FIT-study.

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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...

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

Samenvatting

ID

NL-OMON21831

Bron
Nationaal Trial Register

Verkorte titel
FIT

Aandoening

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
- zorgcoordinatie door praktijkverpleegkundige
- activiteiten van het dagelijks leven

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam/
University of Amsterdam
Overige ondersteuning: ZonMW, national program of care for the older patients, grant no:

60-61900-98-270

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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) 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Terminal illness;

2. Dementia;

3. Does not speak or understand Dutch;

4. Living in a nursing home.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2010
Aantal proefpersonen:	1418
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2010
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	NL2535
NTR-old	NTR2653
Ander register	MEC Academic Medical Center Amsterdam - University of Amsterdam : 10/182
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A