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Short report

Why older people refuse to participate in falls prevention trials: A qualitative study

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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 ≥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.

1. Introduction

The number of older adults worldwide is expected to increase rapidly in the coming decades (Statistics Netherlands (CBS) ; United Nations, 2006). 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 et al., 2011b, 2010, 2011d; Kannus et al., 1999; Stevens et al., 2008). Approximately one third of all community dwelling persons aged 65 years and older fall at least once a year (Dijcks et al., 2005; Stel et al., 2004; Tinetti and Williams, 1997). Falls among this age-group are leading to a high healthcare demand, including Emergency Department (ED) visits, hospitalizations (Hartholt et al., 2011a, 2011b; Kannus et al., 1999; Stevens et al., 2006a), and long term care (Hartholt et al., 2011b), and to high healthcare expenses (Hartholt et al., 2011b; Scuffham et al., 2003; Stevens et al., 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 et al., 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 et al., 2009). Falls prevention studies among older persons generally show poor participation rates of 30–50% (Clemson et al., 2004; Close et al., 1999; Davison et al., 2005; Hartholt et al., 2011c; Hendriks et al.,

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2008; Vind et al., 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 et al., 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 et al., 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 et al., 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 et al., 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 et al., 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).

Table 1
Topics covered to lead interviews.

Topic	Question
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?

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 1st and March 3th 2011. The interviews took 15–25 min 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