

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26195

### Source

Nationaal Trial Register

### Brief title

In Balans

### Health condition

Ageing and fall risk

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Amsterdam

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

The number of falls (with or without injury) as assessed through fall calendars and monthly

telephone calls during 12 month follow up.

## Secondary outcome

Performance based physical functioning

- 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' and the 'Timed Chair Stands Test'
- 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 Pattern based on Inertial Sensors, worn on the lower back for the duration of a week

Questionnaires

- General Health Status with the "Short Form Health Survey - SF-36" and 'Positive Health Inventory Tool'
- Empowerment with the 'Pearlin Mastery Scale' and 'General Self-Efficacy Scale'
- Fear of Falling with the 'Falls Efficacy Scale International -FES-I'
- Walking Confidence with the 'Modified Gait Efficacy Scale -mGES'
- Causes (behavioural, biological, environmental), circumstances and consequences (none, minor, moderate, major) of falls occurring during follow up, with the fall calendar and monthly telephone calls.

Secondary economic outcome measures (assessed at M4, M8, M12) are:

- Quality of Life assessed with the 'EuroQol 5D'.
- healthcare, and patient and family costs: the iMTA Medical Cost Questionnaire (iMCQ) with a recall period of 4 months
- productivity costs: the the iMTA Productivity Cost Questionnaire (iPCQ) with a recall period of 4 months

Demographic measures are collected at M0 and M12:

Age, Sex, Height, Weight, Body Mass Index, Marital status, Living Situation, Education, History of Falls and Fall Injuries, Dizziness, Use of Walking Aids, Vision, History of Fall Prevention Programs, Physical Functioning, Physical Activity, Usage of Medication and Presence of Chronic Diseases.

Frailty Status will be assessed based on the 'Groningen Frailty Indicator- GFI' and '5 Frailty Indicators': weight (loss), weakness, exhaustion, slowness, low physical activity'.

## Study description

### Background summary

**RELEVANCE** – Falls and fall related injuries in our ageing population are a serious threat to life expectancy, quality of life and healthcare costs. Several fall prevention programmes (some with strong evidence for effectiveness) are available in the Netherlands, yet all use different approaches and aim at a different target groups. ‘In Balans’ is a 14-week, low-cost group intervention, that is widely used for a specific target population of pre-frail older adults with an increased risk of falling. The current status of effectiveness of ‘In Balans’ is ‘theoretically well described’, based on one positive effectiveness study in frail and pre-frail elderly living in nursing homes, who showed a strong reduction (61%) in risk of becoming a faller in the pre-frail older adults only. Now it is time to fill the knowledge gap on the (cost-)effectiveness of ‘In Balans’ in its current form, for an extended target group (pre-frail as well as non-frail individuals with an increased fall risk) in its current form. This will serve health care professionals, policy makers and financiers in timely and effective prevention of falls.

**OBJECTIVE** - To assess the (cost-)effectiveness of the falls prevention intervention ‘In Balans’ in community-dwelling older persons with an increased risk of falls, as compared to general exercise recommendations.

**STRATEGY** - We will perform a single-blinded, multicenter cluster randomized controlled trial (RCT) in 256 non- and pre-frail older adults with an increased risk of falls, with stratified randomization at the patient level, over 12 months of follow-up. Primary outcome is the number of falls (with and without injury), monitored over 12 months by a fall calendar and monthly phone calls. As secondary outcomes, we will evaluate the cost-effectiveness of ‘In Balans’ as compared to general exercise recommendations from a societal perspective, and the short- and long-term effects on physical performance, physical activity and perceived health and quality of life. Measurements will be performed at baseline (M0), immediately after the intervention (M4) and 12 months after after baseline (M12). Linear mixed-model analyses will be performed according to the intention-to-treat principle on the whole study population; with subgroup analyses to identify possible differences in intervention effects between non-frail and pre-frail respondents. An increase in physical activity is considered an important secondary outcome, but will also be used for secondary analyses to evaluate the effect of an increase in exposure on the number of falls.

**IMPLEMENTATION** - Based on the results and the process evaluation, we will develop a detailed implementation plan to ensure actual implementation of the project’s results as well as further dissemination.

## **Study objective**

Based on Faber et al. 2006, we expect that the effectiveness of ‘In Balans’ can be replicated and extended in a group of community-dwelling pre-frail and non-frail older adults with an increased risk of falls, with a significant reduction of the number of falls and injuries, lower costs, short-term improvement and long-term maintenance in physical performance, physical activity, perceived health and quality of life.

## **Study design**

Baseline, 4 months, 8 months and 12 months after start of the study

## Intervention

'In Balans' is a 14-week group exercise programme, with the aim to reduce falls by increasing awareness, balance and strength in older (pre-frail) individuals at risk of falling. The first four weeks include counseling and education meetings with topics regarding fall prevention. The last ten weeks contain two exercise meetings per week. Exercises are derived from principles of Tai Chi and mainly focused on balance and strength.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Inclusion criteria:

- community-dwelling older adults
- aged 65 years or older
- have an increased risk of falls according to the fall risk assessment (VeiligheidNL)

### Exclusion criteria

Exclusion criteria :

- are younger than 65 years of age
- have no increased risk of falls according to the fall risk assessment (VeiligheidNL)
- are not able to independently take care of themselves (e.g. going to the bathroom, dressing and undressing) and walk 100 meter
- are not able to read or understand Dutch
- have participated in a fall prevention program in the past 6 months
- have indications for severe cognitive impairment (MiniMental State Examination < 19/30)

- meet 3 or more out of 5 physical frailty criteria, according Fried et al. (2001) and as used by Faber et al. (2006):

- 1) Weight: Body Mass Index  $<18.5 \text{ kg/m}^2$  (as a measure for unintentional weight loss)
- 2) Weakness: Sex and body mass specific grip strength
- 3) Exhaustion: SF-36 vitality score  $< 75$
- 4) Slowness: sex and height specific gait speed
- 5) Low physical activity: SQUASH questionnaire

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	256
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	02-10-2020
Application type:	First submission

## 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
NTR-new	NL9248
Other	METC Brabant : P2055

## Study results