

# FIT-study.

No registrations found.

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

## Summary

### ID

NL-OMON21831

### Source

NTR

### Brief title

FIT

### Health condition

Functional loss among people 70 years and older, expressed as loss of (instrumental) activities of daily living.

- geriatric assessment
- frail elderly
- public health nursing
- activities of daily living
- geriatrisch onderzoek
- kwetsbare ouderen
- zorgcoördinatie door praktijkverpleegkundige
- activiteiten van het dagelijks leven

## Sponsors and support

**Primary sponsor:** Academic Medical Centre Amsterdam/  
University of Amsterdam

**Source(s) of monetary or material Support:** ZonMW, national program of care for the older patients, grant no: 60-61900-98-270

## Intervention

## Outcome measures

### Primary outcome

The level of (instrumental) activities of daily living, measured with the modified Katz ADL (15) index score.

### Secondary outcome

1. Hospital and nursing home admissions;
2. Self-reported health care utilization;
3. Quality of life (EQ-6D);
4. Overall mortality.

## Study description

### Background summary

Background:

In old age, reduction in physical function leads to loss of independence, the need for hospital and long-term nursing-home care, and premature death.

Community-based complex interventions can be effective in maintaining physical function and independence in elderly people.

Study design:

A multicenter, cluster randomized clinical trial at the level of the General Practitioner (GP) comparing a pro-active, multi-component (multidisciplinary and multidimensional) intervention, coordinated by a Health Care Nurse (HCN) specialized in elderly care with care as usual.

Study population:

Community-dwelling elderly people 70 years and older with an increased risk for functional decline.

#### Intervention:

First, all eligible elderly people who are registered with their GP will be sent a postal questionnaire, the Identification of Seniors at Risk in Primary Care (ISAR-PC), that was developed during a pilot study. In half of the GP practices, patients with increased risk for functional decline will be invited to receive a nurse-led comprehensive geriatric assessment (CGA). In the CGA, participants will be screened for over 30 conditions on four domains (physical, functional, mental, social functioning) that are most prevalent among elderly people. The targeted problems are part of an evidence based protocol ('toolkit') that was developed in the Defence-study ([www.defencestudy.nl](http://www.defencestudy.nl)) and further extended in a pilot phase of the FIT-study, and yields a care and treatment plan that is discussed with both patient and GP. When consensus is reached on the intervention, the HCN will coordinate all care and treatment contacts and will frequently see all participating elderly in the office or at home to monitor the effects of all interventions.

#### Main study parameters/endpoints:

The main outcome is the the level of (instrumental) activities of daily living, measured with the modified Katz ADL index score. Secondary outcomes include hospital and nursing home admissions, self-reported health care utilization and quality of life (EQ-6D) and overall mortality.

### **Study objective**

In old age, reduction in physical function leads to loss of independence, the need for hospital and long-term nursing-home care, and premature death.

Community-based complex interventions can be effective in maintaining physical function and independence in elderly people.

### **Study design**

Primary endpoint at 12 months, secondary endpoints at 6, 12, 18 and 24 months.

### **Intervention**

A nurse-led comprehensive geriatric assessment (CGA) in patients at increased risk for functional decline (2 or more points on the ISAR-PC score), a tailor-made care and treatment plan, and seven follow-up contacts during one year.

## Contacts

### **Public**

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### **Scientific**

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## Eligibility criteria

### **Inclusion criteria**

Phase 1 (general screening):

1. Patients aged 70 years and older.

Phase 2 (intervention):

1. An increased risk for functional decline, defined as a score of two or more on the ISAR-PC screening instrument;
2. Speaks and understands Dutch;
3. Patient is registered with a GP.

## Exclusion criteria

1. Terminal illness;
2. Dementia;
3. Does not speak or understand Dutch;
4. Living in a nursing home.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	1418
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	17-12-2010
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 NL2535

NTR-old NTR2653

Other MEC Academic Medical Center Amsterdam - University of Amsterdam : 10/182

ISRCTN ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A