Preventive Medicine Reports 2 (2015) 134–140

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: http://ees.elsevier.com/pmedr

# A feasibility study of a randomised controlled trial comparing fall prevention using exercise with or without the support of motivational interviewing

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ARTICLE INFO

Available online 3 February 2015

*Keywords:*
Exercise
Feasibility study
Motivational interviewing
Older adults
Community-living

ABSTRACT

*Objective.* The aim of this investigation was to study the feasibility of a randomised controlled trial (RCT) based on a multicentre fall prevention intervention including exercise with or without motivational interviewing compared to standard care in community-living people 75 years and older.

*Method.* The feasibility of a three-armed, randomised controlled trial was evaluated according to the following: process, resources, management by questionnaire, and treatment outcomes. The outcome measures were fall frequency, physical performance and falls self-efficacy evaluated after three months. Twelve physiotherapists conducted the measurements and treatments and responded to the questionnaire. The first 45 participants recruited to the ongoing RCT were included: 16 individuals in the Otago Exercise Program group (OEP), 16 individuals in the OEP combined with motivational interviewing group (MI), and 13 individuals in the control group. The study was conducted from November 2012 to December 2013.

*Results.* The feasibility of the study process, resources and management reached the set goals in most aspects; however, the set goal regarding the MI guide and planned exercise for the participating older people was not completely reached. No significant differences were found between the groups regarding the outcome measures.

*Conclusion.* This study confirmed the acceptable feasibility for the study protocol in the ongoing RCT.



## Background

Over one-third of all people 65 years and older fall each year (Cotter et al., 2006), and approximately 10% of all falls result in serious physical injuries, half of which are fractures (Wijlhuizen, 2008). The number of falls and the associated costs are expected to increase with an increasing older population (Merom et al., 2012). The common individual consequences among older people after a fall are anxiety, fear of falling, loss of independence, and balance and strength impairments (Sipilä et al., 2011). A Cochrane review by Gillespie (Gillespie et al., 2012) showed that home-based exercise programs that include balance and strength-training exercises reduce falls and appear to reduce fractures in older people. Adherence to exercise programs increases, according to the elderly themselves, if the program is individually adapted, professionally guided and performed at home (Yardley et al., 2006).

The Otago exercise program (OEP), developed in New Zeeland, is a home-based exercise program including strength, balance and endurance training (Campbell et al., 2001). The program is individualised and progressive. A trained health professional gives instructions to the patient about the program during a home visit and makes regular follow-ups, either at home or by phone. The OEP has been shown to reduce falls, fall-related injuries and mortality in people 80 years and older (Thomas et al., 2010).

Regular physical activity can help reduce fall injuries in older persons (Chodzko-Zajko et al., 2009). In a systematic review of 53 studies (Fei et al., 2013), only two studies reported sufficient physical activity (150 min per week of moderate to high intensity activity) (Gómez et al., 2010; Hillsdon et al., 2008). A current challenge is to motivate older people to perform physical activity over time. It is important to increase the understanding of how intervention programs for the elderly should be presented to maximise the acceptance and participation and, at the same time, fit the recommendations (Yardley et al., 2006).

Motivational interviewing (MI) is a method used to initiate and support behaviour change, and it aims to help people detect and resolve

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http://dx.doi.org/10.1016/j.pmedr.2015.01.007

their ambivalence about a behavioural change (Miller, 1983). A characteristic of MI is that the patient stimulates the motivation to change a behaviour; the therapist then uses a supportive approach to increase self-efficacy for the behavioural change process. Physical exercise, in combination with programs aiming to obtain behavioural change in the elderly, has rarely been evaluated, and there is a need to assess the feasibility of using exercise in the behavioural change process.

The aim of this study was to assess the feasibility of a multi-centre, fall prevention randomised controlled study (RCT) conducted in three Swedish municipalities and including either OEP, OEP combined with MI (onwards termed MI), or standard care (control group) for older people in the community by evaluating A) the study process, resources and management and B) the effects of the intervention programs on fall frequency, physical performance, balance and falls self-efficacy.

## Method

The design of this study was a descriptive feasibility investigation of an RCT.

The Consolidated Standards of Reporting Trials - CONSORT checklist was used for reporting the RCT (Schulz et al., 2011).

### *Participants and recruitment*

Twelve licenced physiotherapists (PTs) from three different municipalities in Sweden conducted the assessments and interventions within the RCT. Four PTs performed the measurements single blindly, and eight PTs administered the treatment, of which five PTs administered the OEP treatment and three administered the MI treatment.

The participants were older community-living individuals seeking walking aid from health centres or seeking home care in a municipality that participated in the study (Table 1). Care managers, occupational therapists or physiotherapists in the three communities collaborated with the research team to recruit participants. Older individuals who fulfilled the inclusion criteria were invited to participate and were reported to the study leaders and then to the PTs. The eligibility criteria for study participation were as follows: being 75 years or older, being able to walk independently in their home and being able to understand written and oral information in the Swedish language. The exclusion criteria were as follows: a score less than 25 on the Mini Mental State Examination (MMSE), ongoing, regular physical therapy treatment due to injury and/or illness or being in terminal care. The study leaders contacted possible participants and patients who had given their consent, and those who met the study criteria were included and randomised by an independent PT. Forty-eight of the 96 eligible older people agreed to participate, but three of the 48 participants did not meet the criteria on the MMSE. Forty-five participants were included in the study: 16 individuals were randomised to the OEP group, 16 individuals were randomised to the MI group, and 13 were randomised to the control group (Fig. 1). There were no significant baseline differences between the three groups (Table 1). The median (min–max) age for the entire group was 83 years (75–96). The questionnaires for the feasibility procedure were analysed for all 45 participants for measurements and on 30 participants who were allocated to the treatment, OEP or MI

**Table 1**
Baseline characteristics.

| | Total n = 45 | OEP n = 16 | MI n = 16 | Control n = 13 | Analysis p-value |
|---|---|---|---|---|---|
| *Age median (min–max)* | 83.0 (75–103) | 82.0 (75–103) | 84.5 (77–92) | 81.0 (76–91) | .11 |
| *Gender, (%)* | | | | | .91 |
| Female | 32 (71) | 12 (75) | 11 (69) | 9 (69) | |
| Male | 13 (29) | 4 (25) | 5 (31) | 4 (31) | |
| *Education level* | | | | | .55 |
| Elementary school | 21 | 9 | 8 | 4 | |
| Secondary school/girl school | 6 | 2 | 4 | 4 | |
| High school/trade school | 7 | 2 | 4 | 1 | |
| University | 11 | 3 | | 4 | |
| *Marital status* | | | | | .85 |
| Married | 19 | 8 | 5 | 6 | |
| Unmarried | 4 | 1 | 3 | 7 | |
| Widowed | 21 | 7 | 7 | | |
| Cohabitation | 1 | | 1 | | |
| *Falls during the past year* | | | | | .60 |
| No | 30 | 12 | 9 | 9 | |
| Yes, 1 time | 7 | 2 | 4 | 1 | |
| Yes, 2–3 times | 8 | 2 | 3 | 3 | |
| *Walking aid* | | | | | .20 |
| No | 4 | 1 | 2 | 1 | |
| Yes | 21 | 15 | 14 | 12 | |
| *Help in daily living* | | | | | .29 |
| No | 27 | 11 | 8 | 8 | |
| Yes from relatives/friends | 10 | 5 | 3 | 2 | |
| Yes from home help services/private firm | 8 | | 5 | 3 | |
| *Activity level during the past six months* | | | | | .09 |
| Mostly sedentary | 13 | 3 | 7 | 3 | |
| Light physical effort | 27 | 12 | 9 | 6 | |
| More strenuous exercise 1–2 h/week | 5 | 1 | | 4 | |
| *Health condition, median (min–max)* | | | | | .99 |
| EQ5DVAS scale (0–100) | 65.0 (35–90) | 70.0 (40–80) | 62.5 (40–90) | 60.0 (35–90) | |

OEP = Otago Exercise Program, MI = Motivational Interviewing.