-up (n=22)	Participants with falls at follow-up (n=18)
Stride length (cm)			
Mean performance	112.3 \pm 21.1	113.6 \pm 22.3	110.8 \pm 20.2
Dispersion (CV in %)	3.6 \pm 2.1	3.5 \pm 1.9	3.8 \pm 2.4
Inconsistency (CV in %)	4.0 \pm 2.6	3.6 \pm 2.5	4.4 \pm 2.7
Stride length (cm); DT effect^c			
Mean performance	5.8 \pm 11.8	3.6 \pm 9.5	8.4 \pm 13.8
Dispersion (CV in %) ^a	-1.2 \pm 3.5	-0.72 \pm 2.4	-1.8 \pm 4.5
Inconsistency (CV in %)	-104.3 \pm 613.9	-181.7 \pm 748.6	-13.9 \pm 408.8
Roll angle (deg)			
Mean performance	5.7 \pm 2.1	5.8 \pm 2.4	5.5 \pm 1.8
Dispersion (CV in %) ^a	-	-	-
Inconsistency (CV in %) ^b	16.7 \pm 13.8	16.2 \pm 14.7	17.2 \pm 13.0
Roll angle (deg); DT effect^c			
Mean performance	-1.1 \pm 3.6	-0.78 \pm 3.6	-1.5 \pm 3.7
Dispersion (CV in %) ^a	-	-	-
Inconsistency (CV in %) ^b	-45.2 \pm 508.5	-108.1 \pm 656.6	21.3 \pm 286.8
Choice decision time (ms)			
Mean performance	415.3 \pm 69.2	405.9 \pm 61.1	427.0 \pm 78.3
Dispersion (CV in %) ^a	17.3 \pm 8.7	18.7 \pm 10.0	15.5 \pm 6.7
Inconsistency (CV in %) ^b	7.2 \pm 5.0	7.7 \pm 3.8	6.7 \pm 6.2
Box task between-search error			
Mean performance	7.2 \pm 4.4	6.6 \pm 4.3	7.9 \pm 4.5
Dispersion (CV in %) ^a	56.8 \pm 47.1	57.3 \pm 141.4	56.1 \pm 141.4
Inconsistency (CV in %) ^b	49.9 \pm 40.1	54.4 \pm 45.6	44.0 \pm 31.9

Data presented as mean \pm standard deviation

^aDispersion is the within-task variability calculated for the first visit, expressed as coefficient of variation (CV). ^bInconsistency is the day-to-day variability calculated over the three baseline visits, expressed as coefficient of variation (CV). ^cDT effect=Dual task effect, is the change in performance as a result of performing the verbal fluency task while walking at preferred velocity.

Discussion

In this study, we described performance and variability in often used measures of gait, balance, and cognition within a single test session and across three different sessions on separate days, *dispersion* and *inconsistency*, respectively, and examined their association with prospectively assessed falls. Gait, balance, and cognitive measures showed dispersion and inconsistency, and especially dual tasking increased inconsistency. However, there were no significant differences in these outcome measures between participants with, and participants without falls at follow-up.

In accordance with previous studies, stride length showed low inconsistency.¹⁷ In contrast, stride-length dual-task effect and roll-angle dual-task effect showed large levels of inconsistency. This large inconsistency was not discriminative for fallers and non-fallers, possibly due to the large range of the variable. The inconsistency may reflect underlying pathology, and may be related to for example, deterioration in gait or cognition. However, since inconsistency was not associated with falls, the validity of this measure is uncertain. In this study, the outcomes were assessed at the same place, the same time of day, and by the same researcher, minimizing inconsistency through the measurements itself. Nevertheless, the inconsistency in gait and balance dual task effect was large, which may reflect a lack of test-retest reliability of dual-task effect.

Choice decision time showed dispersion but, in contrast to previous studies,^{23, 37} little inconsistency. This stable performance indicates that fluctuations in alertness were unlikely the cause of the inconsistent dual-task findings. This finding is also in agreement with previous studies that showed that inconsistency in cognitive tasks increased with task complexity, and diminished when controlling for processing speed.²³

Inconsistency was large for number of between-search errors. A subdivision on MMSE score showed that the inconsistency was higher for non-fallers compared to fallers, suggesting a positive interpretation of the high inconsistency. Inconsistency may represent a learning curve, with lower inconsistency representing an inability to adapt or learn, which may be related to a higher risk of falls. On the other hand, this may also suggest a limitation of the test-retest reliability.

Activity level and fall history were significantly different for faller compared to non-fallers. Lower physical activity was associated with falls at follow-up. A low physical activity may result in a decline in physical health and thus a deterioration of gait and balance, increasing the risk of falls when the persons becomes active.^{5, 38} Thus, physical activity level may be used to estimate fall risk.

For the identification of persons who may benefit from fall prevention interventions, it is necessary to estimate the risk of future falls, in both persons with and without fall history. In concordance with previous studies, the number of participants with a fall

history was higher for the group with falls at follow-up.³⁹⁻⁴¹ Having experienced previous falls is one of the best evidenced risk factors for future falls and may reflect underlying pathology related to risk of falls. However, other measures we assessed that can be regarded as markers for disease did not show predictive value, such as mobility or use of medication. Moreover, fall history itself is unable to explain and predict the future falls at the individual level, since about one third of the participants with a fall history did not fall during follow-up. In addition, about one third of the persons without a fall history experienced a fall during follow-up. Other factors remained unidentified and require further research.

A limitation of this study is the relatively small sample size, which prevents further sub-analyses into other factors that may be related to increased fall risk. Recruitment was a difficult process, and the burden of multiple visits to the hospital for measurements lead to the inclusion of the less frail population. However, identification of fall risk factors in the frailer, not selected population, may be of less importance because the fall risk may be obvious.

Conclusion

This study showed that gait, balance, and cognition show both dispersion and inconsistency, though this variability was not directly related to future falls. Inconsistency in gait and balance may reflect lack of test-retest reliability, questioning the use over time of dual-task ability testing in gait and balance with one measurement. On the other hand, increased inconsistency in spatial working memory may reflect an increased ability to learn, and thus to adapt, which may decrease the risk of falls. This study showed that, while fall history alone is not sufficient to predict future falls, complex variability measures are not very likely to contribute to fall prediction. Thus fall prediction should also focus on other easy to assess measures.

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11

Summary and discussion



Effective fall-prevention interventions in frail older persons are lacking because most fall-prevention intervention studies exclude this population. The aim of this thesis was to develop a fall-prevention intervention specifically aimed at this group and to explore its feasibility and efficacy in preventing falls and reducing the fear of falling. This chapter summarizes the main findings of each study and provides a general discussion of these findings, resulting in recommendations for future research and clinical practice. Because the strengths and limitations of the different studies have been discussed in the previous chapters, this chapter focuses on general considerations.

Summary of the main findings

Impact of falls

In chapter 2, we examined the impact of falls on ten frail older persons who had recently experienced a fall and ten primary informal caregivers through semi-structured interviews. Seven of the patients had (mild) cognitive impairment. The results indicated that falls have major physical and psychological consequences. Patients experience fears of the unknown and potentially serious consequences, such as fractures and loss of independence. Patients had difficulty identifying the cause of their falls, which contributes to their fear and hampers their ability to cope. In particular, the patients with cognitive impairment and their caregivers felt that falls were unavoidable, and they stated that the cognitive impairment was a more important problem than falling. Caregivers experienced feelings of stress, anger, helplessness, and frustration. The three coping strategies that were expressed by both patients and caregivers were problem-focused coping, emotional-oriented coping, and avoidance-oriented coping.

The information from the interviews provided us with guidelines for the development of the fall-prevention intervention. First, the intervention should discuss the causes of each participant's falls and establish a positive attitude toward fall prevention in both the patient and his/her caregiver. Second, caregivers should be included in the intervention to act as co-therapists for the patient and to gain insight into the patient's capabilities to more effectively guide or assist the patient. Both patients and caregivers may benefit from a group format that enables them to contact and learn from others with similar experiences.

Development of a fall-prevention intervention

Chapter 3 provided an overview of the Medical Research Council framework and showed that this framework is useful for the development and evaluation of complex interventions in geriatrics. This framework structures the development process to ensure that the best available evidence is identified, which reduces the risk of



developing and evaluating unrealistic or unwanted interventions. Existing evidence and expert views on geriatric patients who had experienced falls and on similar interventions for other populations were gathered through literature reviews, focus groups, and the Delphi method. We defined the target population, the aims and the outcome measures and developed a theory on the path of causality and change. We targeted patients who were considered frail according to Fried's criteria. Half of the patients experienced a fall at least every month, and seven percent of the patients fell daily. Patients had an overall decrease in cognitive function and a high level of fear of falling. We identified two main groups of patients: those who were fearful and may show avoidance behavior with respect to activities and those who were impulsive or lacked insight and may therefore engage in high-risk behavior. The primary outcomes were fall rate, fear of falling, and caregiver burden. Anticipated barriers for participation and effectiveness were negative attitudes toward fall prevention, scheduling conflicts that made it difficult for the caregivers to attend the intervention sessions, and training-facility characteristics. For optimal recruitment, we designed a multi-stage recruitment process. We tested the proposed recruitment plan and the intervention in a pilot study, which resulted in a reduction of the number of exercises and the psychological component because the functional and cognitive levels of the patients were lower than anticipated. This framework resulted in a fall-prevention intervention that was specifically developed for frail older fallers and their caregivers and was designed to allow for both an effect and process evaluation.

Contents of the fall-prevention intervention

Chapter 4 described the fall-prevention intervention in detail. The intervention was multi-factorial and consisted of ten sessions occurring twice a week for five weeks, with a booster session six weeks after the initial ten sessions. Each session lasted two hours. The intervention comprised several physical and psychological components. We described the components, their rationales and the structure of the intervention in detail. Because of the heterogeneous nature of the group, an important aspect of the intervention was its tailoring for each participant. The components can be used and adapted according to the needs and limitations of the participants.

There were two instructors for each session, a physiotherapist and a psychologist, who had experience with the specific patient population. An important aspect of this intervention was that the caregivers actively participated in the intervention. The intervention was applied in groups of a maximum of six pairs to enable the participants to learn by recognition based on shared experiences and similar needs. To ensure that participants adapted the way they moved and behaved and to promote fitness and strength, participants were assigned homework exercises. The intervention was advertised as a movement course with the aim of stimulating independence in the patients.

Efficacy of the fall-prevention intervention

In chapter 5, the efficacy of the developed fall-prevention intervention was examined in a randomized, controlled trial. Thirty-six pairs of patients and their informal caregivers were randomized to receive either the fall-prevention intervention in addition to the usual care by the geriatric falls clinic or the regular care by the geriatric falls clinic only. Compared to the control arm (regular care only), the fall-prevention intervention was ineffective at reducing either the fall rate or the fear of falling directly after the intervention and six months after its completion. It is possible that the duration and intensity of the intervention were not great enough to be efficacious. However, for many participants, a more intensive intervention would not have been feasible. The educational aspect increased their awareness of their fall risk and their limitations, resulting in a higher sense of mastery. However, this awareness may also have been the cause of the increased anxiety and depressive symptoms in the intervention group. The intervention did not decrease caregiver burden. This result challenges the value of including caregivers in the intervention, especially because it was difficult to motivate the caregivers to act as co-trainers. Furthermore, the inclusion of pairs was difficult because of a low availability of caregivers. Overall, the intervention seemed too burdensome for many patients and caregivers.

Process evaluation

Chapter 6 emphasized the importance of performing a process analysis in addition to the effect evaluation. Based on existing literature, we suggested three main components for the process evaluation of complex interventions: 1. Success rate of the recruitment and selection, 2. Quality of the execution of the complex intervention, and 3. Process of acquisition of the evaluation data. Applying the suggested guidelines showed that a good pre-planned process evaluation uses qualitative and quantitative methods to give a detailed description of the most important components of both the complex intervention and the evaluation of the intervention. The process evaluation of the fall-prevention intervention increased insight into barriers and facilitators and resulted in several recommendations for adaptation. Regarding the study population, participants in the intervention may have been too frail to participate or to benefit. The current intervention seems more appropriate for a less frail population, although the identification and recruitment process must be adapted to reach this group. Participant inclusion should specifically address appropriateness for group participation, including physical and cognitive functioning, and availability to attend the intervention, especially for the caregivers. The components were considered highly valuable, but the intervention should be prolonged to ensure that the benefits of a behavior change outweigh the negative effects of increased insight. In addition, more emphasis should be placed on the importance and benefits of the home exercise. Selected outcome measures should be evaluated at the individual

level and supplemented with goal attainment scaling and outcomes that measure specific training goals. Although the intervention was not implemented in its present form, the acquired information led to a new cycle of development and evaluation.

Fall telephone

To reduce the burden on patients caused by the measurements performed in our study, chapter 7 described a new fall-registration method: the fall telephone. The fall telephone is a touch-tone data entry method that automatically telephones the participant every week and allows them to register their number of falls during that week. Evaluation of the fall telephone showed that it was a feasible, reliable, and valid method to assess falls in frail, community-dwelling older persons. Participants preferred the fall telephone over the most often used method, the fall calendar, because they did not forget to register their falls and completed their fall registration after one telephone call. However, some older persons required multiple instructions to reduce confusion. Instructions were adapted for participants with cognitive or hearing impairments, and caregivers were involved with fall registration when possible. The fall telephone has been implemented in a new research study on falls.

Biofeedback balance training

Chapter 8 explored the feasibility and efficacy of a potential single intervention aimed at improving balance in older persons with impaired balance. We demonstrated that low-intensity, multi-modal biofeedback training (BT) using vibrotactile and auditory signals was well tolerated by geriatric outpatients with impaired balance. Participants required multiple BT protocols to understand the biofeedback system. After the training, roll and pitch angle (sway) decreased when walking with the eyes closed, and pitch velocity decreased when standing with the eyes open and with the eyes closed on a foam surface. Pitch and roll velocity increased when walking while performing a cognitive dual task. This finding indicates that balance for simple tasks may have been improved, but the results of the BT for dual-task performance may suggest an undesired effect. It is recommended that a longer, higher-intensity BT be tested in this population to optimize training effects.

Within-task variability in gait and cognition (dispersion)

To identify and select a less frail population with an increased risk of falls, in chapter 9, we studied gait and cognitive function in older persons in relation to falls. We showed that older recurrent fallers are characterized by increased intra-individual variability within one trial (dispersion) with respect to stride length while performing a secondary cognitive task and in choice decision time. This variability in performance was a more sensitive measure for distinguishing recurrent fallers from non-recurrent fallers than the mean performance itself. Therefore, this measure may be more suitable to identify

future recurrent fallers. However, we used fall history as a fall indicator, and the sensitivity and specificity of the predictive models built with these variability measures were only moderate. Other measures may additionally explain the underlying mechanism and increase the predictive value of the models.

Within-task and day-to-day variability in gait, balance, and cognition (dispersion and inconsistency)

In chapter 10, we studied two types of variability in gait, balance, and cognition in 40 community-dwelling older persons (76.3 ± 7.5 years). Stride length, mediolateral sway (roll angle), choice decision time, and spatial working memory were assessed during three consecutive measurements within two weeks to assess day-to-day variability (inconsistency). In addition, the measurements during the first visit were used to assess within-task variability (dispersion). Falls were registered continuously for six months.

Stride length and roll angle changes during dual tasking showed large inconsistencies (104% and 45%, respectively). Choice decision time showed moderate dispersion (17%), and spatial working memory performance showed both high dispersion and consistency (57% and 50%, respectively). However, these variability measures did not discriminate between fallers and non-fallers within the six-month follow-up. Sub-analysis showed that participants with a Mini-Mental State Examination score (MMSE) equal to or lower than 24 and falls at follow-up had a higher number of between-search errors (spatial working memory) and a lower inconsistency in between-search errors (13.8 [SD 0.6] and 5.7 [SD 4.1], and 15.2 [SD 6.4] and 61.1 [SD 50.4], respectively).

To summarize, when the MMSE score is taken into account, the inconsistency measures are not related to falls, except for the spatial working memory measure. Inconsistency in gait and balance measures may reflect a lack of test-retest reliability of the assessment procedures, calling into question the use of these measures for monitoring persons over time. It could be argued that the inconsistency in spatial memory reflects a better ability to learn and adapt to an unknown environment because it was negatively associated with falls (in other words, a higher inconsistency in non-fallers).



Discussion

Population

We intended to provide a fall-prevention intervention for frail older fallers visiting the geriatric falls clinic. Recruitment was organized in a multi-stage process involving the geriatrician and nurses of the geriatric falls clinic, and an extensive information supply was provided by the researchers. We recruited not only frail older fallers but also their informal caregivers. Patient/caregiver pairs were included because it was found that the intervention benefits in cognitively impaired older persons are better maintained when caregivers act as co-therapists. In addition, a negative attitude of the caregivers toward the intervention reduced the patients' participation and adherence. By including the caregivers, their insight into the capacities and limitations of the patients could be increased, and a positive attitude could be established. An additional aim of this intervention was to reduce caregiver burden.

The recruitment and selection process, possible improvements for both processes, and some general considerations regarding frail older persons as a subject of research will be discussed below.

Recruitment

For the efficacy evaluation of the fall-prevention intervention, we aimed to include 160 pairs. However, recruitment was difficult, and we did not reach this goal. A total of 813 patients were screened, of which 282 were eligible, but only 36 pairs participated (14.5% of the eligible pairs). Two important barriers for recruitment were the general view on falls and the negative attitude toward fall prevention.

Although falls can have a huge impact on the fallers, their social environment, and society, falls are not recognized as a health issue by fallers. When an older person perceives falls as normal or inevitable, they are not likely to participate in fall-prevention interventions.^{1, 2} Older persons need to understand that they are susceptible to falls, which are potentially serious events.³ Putting falls on the societal map and raising social awareness are essential first steps in fall prevention. Fall prevention involves emphasizing that falling is not normal, but pathological. National campaigns and an active approach by general practitioners, geriatricians, and other health-care professionals working with older persons may increase awareness leading to a positive change in social attitude.² This has been seen with other syndromes and diseases, such as diabetes or cardiovascular disease.

Older persons also need to expect that participating in a fall-prevention intervention will be beneficial.⁴ The willingness to engage in a fall-prevention intervention is further influenced by identification with the target group and social norms regarding participation in such an intervention.^{5, 6} Older persons may refuse to participate in fall-prevention interventions because they believe that these interventions are only

meant for "old", frail, or anxious persons who have a high risk of falling. They resist identification with this negative social identity.^{3, 5, 7, 8} To overcome the problem of negative attitudes toward fall-prevention interventions, many fall-prevention interventions are presented as "healthy aging" programs, which promote immediate health benefits in accordance with a positive self-identity, rather than perceived risk of harm.^{2, 5, 7} However, this approach may be counter-productive because awareness of the risk of falling and attitude changes are major components of fall prevention. Helping people to reflect on their falls and to understand why the falls occurred will help to prevent future falls. Older persons who reflect on falls and seek to understand why and how they occurred develop strategies to prevent future falls, reduce fear, maintain control and autonomy, and continue with the activities of daily living.⁹

Thus, successful recruitment requires changing a negative attitude toward fall prevention into a positive one. To achieve an attitude change toward fall prevention and to increase the willingness to participate in research and innovation on this theme, falls and fall-related attributions should be discussed with individual potential participants via a dialogue with health-care professionals and/or the research team. To make well-informed, rational, and positive choices about health-promoting behaviors, patients and caregivers should be provided with basic information about the benefits of preventive behavior. In addition, it is important to identify lifestyle aspects that the fallers are willing to modify and the changes they are prepared to make to reduce their risk of falling.⁶ Social encouragement may be achieved by positive media images and peer role models to illustrate the social acceptability, safety, and multiple benefits of taking part in research on fall-prevention interventions. In addition, it is important to establish support from the faller's social environment and professionals.^{7, 8} Creating awareness will encourage caregivers to take part in fall-prevention interventions and will stimulate patient/caregiver pairs to take part in scientific studies on interventions. Better understanding of the problem of falling leads to the understanding of the need to study improvements in treatment, especially in frail older persons.

Researchers may increase recruitment by including potential participants in study design and recruitment processes. Patient participation is a rapidly growing field of interest that may include multiple levels or stages of the research process.^{10, 11} Because both patients and caregivers have an interest in and are affected by decisions and are potentially relevant experts, their input is highly valuable. This inclusion results in research that is better suited to the needs of potential participants and is based on their experiences, problems, and wishes.¹² These methods will also increase the support and legitimacy of the research, which increases the likelihood of participation.¹²



Selection

To obtain a sample with high external validity, we used only a few exclusion criteria. Due to the nature of a geriatric population, this resulted in a heterogeneous group with multiple and diverse co-morbidities and different causes of falls. However, a portion of our target group was too frail to participate, and some participants were likely too frail to benefit from the intervention.

Many eligible patients declined participation because of their inability or reluctance to visit the hospital. Some patients were unable to come to the hospital due to decreased health and impaired mobility. Furthermore, some patients were unwilling to visit the hospital for the intervention because they already visited the hospital often for treatment or monitoring of their multiple co-morbidities. Treatment of some of the co-morbidities was considered more important than fall prevention.

Some participants may have been too frail to benefit. Frail older persons, especially those who are the frailest, may appear to be “in balance” but may have a subclinical capacity loss in multiple systems, which substantially increases their fall risk. These systems may be easily disturbed because of a narrowed tolerable range of disturbance. This narrow range is due to a decrease of available physiological reserves; more physiological reserves are already being used for normal gait and balance. As a result, one small disturbance may lead to a collapse of this entire interactive physiological system. In the frailest fallers, it may be a higher priority to detect these decreased reserves and to treat and enhance them first, focusing on the “weakest link”. Unless these underlying severe pathologies are diminished, fall prevention may be in vain. Any small disturbance or change may lead to serious deterioration and to falls if only one part of the physiological chain is improved.

Selection may be optimized by focusing on a sample population that is most likely to benefit. A stricter selection process could increase the effectiveness for specific groups of fallers. This finding suggests that future studies must be conducted in small groups with higher homogeneity. The clinician must understand who is appropriate for inclusion in which group to achieve clinical improvement. However, identifying who is at risk and determining their level of frailty is complicated.

We have demonstrated that older persons have a large variability in biological measures, as described in chapters 9 and 10. Fluctuations in performance were thought to be an important prognostic factor, but this thesis showed that inconsistency does not accurately predict a future fall. Variability may provide insight into the underlying mechanisms of dysfunction in daily living. However, these outcomes may only be suitable for assessment at the group level and not for individual patients, which limits their applicability for selection in clinical practice. Future research should be directed toward developing and validating better prognostic measures that are clinically applicable, easy to interpret and easy to assess.

We can search for other measures to understand variability in gait, balance, and cognition, either separately or as unified concepts. For example, studying general cortical atrophy and the percentage of white matter lesions may improve the understanding of the loss of stability and increased dispersion and inconsistency over time with aging. Reaction time variability is negatively associated with white matter brain volume.¹³ The volume of white matter lesions (WML) is greater in recurrent fallers, is associated with a higher risk of falls during follow-up, and correlates with poorer gait performance.^{14, 15} WML may interrupt important cerebral white matter connections that are required for motor control and balance. Thus, cortical atrophy and/or global or focal WML could act as prognostic biomarkers to identify subjects who may or may not benefit from specific forms of fall-prevention interventions.

Intervention

Development

The fall-prevention intervention and its evaluation were developed according to a thorough and carefully planned process and followed the Medical Research Council (MRC) framework.¹⁶⁻¹⁸ The steps taken reflect the research cycle that every researcher should follow. However, many research studies lack this systematic approach due to a lack of resources (mostly time and money). Often, the development of an innovative intervention is not considered a goal, but rather a means to begin the evaluation process. The use of this MRC framework is recommended because it guides the development of complex interventions and optimizes the planning and structuring of evaluating such a complex intervention.^{19, 20}

Although the framework is extensive, completing one cycle of the framework did not immediately result in the development of an effective intervention. However, it did result in an intervention and study design that was most likely to be effective based on existing evidence. This evidence has mainly focused on fall prevention in more fit older persons. We used this evidence and knowledge of research among frail older persons on other topics to adapt effective interventions to the physical and cognitive limitations of this group. Although we were unsuccessful in developing an effective intervention, this process has been valuable because it increased our insight and knowledge on fall prevention in this specific group of frail older persons. This finding underlines the importance of a thorough process evaluation and provides the opportunity to redesign both the intervention and its evaluation.

Limitations of the intervention

Although our study resulted in valuable insights, several limitations of this intervention can be identified, and specific recommendations for improvement and future research can be made.

Our hypothesis was that a more effective treatment would be accomplished with a



guided physical and behavioral program to increase physical fitness. Furthermore, the aim was to increase insight into the participants' personal capacity in high-risk situations and thereby achieve a change in behavior. Both an increase in physical fitness and a change of behavior would result in a decreased fall frequency and fear of falling.

The duration and the intensity of the exercises may have been too low to result in a physical benefit. Because the intervention consisted of only ten sessions, an important part of the physical training was performed by the participants at their homes. Although the importance of homework exercises was emphasized during the intervention, adherence to the homework exercises was moderate.

Previous studies have shown the effectiveness of home exercise in increasing leg strength and, consequently, increased gait speed and fall efficacy.²¹ However, the strength training did not result in an improvement in balance, endurance, or disability measures, and falls were not assessed as an outcome measure.

In fall-prevention interventions using less frail community-dwelling older persons, a short, low-intensity intervention was successful in reducing both the number of falls and the number of fallers.^{22,23} Furthermore, a 46% reduction in the number of falls was achieved, which is greater than previous studies.²⁴⁻²⁷ However, the beneficial outcome of such interventions may be attributed not to the physical training but to the exercise environment that simulated complex situations of everyday life,^{22,28} which is similar to our intervention. The cognitive and behavioral changes due to this type of exercise, in which participants learned to recognize situations with an increased fall risk and developed strategies to reduce their risk of falling, may be more important than increased muscle strength and physical fitness. Qualitative analysis has shown that increased insight was achieved in most participants in our intervention. However, behavioral changes may not have been accomplished. It is possible that although participants were willing to change, they were unable to incorporate changes into their daily life, which resulted in a lack of adherence. Perhaps increasing the number and duration of sessions would result in behavioral changes. However, ten sessions were already burdensome for the older fallers and especially for the caregivers. The intervention should also focus on increasing confidence in self-management, which enables participants to translate and incorporate their new insights into daily life. This may be achieved by supporting realistic positive beliefs, building self-confidence, and providing practical support for the planning and implementation of changed behavior.⁷ The motivation and self-efficacy of older persons is increased by giving them an active role in the selection of activities and setting goals, and this also results in greater compliance.^{7,29}

The participants reported that they appreciated the group format because they met peers with comparable experiences and learned through these interactions. However, some of the eligible frail older persons we screened at the geriatric falls clinic preferred

an individual intervention. An advantage of an individual intervention is that it allows for a more tailored approach and, more importantly, allows individual planning of the actual intervention. This decreases the burden of the intervention, especially on the caregivers, although it may not be necessary to include a caregiver in all situations or in all sessions. Qualitative analysis showed that the caregivers increased their insight into the patients' limitation and abilities and were able to assist the patient. However, this did not result in a decrease in caregiver burden, and caregivers reported that they were not able to act as co-trainers in encouraging the patient to complete their home exercises.

Future fall-prevention interventions

Fall-prevention interventions may be conducted in three ways, depending on the population. In addition to feasibility issues, views about which lifestyle changes are acceptable vary widely, and persons have different needs and desires in relation to prevention interventions.⁶

First, the current intervention may be beneficial for less frail older fallers. However, before this intervention is implemented, it requires adaptation that takes into account the shortcomings described previously. In particular, the focus on achieving behavioral changes should be increased, possibly by embedding the intervention in regular care and activity programs.

Second, this intervention was not feasible for frailer older fallers because of multiple co-morbidities, the distance to the facility, and the availability of caregivers. During the recruitment, we learned that a significant portion of this group would have preferred an individual, home-based fall-prevention intervention. This intervention could be provided by a physical therapist because home-based physical therapy is covered by health insurance in the Netherlands. This intervention requires training of the physical therapist delivering the intervention to ensure that the psychological components are also delivered. This includes establishing a positive attitude toward fall prevention, increasing insight into limitations, capabilities, the cause of falls and fall-risk behavior, and establishing changes in behavior. Such an approach may increase effectiveness because the intervention is individualized and its feasibility is increased. It would be easier for caregivers to attend these sessions because appointments could be made individually at the preferred day and time. Finally, home-based interventions would eliminate transportation issues for frail older persons. This adapted home-based version is currently being evaluated in a pilot study.

Third, it may be neither feasible nor effective to continue to improve complex interventions for the frailest older fallers. Perhaps the focus should shift from complex interventions to single-component interventions. Simple interventions may be more feasible and less expensive, although only a few single-facet interventions are

supported with sufficient evidence. Interventions with at least some available evidence are strength and balance exercises, withdrawal of psychotropic medication, administration of vitamin D and calcium, home hazard modification, and managing fear of falling.^{30, 31} However, such interventions may not be effective if recommendations or referrals are not followed.^{32, 33} Moreover, as stated previously, the priority lies with the treatment of the underlying pathology.

The next step for the development of effective and efficient fall-prevention interventions in frail older persons should come from studies of groups that are either less frail or less heterogeneous or from studies on individual interventions, which may be complex or may consist of series of single interventions for the frailest fallers.

Evaluation and outcomes

We primarily evaluated the effect of the intervention on fall frequency, fear of falling, and caregiver burden. In addition, we included several secondary outcome measures to gain insight into gait, balance, physical activity, and mood.

One difficulty in conducting research with frail older persons is their decreased physical and cognitive tolerability. When performing research studies in this population, researchers may be inclined to perform extensive evaluations to assess as much information as possible to explain changes and their underlying processes. However, this is a serious limitation for the recruitment of studies with frail older persons because eligible potential participants may decline participation because of the high burden. The benefit-to-burden ratio of including more measurements should be optimized by carefully selecting primary and secondary outcome measures. This optimization may also be accomplished with the use of patient participation, by asking potential participants to judge the benefit-to-burden ratio. Small, low-burden studies may assess the primary outcomes first, followed by the assessment of secondary outcome measures in follow-up studies. This finding illustrates the importance of performing a series of smaller studies that may be more experimental in nature to unravel the underlying mechanisms of falling and to identify at-risk persons rather than setting up one large trial. An additional benefit is that this approach enables the continuous adjustment of the intervention, and the process can be optimized based on new findings. Less burdensome methods may be developed and tested, similar to the evaluation of the fall telephone described in chapter 7, which now replaces the burdensome and time-consuming fall calendars. The selected outcome measures may not have been optimal to identify an effect. The heterogeneity of the group resulted in large inter-individual differences with different aims and benefits of the intervention, which were not visible or assessed through our generic outcome measures. Future studies should base outcome selection in such a heterogeneous group on individual measures and measures that more closely fit the training goals. An example of such an outcome method is the use of goal attainment

scaling,³⁴ which sets a goal for each individual participant and objectively assesses the extent to which this goal was achieved. This type of scaling overcomes the problem of some participants needing to increase their activity while others may need to reduce their activity. In addition, the process of change should be monitored. Interventions can only be successful when changes in behavior are achieved. Behavioral change should be an important goal that should also be assessed.

Although this trial was negative in its overall outcome and included a relatively small sample, it has provided important evidence regarding the recruitment, selection, and adherence of frail older fallers. In addition, this study represents a step forward in the challenge of fall prevention among this frail group. This underlines the benefit of publishing small sample studies and trials with negative outcomes that are too often not published or accepted by scientific journals.³⁵

Conclusions and recommendations

Conclusions

This thesis provided new evidence and directions for the complex aim of preventing falls in frail older persons. The main conclusions can be summarized as follows:

1. Increasing awareness, social acceptance, and establishing a positive attitude toward fall prevention are necessary to motivate older persons to participate in developing, testing, and implementing new interventions to prevent recurrent falls.
2. A complex group intervention (such as the one presented in this thesis) may be more appropriate for a pre-frail group of older persons with a high risk of falls. Working in a group and working on multiple components requires a cognitive reserve, which is already diminished in most frail older persons. The current intervention may be adapted to ensure a change of behavior in a pre-frail group.
3. Frailer fallers are probably better served by a home-based fall-prevention intervention, which is less invasive and less stressful. Such an intervention can be entirely adapted to the individual, thereby increasing effectiveness.
4. For preventing falls in the frailest population of fallers, the focus should shift to increasing evidence for population-based single interventions and understanding (and eventually treating) the underlying pathology. A small benefit from a single-component intervention in a large group will serve more persons and is more efficient than an intensive complex intervention, which may help a small proportion of frail older persons.
5. When evaluating new interventions in frail older persons, individualized and goal-oriented outcome measures should be assessed in addition to the process of changing the intervention study. However, studies should carefully select primary

(and secondary) outcome measures, limiting the number of assessments required in this frail population and optimizing the benefit-to-burden ratio.

Recommendations for future research

Future studies on fall prevention in frail older persons should take a more selective approach. The participants who can benefit from the different types of interventions must be identified. Targeting the different interventions to these persons may be the most important key to success because it is highly unlikely that all persons aged 55-115 years with an increased likelihood of falling will benefit from the same intervention. Research should be continued in small studies with a more experimental approach, continuously optimizing the selection of participants and the components of interventions, in addition to large-scale, population-based simple interventions. To minimize the burden of participation in trials, the number of assessments or site visits should be minimized, with a focus on developing less burdensome research methods. Adjusting these aspects may increase the likelihood of participation, even among frail older persons and their caregivers. Important factors in recruitment include establishing awareness of the fall risk, a positive identification with participation in a fall- prevention intervention, and a positive attitude concerning the benefits of participation. The benefits of including the caregiver in fall-prevention interventions should be assessed carefully and weighed against the disadvantages, mainly in terms of the caregivers' availability. Patient participation in the development of research studies may provide valuable information and may result in studies that are more suited to the needs of potential participants with research based on their experiences, problems, and wishes. These developments will increase the support and legitimacy of the research, thus increasing the likelihood of participation.

Take-home message for the clinician

One-third of the population aged 65 years and over experiences at least one fall each year, and this number is even higher among frail older persons. Falls have a significant impact on patients and their informal caregivers. Falls are not a normal, inevitable consequence of aging, and this fact should be emphasized to patients who experience a fall. Fall prevention begins by increasing awareness and establishing a positive attitude toward fall prevention. The type of intervention should match the level of frailty of the older person, ranging from a tailor-made group intervention to home-based, individual, multifaceted or single-component interventions and single-component, large-scale interventions all aimed at reducing the risk of falls.

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**Samenvatting in het Nederlands
(Summary in Dutch)
Dankwoord (Acknowledgements)
Curriculum Vitae
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Donders Series**





Samenvatting in het Nederlands
(Summary in Dutch)

Valpreventie op maat

Ouderen denken dat vallen hoort bij het ouder worden en onvermijdelijk is. Maar dat is zeker niet het geval. Dat hier meer aandacht voor nodig is, blijkt uit promotieonderzoek van Miriam Reelick (Radboud Universiteit Nijmegen). Eerder onderzoek toonde aan dat jaarlijks meer dan een miljoen ouderen vallen. Heup- of polsbreuken zijn vaak voorkomende gevolgen, soms een combinatie van beide. Behandeling en revalidatie kost de maatschappij ongeveer 725 miljoen euro per jaar.

Mensen op leeftijd die impulsief reageren of die bang zijn te vallen, vallen daardoor eerder. Overbezorgdheid over vallen zorgt ervoor dat mensen activiteit vermijden of dat een mantelzorger teveel taken overneemt. Hierdoor bewegen mensen minder en dat vergroot hun kwetsbaarheid. Naast overbezorgde ouderen zijn er ook impulsieve ouderen en ouderen zonder angst te vallen. Zij nemen juist onverantwoorde risico's en vallen daardoor vaker. Een programma op maat kan voor beide groepen de kans op een val verminderen. Dat is geen overbodige luxe, vindt Reelick. Zij promoveert op 30 september 2011.

Eerder vallen

Opvallend resultaat van haar onderzoek was dat mensen met valangst of juist met impulsief gedrag eerder vallen. Ook mensen met variatie in het nemen van grote en kleine stappen tijdens het lopen, of met een sterk variabele reactiesnelheid hebben een verhoogd risico. Voor haar onderzoek ontwikkelde en evalueerde Reelick een valpreventieprogramma voor kwetsbare ouderen en hun mantelzorger.

Valkuilen vermijden

De cursus bestond uit groepsgesprekken en bewegingsoefeningen waarbij veel aandacht was voor het leren kennen en leren accepteren van je grenzen. Binnen deze grenzen is het belangrijk om zo actief mogelijk te zijn. Niet alleen de oudere, ook zijn (of haar) mantelzorger zijn bang voor vallen omdat ze niet weten waardoor het vallen komt. Bovendien bestaat de angst voor de gevolgen van vallen. Doordat ze de oorzaak van hun vallen niet weten, ontstaan gevoelens van frustratie en machteloosheid. Door tijdens de cursus alledaagse situaties te bespreken, kregen de deelnemers meer inzicht in hun eigen gedrag. Daardoor leren cursisten om risico's te vermijden en hulp aan anderen te vragen.

Na het groepsgesprek oefenden de deelnemers wat ze hadden besproken. Dat gebeurde in een parcours waarin de deelnemers dagelijkse handelingen deden. Ook oefenden ze met het opstaan na een val. Dat gebeurt omdat veel ouderen bang zijn dat ze na een val lang hulpeloos op de grond blijven liggen.

Mantelzorgers doen mee

De mantelzorger deed ook mee aan de lessen. Mantelzorgers leren zo hoe ze hun naasten het beste kunnen begeleiden. Daarnaast verhoogt het samen praten en oefenen het inzicht in wat hun naaste kan. Hierdoor leren mantelzorgers wanneer ze moeten helpen en wanneer niet. De cursus bestond uit tien lessen, bestemd voor een groep van maximaal zes koppels van valler en mantelzorger.

Preventie op maat

Als u zo'n cursus wilt volgen, moet u nog even geduld hebben. De onderzoekers hebben namelijk geleerd dat dezelfde cursus niet voor iedereen geschikt is. Mensen die bijvoorbeeld slecht kunnen horen, of mentale problemen hebben, kunnen beter individueel les krijgen. Daarom is voor deze meest kwetsbaarste ouderen een aangepaste cursus gemaakt. Een fysiotherapeut kan deze cursus individueel, thuis geven. Voor anderen is het juist belangrijker om met elkaar te oefenen en te praten. Wat je op de cursus kan leren is dan beter te volgen en de informatie blijft beter hangen. Bovendien is het fijn om te ervaren dat je hier niet alleen in staat en van elkaar kunt leren.

Toekomst

De impact van vallen is zeer groot. Voor degene die valt, voor zijn omgeving, maar ook voor een snel vergrijzende maatschappij die de kosten van behandeling en revalidatie moet dragen. Het beter kunnen opsporen van mensen met een groot risico om te vallen is daarom volgens **Reelick** van groot belang. Daarnaast moet ook de valpreventie worden verbeterd. Het onderzoek toont aan dat een 'zorg op maat' aanpak zeer belangrijk is voor een efficiënt preventieprogramma.

Om verder te komen op het gebied van valpreventie is het volgens **Reelick** belangrijk om ouderen bewust te maken dat vallen een probleem is. Zij vindt het ook belangrijk taboes rondom vallen te doorbreken. Ouderen verzwijgen soms dat ze vallen uit angst voor negatieve reacties van de omgeving, of omdat ze bang zijn daardoor in een verzorgingshuis terecht te komen.



Dankwoord (Acknowledgements)

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Curriculum Vitae

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Curriculum Vitae

Miriam Reelick werd geboren in Den Helder op 19 augustus 1983 en groeide op in Uithoorn en Boxmeer. Zij behaalde in 2001 cum laude haar VWO diploma aan het Elzendaal college te Boxmeer, waarna ze startte met de bacheloropleiding Biomedische Wetenschappen aan de Radboud Universiteit Nijmegen, gevolgd door de masteropleiding Bewegingswetenschappen.

Voor haar wetenschappelijke stage werkte ze in 2005 vier maanden aan het Institute for Exercise and Environmental Medicine in Dallas, Texas. Onder leiding van prof. dr. Benjamin Levine en dr. Qi Fu maakte ze kennis met een breed scala aan onderzoeksmethoden.

Op dit instituut interesseerde dr. Jurgen Claassen haar voor onderzoek op de afdeling geriatrie op het Universitair Medisch Centrum St. Radboud. Ze realiseerde eerst als student-assistent een database en het jaarverslag voor de geheugenpoli van de afdeling. Vervolgens deed ze onderzoek naar de invloed van valangst op lopen en balans bij ouderen onder leiding van dr. Marianne van Iersel. Voor de wetenschappelijke presentatie over dit onderzoek kreeg zij in 2006 de Radboud Universiteit Bewegingswetenschappen Studenten Prijs.

Na haar afstuderen in 2006 kreeg haar stage in 2007 een vervolg in een promotietraject aan de Radboud Universiteit Nijmegen. Ze werkte onder leiding van prof. dr. Marcel Olde Rikkert, prof. dr. Roy Kessels, dr. Rianne Esselink en dr. Arenda Dado-Van Beek aan het onderzoek wat leidde tot dit proefschrift.

Tijdens dit traject was ze voorzitter van de Jubileumcommissie van de afdeling Geriatrie. Dankzij deze commissie zijn er op markante plekken door heel Nijmegen zeven 'Nestorbanken' geplaatst als eerbetoon aan ouderen. Ook heeft ze een docentschap aanvaard in de PAOG Heyendaal cursus 'Vallen en syncope diagnostiek' en initieerde ze, en was ze voorzitter van de onderzoeksbespreking van de afdeling Geriatrie.

Momenteel werkt ze bij Alzheimer Nederland (Bunnik) op de afdeling Onderzoek en Beleid.

<http://nl.linkedin.com/in/miriamreelick>



Curriculum Vitae

Miriam Reelick was born on August 19, 1983 in Den Helder, the Netherlands and grew up in Uithoorn and Boxmeer. In June 2001, she graduated cum laude from the secondary school 'Elzendaal college Boxmeer'. She subsequently received a Bachelor's degree in Biomedical Sciences and a Master's degree in Movement Sciences at the Radboud University Nijmegen.

For her research internship in 2005, she went to Dallas, Texas. At the Institute for Exercise and Environmental Medicine, Professor Benjamin Levine and Dr. Qi Fu introduced her to a wide variety of research methods.

At this institute, Dr. Jurgen Claassen motivated her to conduct research at the department of Geriatric Medicine at the Radboud University Nijmegen Medical Centre. She started as a research assistant and became an intern, working under the supervision of Dr. Marianne van Iersel. She did research on the influence of fear of falling on gait and balance in older persons. For her scientific presentation, she received the Movement Sciences Student Award (Radboud University Nijmegen) in 2006.

After her graduation in 2006, she began the research project presented in this thesis in 2007 under the supervision of Professor Marcel Olde Rikkert, Professor Roy Kessels, Dr. Rianne Esselink and Dr. Arenda Dado-Van Beek.

During this project, she was chair of the Jubilee Committee of the department of Geriatric Medicine. This committee realized the placement of seven 'Nestor Sofa's' at prominent locations all over Nijmegen as a tribute to older persons.

She also accepted a teaching position in the PAOG Heyendaal course 'Falling and syncope diagnostics' and initiated and was chair of the research meeting of the department of Geriatric Medicine.

She currently works at 'Alzheimer Nederland' in the department of Research and Policy.

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List of publications

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List of publications

Studies with group treatment required special power calculations, allocation methods, and statistical analyses. Faes MC, Reelick MF, Perry M, Olde Rikkert MGM, Borm GF. Journal of Clinical Epidemiology. Accepted 2011

How to Perform a Preplanned Process Evaluation for Complex Interventions in Geriatric Medicine: Exemplified With the Process Evaluation of a Complex Falls-Prevention Program for Community-Dwelling Frail Older Fallers. Reelick MF, Faes MC, Esselink RA, Kessels RP, Olde Rikkert MG. J Am Med Dir Assoc. 2011 Feb 15.

Multifactorial Fall Prevention for Pairs of Frail Community-Dwelling Older Fallers and their Informal Caregivers: A Dead End for Complex Interventions in the Frailest Fallers. Reelick MF, Faes MC, Melis RJ, Borm GF, Esselink RA, Olde Rikkert MG. J Am Med Dir Assoc. 2010 Dec 23.

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About the dvd

Format: PAL, widescreen

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Gait and balance assessment

Duration ± 8 minutes

Illustration of the gait and balance assessment as performed in the studies of this thesis. Gait and balance in participants are measured simultaneously with use of an electronic walkway and angular velocity device. Tasks follow a standardized protocol including tasks challenging sensorimotor functions and cognitive function. Instructions are provided before each task. The researcher walks or stands close by to ensure safety of the participant. *See also chapter 1B of this thesis.*

Participant: Mrs. Fleerkamp (She was not a participant for the studies presented in this thesis.)

Researchers: M.C. Faes, MD, MSc

M.F. Reelick, MSc



Choice reaction time task

Duration ± 8 minutes

Illustration of the assessment of reaction time as performed in the studies of this thesis. Choice reaction time is assessed with use of the Cambridge Neuropsychological Test Automated Battery (CANTAB™). Participant release a press-pad button to touch the location where a stimulus was presented. Instructions of the researcher emphasize speed of performance.

See also chapter 1B of this thesis.

Participant: Mrs. Fleerkamp (She was not a participant for the studies presented in this thesis.)

Researcher: M.F. Reelick, MSc



Falls clinic

Duration ± 8 minutes

Illustration of the multidisciplinary diagnostic assessment at the geriatric falls clinic at the department of Geriatric Medicine (Radboud University Nijmegen Medical Centre, the Netherlands).

Participants: Mr. and Mrs. Hendriksen.

Geriatrician: Drs. Y. Schoon.

Nurse: H. Schuwer.

Physical therapist: M. de Roode.



Fall-prevention intervention

Duration ± 8 minutes

Illustration of fall-prevention intervention of the department of Geriatric Medicine (Radboud University Nijmegen Medical Centre, the Netherlands). The intervention is specifically designed for frail older fallers and their caregivers and consists of ten sessions. A maximum of six pairs may participate, this course three pairs participate. *See also chapter 4 of this thesis.*

Participants: Mr. and Mrs. Hendriksen,
Mrs. Huwae and family
Mrs. Gerrits and daughter.

Instructors: M. de Roode (physical therapist)
Drs. N. Schuylenborgh (psychologist)