# Effect of a foot muscle strengthening program in mobile older adults

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To investigate the effect of adding PIFM strengthening exercises to a functional exercise program compared to a functional exercise program alone on maximum gait speed in mobile older adults. The secondary objective is to also investigate the effect...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

# Summary

### ID

NL-OMON51601

**Source** ToetsingOnline

Brief title STIFF RCT

### Condition

• Other condition

#### Synonym

n/a

### **Health condition**

geen aandoening

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Fontys Hogescholen Source(s) of monetary or material Support: NWO

### Intervention

Keyword: Exercise training, Foot muscles, Mobility, Older adults

### **Outcome measures**

#### **Primary outcome**

The post-intervention difference between the intervention and control group in maximum gait speed.

#### Secondary outcome

The post-intervention difference between the intervention and control group in

foot muscles\* size, foot function during gait, balance during gait, discomfort

during or after the training, self-reported mobility limitations, physical

activity level, fall incidents during the intervention, fear of falling, foot

plantar pressure during gait, static balance, toe flexor strength, physical

functioning, foot morphology, foot posture.

# **Study description**

#### **Background summary**

Falling is highly prevalent among older adults and has serious societal impact. Falls occur mainly during walking as a result of altered gait and/or the inability to maintain balance. The plantar intrinsic foot muscles (PIFM) have a role in these dynamic functions. When these muscles atrophy, as happens with advancing age, strengthening these muscles may be beneficial in order to improve or retain gait performance.

### **Study objective**

To investigate the effect of adding PIFM strengthening exercises to a functional exercise program compared to a functional exercise program alone on maximum gait speed in mobile older adults. The secondary objective is to also investigate the effect on: foot muscles\* size, foot function during gait, balance during gait, discomfort during or after the training, self-reported mobility limitations, physical activity level, fall incidents during the intervention, fear of falling, foot plantar pressure during gait, static balance, toe flexor strength, physical functioning, foot morphology, foot posture.

### Study design

An investigator-blinded parallel RCT, with a 12-week PIFM strengthening intervention period and pre- and post-intervention laboratory measurements.

#### Intervention

Both the control and the intervention group continue with the regular functional exercise program. On top of this, the intervention group is delivered a 12-weeks exercise program consisting of foot strengthening exercises prescribed for 5 daily sessions a week, of which 1 supervised, 20 minutes per session.

### Study burden and risks

The burden for the participant consists mainly of 1) the time spent and effort put in engaging in the exercise therapy, 2) any discomfort (e.g., fatigue) or pain (e.g., cramp, muscle soreness) during or after the exercises, 3) the time that is spent on the measurement occasions (home visits:  $1 \times 1$  hour (+  $1 \times 30$ minutes for the intervention group); laboratory:  $2 \times 3$  hours), 4) the necessity of travelling to the motion analysis laboratory, 5) the inconvenience of wearing the activity monitor attached to the skin of the thigh for 7 days, and 6) questionnaires may unintentionally make the subject aware of declined health conditions.

# Contacts

#### **Public** Fontys Hogescholen

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Fontys Hogescholen

Dominee Theodor Fliednerstraat 2 Eindhoven 5631 BN NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Elderly (65 years and older)

### **Inclusion criteria**

In order to be eligible to participate in the study, a respondent must:

- be 65 years of age or over;

- be able to ambulate 10 meter without using a walking aid;

 engage in a functional exercise program (e.g. gymnastics, senior fit programs), delivered by an educated or certified physical therapist or trainer to a group of older adults;

- report to have 1) fear of falling OR 2) experienced a fall in the previous 12 months OR 3) difficulties with mobility, gait, or balance;

- be able to arrange their own transport to the movement analysis laboratory.

### **Exclusion criteria**

A respondent who meets the following criteria is excluded from participation in this study:

- The respondent is a minor or legally incompetent adult;

- Self-reported presence of any disorder interfering with the execution of the exercises.

# Study design

# Design

Masking:	Open (masking not used)
Allocation:	Randomized controlled trial
Intervention model:	Parallel
Study type:	Interventional

Primary purpose: Prevention

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	10-10-2022
Enrollment:	58
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	26-04-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	22-11-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

# **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** ClinicalTrials.gov CCMO

ID NCT05531136 NL80110.015.21