The Social Fitness Study

Gepubliceerd: 23-12-2013 Laatst bijgewerkt: 18-08-2022

Enrolment in the Social Fitness programme improves participants' performance and satisfaction with meanungful social activities, their quality of life, patients’ mobility, caregivers’ sense of competence and a decreases resource utilization.

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

Samenvatting

ID

NL-OMON24186

Bron
NTR

Verkorte titel
n/a

Aandoening

dementia, memory problems, caregivers, social participation, psychosocial intervention, occupational therapy, physiotherapy, welfare/
dementie, geheugenproblemen, mantelzorgers, sociale participatie, psychosociale interventies, ergotherapie, fysiotherapie, welzijnswerk.

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Radboud Univerisity Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is patients' and caregivers' participation in meaningful social

activities, assessed with the performance and satisfaction rating of the Canadian Occupational Performance Measurement (COPM).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Social exclusion is a common problem among community-dwelling older people with dementia and their caregivers, and it can result in serious health consequences. In contrast, social inclusion is one of the four central themes for good quality of person centred care in dementia in Europe. Studies on effectiveness of person centred programmes on improving social participation in meaningful social activities are scarce.
Objective: The main objective of this study is to evaluate the effectiveness of a newly developed interdisciplinary tailor-made social fitness programme on the participation in meaningful social activities of community-dwelling older people with dementia and their caregivers (dyads). In addition, cost analyses will be performed.
Study design: A single blinded randomised controlled trial with randomisation at individual dyad level.
Study population: 92 community-dwelling older people with (signs of) dementia and their caregivers, with goals to maintain or to improve their social participation or to reduce feelings of loneliness.
Main study parameters/endpoints: The primary outcome measure is patients' and caregivers' participation in meaningful social activities, assessed with the performance and satisfaction rating of the Canadian Occupational Performance Measurement (COPM).

Doel van het onderzoek

Enrolment in the Social Fitness programme improves participants' performance and satisfaction with meanungful social activities, their quality of life, patients’ mobility, caregivers’ sense of competence and a decreases resource utilization.

Onderzoeksopzet

Participants who fulfil inclusion criteria receive a baseline assessment (to), a measurement after three months (t1), and a final measurement after six months (t2).

Onderzoeksproduct en/of interventie

In the experimental group, patients and their caregivers will receive treatment and guidance according to the newly develloped Social Fitness Programme (SFP). SFP contains up to two interdisciplinary professional home visits a week during 3 months: an occupational therapist (OT) performs the COTiD-program, a physiotherapist (PT) performs the Coach2Move protocol and elderly advisors from a welfare organisation stimulate and guide dyads to participate in social activities. Dyads in the control group receive usual care.

Contactpersonen

Publiek

Radboud UMC
Hanneke Donkers
Nijmegen
The Netherlands
-

Wetenschappelijk

Radboud UMC
Hanneke Donkers
Nijmegen
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible participants for this study meet all of the following criteria:
- Home dwelling patients with dementia diagnosis (MMSE ≥10); or home dwelling patients with memory problems signaled by the referring professional (MMSE 10-24); or home dwelling patients with memory problems and with high intelligence or high levels of education resulting in an MMSE-score between 25 and 30, with a primary caregivers' score of ≥3.6 on the IQCODE-N.
- Who have a caregiver who is available for informal support at a minimum of one time a week.
- The patient and caregiver wish to maintain or improve their level of social participation, or to decrease their feelings of loneliness.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No goals in total (patient and caregiver together) for social participation.

2. People who are not capable of completing the self assessment forms.

3. Co-morbidity with symptoms that interfere with actively taking part in the intervention

4. Not stable use (< 3 months on the same dose) of medication which influences cognition

5. Palliative phase of illness

6. Acute illness with hospital indication

7. Current participation in other health research

8. Received physiotherapy according to the Coach2Move protocol in the last 6 months.

9. Received occupational therapy according to the COTiD-programme in the last 6 months.

10. No financial possibilities to receive occupational therapy

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	92
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-12-2013
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	NL4196
NTR-old	NTR4347
Ander register	- : n/a
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A