In Balans: the (cost-)effectiveness of the In Balans fall prevention training on falls and fall injuries in community-dwelling older adults with an increased risk of falls

Published: 10-02-2021
Last updated: 21-09-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52325

Source
ToetsingOnline

Brief title
In Balans

Condition

- Other condition

Synonym
age related decline and fall risk

Health condition

ouderdom en valrisico

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: (cost-)effectiveness, elderly, fall prevention, training program

Outcome measures

Primary outcome

The primary outcome measure is the number of falls (with and without injuries) and will be assessed using fall calendars and monthly telephone calls during the 12-month follow-up.

Secondary outcome

Secondary outcomes (assessed at baseline, at 4 months, and at 12 months) are divided into physical tests and questionnaires.

Physical tests:

- Balance measured with the 'Performance - Oriented Mobility Assessment - Balance', the 'Four Stage Balance Test' and the 'Timed Up and Go Test'

- Mobility measured with the 'Performance - Oriented Mobility Assessment - Mobility'

- Muscle strength measured with the 'Hand Grip Strength Test', the 'Timed Chair Stands Test' and the *Short Physical Performance Battery*

- Walking speed measured with the '10 Meter Walk Test '

- Aerobic endurance measured with the' 2-minute Step Test '

- Fall risk measured with the' LASA Fall Risk Questionnaire '

- Daily physical activity and gait based on data from movement monitors worn on the lower back for 1 week

Questionnaires:

- Overall health status assessed by means of the 'Short Form Health Survey - SF-36' and the 'Positive Health Inventory Tool'

- Self-determination assessed using the 'Pearlin Mastery Scale' and the 'General Self-Efficacy Scale'

- Fall anxiety assessed using the 'Falls Efficacy Scale International - FES-I'

- Confidence while walking assessed using the 'Modified Gait Efficacy Scale - mGES'

- Frailty assessed using the 'Groningen Frailty Indicator'

Demographic characteristics (assessed at baseline and at 12 months):
Age, sex, weight, marital status, level of education, use of medication (number), and presence of chronic disease.
The frailty status is determined based on the '5 Frailty Indicators': weight (loss), weakness, fatigue, slowness and low physical activity.

Moreover, we will ask for the number, of falls, the cause (behavioral, biological, environment), circumstances and consequences of falls (none, small, medium, large) during the 12 month follow-up using the fall calendar and monthly telephone calls

In order to determine cost-effectiveness (after 4, 8 and 12 months), we measure:

- Quality of life assessed using the 'EuroQol 5D' and the 'and the Adult social care outcomes toolkit (ASCOT)'

- Healthcare, patient and family costs assessed using the 'iMTA Medical Cost Questionnaire (iMCQ)

- Productivity costs assessed using the' iMTA Productivity Cost Questionnaire (iPCQ)

Study description

Background summary

Falls are the leading cause of injury in the elderly. Training in the form of a fall prevention program can reduce the risk of falls and injury. Moreover, a fall prevention program could increase self-confidence during walking. 'In Balans' is such a fall prevention program that is already being used.

One previous study, conducted in 2006, investigated the effectiveness of an 'In Balans' program of 20-weeks in elderly people living in a care home. This study found that participating in the 'In Balans' program resulted in a 61% reduction in the risk of falling in prefrail older people, but had no effect in frail older people. Currently, the duration of the 'In Balans' training is14 weeks and mainly particpated by non- and prefrail community-dwelling older adults. The effect of 'In Balans' in its current form has not yet been evaluated. Therefore, we want to investigate the (cost-)effectiveness of the 'In Balans' training in older adults living at home with an increased risk of falling.

Health insurance companies ask for proof of effectiveness in order to be able to decide whether the 'In Balans' program will be reimbursed or continue to be reimbursed. If the effectiveness of the 'In Balans' program is clear, paying parties will be more motivated to invest in 'In Balans'. This could enable more older adults to participate in and benefit from the 'In Balans' program in the future. Therefore, results of this study will help health care professionals, policymakers and paying parties to prevent falls in older adults in a timely and effective manner.

Study objective

The aim of this study is to investigate the (cost-)effectiveness of the 'In Balans' fall prevention program. We will research the effect of 'In Balans' on the number of falls, fall injuries, physical performance (including balance, strength and walking speed), physical activity, health and quality of life. We also want to examine the cost-effectiveness from a social perspective.

Study design

This study is a single-blind, multicenter randomized clinical trial (RCT) with 12 months of follow-up. Participants are stratified and randomized by their frailty score according to Fried et al.. These criteria are having a low body weight (BMI <18.5), low grip strength, fatigue (SF-36 vitality score <75), slow walking speed and low physical activity. If a participant does not meet any of these criteria, the participant is classified as non-frail. If a participant meets 1 or 2 criteria, the participant is classified as pre-frail. If a participant meets 3 or more criteria, the participant is classified as frail and will be excluded from the study. Participants are randomized according to their frailty status (1:2 pre-frail versus non-frail older adults in the intervention and control group).

Intervention

'In Balans' is a fall prevention program of 14 weeks that will be provided by a certified physiotherapist or remedial therapist who has followed a training program to become an 'In Balans' trainer. The 'In Balans' program is followed in a group with a maximum of 12 people. The first 4 weeks consist of 1 meeting per week in which information is given about the impact a fall can have on the subjects' life, the purpose of the 'In Balans' program, creating awareness about the subjects' fall risk and balance disturbances, how to deal with effective fall prevention methods and become familiar with the coming training weeks. The remaining 10 weeks consist of 2 meetings per week of 1 hour per meeting in which exercises aimed at balance, strength and mobility will be executed. These exercises are derived from the principles of Tai Chi.

The control group will receive written general recommendations on balance, strength and physical activity according to the Dutch guidelines for physical activity, drawed up in 2017.

Study burden and risks

As far as the researchers can assess, there are no risks associated with the study. The training program is harmless, but may cause discomfort. For example, participants may experience muscle pain when starting with the 'In Balans' program. This muscle pain normally lasts 1 to 2 days. Furthermore, the participants could experience discomfort when wearing the movement monitor. Moreover, the burden for the participants is low. The subjects who are assigned

to the intervention group follow the 14-week 'In Balans' fall prevention program that is provided by a certified physiotherapist or remedial therapist who has followed training to become an 'In Balans' trainer. The first 4 weeks of the 'In Balans' training consist of 1 meeting per week in which information is given about falls and fall prevention. The remaining 10 weeks consist of 2 meetings per week in which exercises aimed at balance, strength and mobility will be done. The control group receives written general guidelines on physical activity, drawed up in 2017. During the 12 months study, there are 3 measurement moments of approximately one hour per measurement moment, participants wear a movement monitor 3 times for 1 week and have a telephone conversation of approximately 15 minutes with 1 of the researchers once a month. It is important that the (cost-)effectiveness of the 'In Balans' program is investigated, because paying parties will then be more motivated to invest in the 'In Balans' program. This could enable more older adults to participate in and benefit from the 'In Balans' program in the future.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

65 years of age or older
Increased fall risk according to the fall risk assessment of VeiligheidNL
Able to read and understand Dutch
Being able to independently take care of themselves (e.g. going to the bathroom, dressing and undressing) and walk 100 meter
Classified as non- or pre-frail, based on the frailty criteria according to Fried et al.(body weight (BMI >18.5), grip strength, fatigue (SF-36 vitality score >75), walking speed and physical activity)

Exclusion criteria

Younger than 65 years of age
No increased fall risk according to the fall risk assessment of VeiligheidNL
Indications of serious cognitive problems (MiniMental State Examination <19 / 30)
Classified as frail according to the frailty criteria of Fried et al. having a low body weight (BMI <18.5), low grip strength, fatigue (SF-36 vitality score <75), slow walking speed and low physical activity)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2021

Enrollment:	256
Type:	Actual

Ethics review

Approved WMO Date:	10-02-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75305.028.20