The Social Fitness Study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24186

Source
NTR

Brief title
n/a

Health condition

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

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Radboud Univerisity Medical Center

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Patients' and caregivers' quality of life (DQoL) and health related quality of life (EQ-5D); patients’ mobility (TUG), caregivers’ sense of competence (SCQ); resource utilization (RUD 4.0) and socio-demographics. Patients' frailty is measured as a covariate (EFIP).

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Radboud UMC
Hanneke Donkers
Nijmegen
The Netherlands
-
Scientific
Radboud UMC
Hanneke Donkers
Nijmegen
The Netherlands
-

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	92
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-12-2013
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	NL4196
NTR-old	NTR4347
Other	- : n/a
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A