

# **Why Older People Refuse To Participate In Falls Prevention Trials:**

## **A Qualitative Study**

Abbreviated Title: **Why older persons refuse study participation**

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## **Abstract**

**Background/Objectives:** Falls are a major public health problem. Older persons are frequently underrepresented in trials, including falls prevention trials. Insight into possible reasons for non-participation could help to improve trial designs and participation rates among this age-group. The aim of this study was to explore reasons why older people refuse to participate in falls prevention trials.

**Setting:** A qualitative study.

**Participants:** Community-dwelling adults aged  $\geq 65$  years who attended the Emergency Department due to a fall and refused to participate in a falls prevention trial (IMPROVeFALL-study).

**Measurements:** A structured interview guide was used, and interview transcripts were subjected to an independent content analysis by two researchers.

**Results:** 15 interviews were conducted. A main reason to refuse trial participation was mobility impairment. In contrast, younger and more “active” and mobile seniors considered themselves “too healthy” to participate. Persons with multiple comorbidities mentioned that they attended a hospital too often, or experienced adequate follow-up by their own physicians already. Transport problems, including distance to the hospital, parking facilities, and travel expenses were another issue. During the interviews it was emphasized by the patients, that they knew the reason for their fall. However, they were not familiar with the positive effects of falls prevention programmes.

**Conclusions:** Older persons reported multiple reasons to refuse participation in a falls prevention study, such as health-related factors, several practical problems, and personal beliefs about the causes and preventability of falls. Anticipation of those issues might contribute to an improvement in participation rates of older fallers, shorter study duration, and a better generalizability of research findings.

**Key words:** Falls prevention, older persons, qualitative exploration, trial participation, participation refusal

## **1. Introduction**

The number of older adults worldwide is expected to increase rapidly in the coming decades (Statistics Netherlands (CBS) ; United Nations 2007). As a result of the increasing life expectancy, an increase in age-related diseases, syndromes and injuries is to be expected (Perenboom 2005). The majority of injuries among older adults are caused by falls, which represent a major and increasing public health problem (Hartholt and others 2011b; Hartholt and others 2010; Hartholt and others 2011d; Kannus and others 1999; Stevens and others 2008). Approximately one third of all community dwelling persons aged 65 years and older fall at least once a year (Dijcks and others 2005; Stel and others 2004; Tinetti and Williams 1997). Falls among this age-group are leading to a high healthcare demand, including Emergency Department (ED) visits, hospitalizations (Hartholt and others 2011a; Hartholt and others 2011b; Kannus and others 1999; Stevens and others 2006a), and long term care (Hartholt and others 2011b), and to high healthcare expenses (Hartholt and others 2011b; Scuffham and others 2003; Stevens and others 2006b). Falls do not only have a large impact on society as a whole, but also on the quality of life of the individual patient (Hartholt and others 2011b). Therefore, it is important to prevent falls in order to limit the related burden and healthcare demand in ageing societies.

For a development of effective falls prevention strategies, an evidence based approach is needed. This can only be done by an implementation of results of RCT's. However, older persons are frequently underrepresented in randomized controlled trials, including falls prevention trials. In addition, in studies specifically targeting older age groups, there is a large 'refusal to participate', especially among the oldest old and those who might possibly benefit

most (Vind and others 2009). Falls prevention studies among older persons generally show poor participation rates of 30-50% (Clemson and others 2004; Close and others 1999; Davison and others 2005; Hartholt and others 2011c; Hendriks and others 2008; Vind and others 2009). However, in most of these studies the reasons for non-participation are not mentioned. Hendriks *et al.* briefly mention two reasons for refusing, *e.g.* not interested or study participation is too time consuming (Hendriks and others 2008). Vind *et al* showed that non-responding non-participants of a trial of multifactorial falls prevention differed significantly from study participants in terms of socioeconomic status and morbidity variables and that non-responders were more likely to be hospitalized or deceased during a 6 months follow-up period. But the authors do not describe reasons for non-participation (Vind and others 2009). It has been suggested in a physical activity promotion trial that recruitment of 'hard to engage' individuals requires careful phrasing of the message to focus on their personal goals and to address gaps in their knowledge about physical activity (Chinn and others 2006).

Therefore it is important to understand why older people refuse to participate in clinical trials. Future randomized controlled trials could benefit from knowledge on this topic, which might help investigators to make a better study design for this specific old age-group, and achieve better participation rates. Better inclusion rates reduce the inclusion period, improve the generalizability and representativeness of a study, and limit the study related costs. Qualitative research could be used to explore the reasons for non-participation in falls prevention trials. It is an important first step in a stepwise approach to understand refusal to participate among older adults. As far as we are aware at this time qualitative methods have rarely been used to evaluate non-participation among older persons. The aim of this study was to explore reasons why older people refuse to participate in falls prevention trials.

## **2. Methods**

The current qualitative study was added to a multicenter randomized controlled trial [IMPROveFALL-study (Hartholt and others 2011c)] on the prevention of future falls among community dwelling individuals aged 65 and older, who had sustained an injurious fall leading to medical treatment at an ED. The intervention consists of withdrawal (if possible) of fall-risk increasing drugs versus “usual care” with a 1-year follow-up in order to reduce the risk of future falls. The complete IMPROveFALL-study protocol by Hartholt *et al.* has been published elsewhere (Hartholt and others 2011c). All patients received verbal and written information about the IMPROveFALL-study. Patients who decided not to participate after having been informed about the IMPROveFALL-study were eligible to be included in the current study. Potential respondents were invited for this qualitative study at the moment they reported their decision not to participate in the main IMPROveFALL-study. To ensure maximum levels of participation in the current study, the interviews were held by telephone. After verbal consent, a short telephone interview took place.

All interviews were held by one interviewer (A.E.). At the start of the interview, it was emphasized that the interview was not an attempt to convince the person to participate in the IMPROveFALL-study, that the interview was not a test (*i.e.*, that there were no good or wrong answers), and that all opinions and reasons for refusal were respected. After the serial conduction of 10 interviews, saturation of opinions was reached. To ensure complete saturation, 5 additional interviews were performed. The interviews were directly fully digitally transcribed in Microsoft Word. The Institutional Review Board of the Erasmus MC, University Medical Center Rotterdam , approved the study (MEC-2010-403).

### **2.1 Structured-Interview Guide**

All interviews were conducted in accordance with a structured-interview guide to ensure that all topics of interest were covered (see table 1). The interview guide was developed prior to

the start of the study, and aimed to explore a multitude of factors, including attitudes (*i.e.*, perceptions of different positive and negative consequences of study participation) and subjective norms (*i.e.*, the perceived opinions of others concerning participation).

## **2.2 Analysis**

A systematic content analysis for the collection of qualitative data of all digital interview transcripts was performed by using Nvivo software, version 9 (QSR international, Doncaster, Australia). After the content analysis, data were assigned codes, and code-specific reports were generated to detect common themes and key points. A content analysis was performed independently by two researchers (A.B.M.E. and K.A.H.). Disagreements were resolved by a third researcher (T.J.M.V.D.C.).

### **3. Results**

In total 15 individual telephonic interviews were conducted with non-participants, between February 1<sup>st</sup> and March 3<sup>th</sup> 2011. The interviews took 15-25 minutes per interview.

#### *3.1 General impression of falls prevention trials.*

Participants in the current study had the impression that falls prevention is only about giving advice (“I’m thinking of paying attention to loose carpets and other loose objects, or telling people to be more careful”). It was mentioned that falls prevention is useful for older adults with mobility problems, balance problems, or vertigo, and that such persons would benefit more from a walking device than from a falls prevention training. It was put forward that falls prevention training would not have any effects in their own case (“I have my doubts about the effects of this research”).

#### *3.2 Non-participants’ perception of reasons to agree with participation in a falls prevention trial*

The non-participants thought that persons would agree to participate in the falls prevention study, when the study is a medical check-up to assess if there are any “new” medical problems or conditions, and when advice is given on how to prevent a new fall. It was also mentioned that participation should provide valuable information on how to improve the scientific knowledge about older adults. Another positive reason to participate which was mentioned was that some people were frightened to fall again

#### *3.3 Reasons to refuse participation in a falls prevention trial*

The reasons to refuse participation could be divided in five categories: personal, study, environment, hospital and transport related factors (Table 2). People emphasized that they knew the reason for their fall (“This fall was really my own fault, it was an accident”), and falls prevention strategies could not prevent a further fall (“It’s your own responsibility to be

careful and not to fall, it's not a problem which can be prevented"). People explained that mobility problems made it hard to visit the hospital for a study visit ("Since the fall, my mobility has declined, that is the reason why it's so hard for me to visit the hospital"). On the other hand, some older adults stated that they were "too healthy" to participate in this trial, and therefore falls prevention was not useful for them. However, importance of the intervention was recognized and recommended for other more frail older people ("Maybe there are people who really need this, but I don't, because in my case I know it was an accident"). Also, participation was refused because the patients have their own physicians who do "similar medical check-ups" ("I've got my own doctors who keep an eye on me, and I'm satisfied"). Another reason to refuse was that some people were "tired" of visiting healthcare professionals for their own and/or partner's health issues, others already had "too many different physicians and wanted no new doctor to assess them". It occurred that in some cases study participation was discouraged by the General Practitioner of the patient. Some patients were afraid to fall again, and preferred not to leave their home, unless there was no other option. Furthermore, a lack of time was mentioned to refuse participation.

Study related factors included among others anxiety for new diagnoses at their age. However, it was noticeable that this option was not mentioned as their own reason to refuse, but that patients thought that others would have this problem. The extra study visit to the hospital was another reason for non-participation. Patients mentioned that the university medical centre where the research took place is too large and that visiting the hospital was not suitable for them, because of the distance from the parking facility to the outpatient clinic. Transport to the hospital for an outpatient clinic visit was an issue as well. Some older patients are dependent on a relative for transport, but not all participants wanted to ask a relative or use public transport ("The reason for refusing is that I'm dependent on someone else"). Also travel distance, parking problems, and the distance to walk from the parking area to the outpatient clinic were mentioned as reasons to refuse participation. In case mobility



problems were the main reason to refuse participation, persons were asked if they would participate if the study assessment took place at home, and all responded positively. Also, the weather forecast played a role, when both poor and excellent weather conditions were expected, the patients preferred not to come to the hospital.

Patients were also asked to name the most important reason to refuse participation in a falls prevention study. Most frequently mentioned reasons were that older persons already had their own physicians who took care of them, and transportation difficulties. Potential participants were asked how to improve the recruitment of older adults. It was suggested to arrange transport or to perform home visits. Also it was thought that it would be helpful to educate older adults about the importance of falls prevention with extra flyers, media attention and articles.

#### 4. Discussion

The reasons to refuse participation include person related factors, study-related factors, and environmental factors. A common reason to refuse participation were mobility difficulties. On the other hand, younger or “active” seniors explained that they were “too healthy” to participate. Persons with multiple comorbidities mentioned that they attended a hospital too often, or experienced adequate follow-up by their own physicians already. Transport problems, including distance to the hospital, parking facilities, and travel expenses were another issue.

The qualitative study design of the current study made it possible to explore the reasons to refuse participation of older fallers in a falls prevention trial. To optimize future studies among older adults, we recommend that researchers should anticipate on reasons of refusal in their study design.

Research among older patients is essential in ageing societies worldwide. However, the fastest growing segment of the population (Statistics Netherlands (CBS) 2011; United Nations 2007) is frequently underrepresented in studies. In addition, in studies specifically designed for and targeted at the older age groups, those who participate may not be representative for the population under study as a whole. Vind *et al.*, found different characteristics between participants and non-responders and non-participants in a study aimed at older fallers who had attended the ED because of a fall (Vind and others 2009).

Multiple falls prevention strategies have been developed (Gillespie and others 2009; Stevens and Sogolow 2008). In order to determine adequate preventative strategies for older adults, medical research is necessary to determine the effect of the interventions in this age-group since not all interventions are (cost)effective (de Vries and others 2010; Gillespie and others 2009). Participation rates of fall prevention studies range from 30 – 50% of the potential study candidates (Clemson and others 2004; Close and others 1999; Davison and

others 2005; Hendriks and others 2008; Vind and others 2009). However, if the participants in a study are not representative of the group as a whole, the study results cannot be translated to the population from which the study participants were selected, but only to a population which is comparable to the study participants. Elzen *et al.* described reasons for refusing to participate in a self-management intervention for chronically ill older people. The main reasons given by the non-participants in their study were: no time, travel distance too far, transport problems, no need to attend a course, or attending a course is too strenuous (Elzen and others 2008). The self-management intervention consisted of six weekly meetings, therefore the first and last reasons are not comparable with the reasons for non-participation in the IMPROveFALL-study. In the current study transportation problems and “no need” also were important reasons for refusal to participate, which indicates that these reasons are not probably more generalizable to ‘refusal to participate’ by older persons.

Easy measures to improve the recruitment according to the interviewed persons in the current study are to arrange transport or to visit people at home. Also education about the importance of falls prevention training might be useful. Furthermore, Samelson *et al.* recommended that other points could also contribute to a better recruitment rate of older persons. These issues included: face-to-face contact, recommendation by community leaders, trained personnel, and a positive and accessible environment for study participants (Samelson and others 2008).

In the Netherlands several falls prevention strategies and campaigns have been introduced and promoted by the government (The Dutch Institute for Healthcare Improvement 2004). In the IMPROveFALL-study all potential participants receive a verbal explanation and an information brochure about the study procedures, including the insurance policy, which is required for medical intervention studies. Although potential participants received extensive study information, both verbal and written, most persons who refused participation did not know the correct meaning of the IMPROveFALL-study. Interviewed

people thought it was only about giving advice, mobility exercise or balance training. This means that besides all the reasons given for non-participation, older adults frequently do not understand or have a different perception of falls prevention. It seems difficult to overrule pre-existing ideas about falls-prevention, even if established by implementation of government policy prior to the study. This means that explanations should be made clearer for this particular topic and for this particular age- and patient-group, *i.e.* older persons who have recently experienced a fall, for which they attended an Accident and Emergency Department.

This study has several strengths and limitations. A strength of the current study was that after five structured interviews were held, answers to the questions started to be repeated, and after ten interviews a saturation of the different answers was achieved. To assure that complete saturation was achieved, five more patients were included, and no new answers were given. A possible limitation of the study includes that all interviewed persons were recruited from a single hospital. Some answers might therefore possibly be specific for this region, such as parking problems. Furthermore, it has been argued that telephonic interviews are less reliable, but the quality of data obtained by telephone on complex attitudinal and knowledge items as well as on personal items has been shown to be comparable to that collected in person (Rogers 1976).

Future research has to be performed in order to improve the knowledge about the ideas of older adults to participate in falls prevention. The identified reasons in this study should be quantified in future research to determine the importance of the single reasons. Since qualitative research may provide (new) hypotheses, it is not possible to show how extensive the problem is. A new study could be based on non-participants of other (large) trials in the world using questionnaires on specific determinants.

In conclusion, this qualitative study indicates that older fallers report multiple reasons to refuse participation in falls prevention study. It seems that some problems, such as mobility and transportation issues, can be solved by arranging suitable transport, or by performing

home visits. Personal beliefs may be influenced by well-designed communication strategies. Anticipation on those issues might contribute to an improvement in participation rates of older fallers, leading to shorter study durations and a better generalizability of research findings.

## **6. Conflict of interest statement**

None declared

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## **8. Authors’ contribution**

Drafted paper: A.E., K.H., E.V.B

Data collection: A.E., K.H.

Data analysis & interpretation: A.E., K.H., P.P., E.V.B, T.V.D.C.

Critical revision: K.H., P.P., E.V.B, T.V.D.C.

Supervision: P.P., T.V.D.C.

Approved final version: A.E., K.H., P.P., E.V.B, T.V.D.C.

**Table 1.** Topics covered to lead interviews

<b>Topic</b>	<b>Question</b>
Transition question	Who benefits from falls prevention trials?
Key questions	What are (dis)advantages of participating in a falls prevention trial?  What are reasons for participating/refusing to participate in a falls prevention trial?  What can be obstructive to participate in a falls prevention trial?  How could participation in a falls prevention trial be stimulated?  How important is falls prevention for you?  When do you like to participate in a falls prevention trial?

**Table 2.** Main reasons to refuse participation in a falls prevention study

<b>Category</b>	<b>Reason</b>
Personal factors	<ul style="list-style-type: none"><li>- Lack of time</li><li>- “Too healthy”</li><li>- Impaired mobility</li><li>- Already high number of doctor visits</li><li>- Perception fall was a true accident</li></ul>
Hospital factors	<ul style="list-style-type: none"><li>- Hospital is too large / unknown</li><li>- Walking distance in / around hospital to far</li></ul>
Environmental	<ul style="list-style-type: none"><li>- Weather condition (poor / excellent)</li></ul>
Study related	<ul style="list-style-type: none"><li>- Study has no effect</li><li>- Anxiety for new underlying comorbidities</li></ul>
Transport	<ul style="list-style-type: none"><li>- Dependent for transport of somebody else</li><li>- Difficult to reach the hospital</li><li>- Travel expenses (taxi / public transport)</li><li>- Too far away</li></ul>



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