

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.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26195

Bron

NTR

Verkorte titel

In Balans

Aandoening

Ageing and fall risk

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of falls (with or without injury) as assessed through fall calendars and monthly telephone calls during 12 month follow up.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

'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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria:

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 ea. (2001) and as used by Faber ea. (2006):
 - 1) Weight: Body Mass Index <18.5 kg/m² (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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-03-2021

Aantal proefpersonen: 256

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-10-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9248
Ander register	METC Brabant : P2055

Resultaten