What is the effectiveness of a tailor-made social fitness program for community dwelling older people with dementia and their caregivers?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON38527

Source
ToetsingOnline

Brief title
Social fitness study

Condition

- Cognitive and attention disorders and disturbances
- Age related factors

Synonym
social inclusion, social participation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Alzheimer Nederland

Intervention

Keyword: dementia, psychosocial intervention, quality of life, social participation

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

Secondary outcomes include: 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-lite) and socio-demographics. Patients' socio-demographics and frailty (EFIP) are measured as a covariate.

Study description

Background summary

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.

Study 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 blind randomised controlled trial with randomisation at individual dyad level.

Intervention

In the experimental group, patients and their caregivers will receive treatment and guidance according to the newely developed 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. On demand, this guidance by the elderly advisors is also possible after 3 months of intervention. Dyads in the control group enrol on a waiting list. They can receive delayed SFP following their last assessment (after 6 months).

Study burden and risks

Treatment according to the SFP does not entail more risk compared to usual care. Clients will only be included if they experience problemsn in social participation and if they have goals they can work on during treatment. Data show that persons with dementia can be considered good informants of their own subjective states (Brod et al., 1999). Participants who fulfil inclusion criteria receive a baseline assessment (to), a measurement after three months (t1), and a final measurement after six months (t2). Measures are assessed during home visits, separately with the patient (face to face) and caregiver (face to face, and using questionnaires). The caregiver can fill in the questionnaires during the face to face assessments with the patient. The total expected time of the first (baseline) home visit is 135 minutes: 10 minutes for the informed consent procedure, 10 minutes to check in- and exclusion criteria (i.e. MMSE-score if not available), and 75 minutes for the face to face measures with the patient and 40 minutes for the face to face measures with the caregiver. It will take the caregiver approximately 35 minutes to fill in the questionnaires. At t1 and t2 the face to face measures with the patient will take 45 minutes; the face to face measures with the caregiver will take 10 minutes; and it will take caregivers approximately 30 minutes to fill in the questionnaires. Resource utilization will additionally be assessed using a ten minute telephone interview with the caregiver at 1.5 month and 4.5 month after

baseline measurement. The results of the baseline measurement (interview and questionnaires) are also relevant for the occupational therapist (COPM) and physiotherapist (EFIP and TUG). After consent these data will become available to the participating therapists, to minimise the burden of the clients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Home dwelling patient with memory problems (MMSE 10-24);
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.
Both the patient and the caregiver signed the informed consent form.

Exclusion criteria

1. No goals in total (patient and caregiver together) for social participation, assessed during the screening interview using the COPM.
2. People who are not capable of completing the self assessment forms (i.e. due to language problems).
3. Co-morbidity with symptoms that interfere with actively taking part in the intervention (e.g BPSD, severe heart condition).
4. Unstable use (<3 months) 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 (i.e. because OT has already been received in the last calendar year).

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2014
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL45393.091.13