Research protocol

Effectiveness of community occupational therapy in dementia patients and their primary caregivers

December 27th, 2000

Effectiveness of community occupational therapy on the daily performance of geriatric patients with dementia and on the sense of competence of their primary caregivers
1. BACKGROUND

Dementia has far-reaching consequences for patients and their informal caregivers. Major problems associated with dementia are patients' loss of independence, initiative, and participation in social activities. These problems decrease the autonomy, daily functioning, social participation and quality of life of dementia patients and put pressure on both family relationships and friendships. Two third of dementia patients is cared for at home by informal caregivers (Dutch Health Council, Gezondheidsraad, 2000). Dementia care at home is intensive and burdensome (Jepson et al., 1999). Indeed, caregivers often experience feelings of helplessness, social isolation, and loss of autonomy (Coen, 1998, Jepson, 1999).

The central health care problem addressed in this study is that, so far, dementia care is focussing on patient directed hospital and nursing home care, and no systematic care or training is given at home to both dementia patients and informal caregivers, which is both highly inefficient and denies the serious problems in activities of daily living and quality of life of these patients and their informal caregivers.

It was found that caregivers of dementia patients experienced higher levels of burden than caregivers of other chronically ill patients (Draper et al., 1992). Overburdened caregivers have a high depression risk (Burns, 2000). Support by information, advice, practical support and counselling is required to prevent caregivers from being overburdened and depressed (Vernooij-Dassen, 2000).

Currently, occupational therapy for dementia patients and their informal caregivers is given at home, according to a consensus based guideline (Melick & Graff, 1998, 2000; Graff & Melick, 2000). The primary focus of occupational therapy in dementia is to improve patients' ability to perform activities of daily living and hence promote independence and participation in social activities and to reduce the caregiver burden, by increasing caregivers' sense of competence and ability to handle the behavioural problems they encounter (Corcoran, 1992, Burgener, 1998, Graff, 2000, Melick & Graff, 1998, 2000).

In an uncontrolled pilot study (Graff, 1998, 2000), we found improvements on the daily functioning of dementia patients after community occupational therapy intervention and a decreased need for assistance in activities of daily living and
improved sense of competence of their informal caregivers. The occupational intervention was a comprehensive community occupational therapy intervention using this consensus based guideline directed at dementia patients and their informal caregivers (Melick & Graff, 1998, 2000; Graff & Melick, 2000). This comprehensive occupational therapy intervention consisted of 10 1-hour sessions held over 5 weeks and focused on both patients and their primary caregivers, including cognitive and behavioural interventions, used to train patients in the use of aids in activities of daily living to compensate for cognitive decline and caregivers in coping behaviours and supervision. Similar results as in this pilot study were found in a study of community occupational therapy in dementia patients and their informal caregivers of Burgener (et al., 1998).

To determine if this comprehensive consensus based occupational therapy intervention is effective or not, a randomized controlled trial should be developed to determine the effects of this community occupational therapy intervention on the daily performance and need for assistance of the patients and the sense of competence of their primary caregivers.

2. **RESEARCH QUESTION**

Our hypothesis is, that this comprehensive community occupational therapy intervention improves the daily functioning and decreases the need for assistance in daily activities of dementia patients and improves the sense of competence of their informal primary caregivers.

*The research question is:*

"What are the effects of community occupational therapy on the process skills in performing daily activities of dementia patients and on their need for assistance and what are the effects on the sense of competence of their primary caregivers?"

Other and secondary research questions are: what are the effects of this occupational therapy intervention on the motor skills and initiative of the patients and on the mood, quality of life and health status of both patients and informal caregivers and sense of mastery of the caregivers? “
3. RESEARCH DESIGN

A prospective single blind randomised controlled clinical trial will be conducted. The intervention group will receive 10 sessions occupational therapy during 5 weeks of one hour duration. The control group will be the group on hold and receives usual care which includes no occupational therapy. After measurements are finished, after 3 months, the same occupational therapy intervention will be given to the control group. Both groups receive the same measurements at the same measurement moments:

1) at t0: at baseline, before intervention
2) at t1: directly after intervention, at 6 weeks
3) at t2: at follow-up, after 3 months after baseline

3.1 Patients

100 patients with mild to moderate dementia are needed using a power of 0.8 and an alpha of 0.05, to determine the effects of this intervention on the primary outcome variables. The power analysis (Graff, 1999) was computed on the outcomes of the pilot study (Graff, 1998). Based on a drop-off percentage of 26% in the pilot study, we will include 135 patients for this study to follow at least 100 patients and their informal caregivers (50 in the intervention group and 50 in the control group) at all measurement moments.

Inclusion criteria
Patients with mild to moderate dementia (MMSE score 10-24, Camcog <79/80 & DSM IV criteria for dementia), who are living at home and who have an informal caregiver who cares for the patient at least once a week.

Diagnostics of dementia will be carried out by a geriatrician using the DSM IV criteria, including the MMSE and CAMCOG. Patients with different kinds of dementia will be included because the occupational therapy intervention is based on the same client centered guideline for all patients with mild to moderate dementia.
**Exclusion criteria**

Patients are excluded in case of: severe dementia, depression (GDS >12), severe behavioral or psychological symptoms in dementia (BPSD), severe illnesses at time of inclusion, no motivation or goals for occupational therapy intervention.

Depression, severity of BPSD and illnesses will be measured or judged by a geriatrician.

**Stop criteria**

1) Severe BPSD or illnesses
2) Admission into hospital or nursing home
3) No motivation for participation in the study

### 3.2 Recruitment

Geriatric patients with mild to moderate dementia of the memory clinic and geriatric department of the UMCN meeting the inclusion criteria will be recruited. General practitioners and home care offices will be informed about this study and advised to refer patients for screening and occupational therapy intervention to the memory clinic.

**Informed consent**

At the memory clinic and geriatric department patients and their informal primary caregivers will receive verbal and written information from the geriatrician and the researcher about the contents of the occupational therapy intervention, the study protocol, the randomisation of the patients over the two groups and the study procedures, like duration of the measurements, kind of observations and questionnaires assessed. Written informed consent and full agreement with the contents and procedures of the study must be received from both patients and primary caregivers, before participation in the study is allowed.
3.3 Randomisation and procedures

Patients will be stratified into two groups: a group with patients with mild dementia (Brief Cognitive Rating Scale, BCRS, Muskens, 1993, BCRS score 9-25) and the other with patients with moderate dementia (BCRS score 25-40). Per stratum, patients will at random be allocated to the intervention and control group, based on a block randomisation procedure carried out by an independent statistician. The researcher and research assistant are blinded for the allocation of the patients. This allocation procedure will be carried out with sealed envelopes that will be opened by an independent secretary. Patients of the intervention group receive occupational therapy intervention directly after randomisation, those of the control group receive the same intervention after 3 months. The researcher and research assistant are not informed and visit all patients with their primary caregivers directly after randomisation for baseline measurements at patients’ homes. The independent secretary will plan the first occupational therapy visit in the diary of the occupational therapist after the patients have completed the baseline measurements with the researcher or research assistant. This first occupational therapy visit will be within one week after baseline measurement or after 3 months after baseline measurement. Second measurement (T1), the effect measurement, will be after 6 weeks after baseline and this will be directly after the occupational therapy intervention is completed or after 6 weeks of no occupational therapy intervention in the control group. One week before this effect measurement, patients and informal caregivers will be sent written information in which they are asked not to tell the researcher or research assistant if they had received occupational therapy or not. At the start of the effect measurement the researcher also repeats this information about not informing them. The last measurement will be after 3 months after baseline (T2) and is the follow-up measurement. A check about the blinding of the researcher and research assistant will be carried out after each measurement by asking the researcher and assistant to respond the question if they have an idea to what group this patient was allocated.

The study protocol is approved by the medical ethics committee of the UMCN number CWOM0012-0292.
3.4 Occupational therapy intervention

The occupational therapy treatment will consist of 10 sessions of 1 hour duration held over 5 weeks and will be focused on both patients and their primary caregivers. The intervention is directed at the improvement of skills of the patients and of the primary caregivers. In the first four sessions of diagnostics and goal defining, patients and primary caregivers learn to choose and prioritize meaningful activities they want to improve. Therefore, the occupational therapist will use three client-centred narrative interview instruments: the Occupational Performance History Interview directed at the patient; the ethnographic interview for the primary caregiver and the Canadian Occupational Performance Measure (COPM) for both the patient and primary caregiver. The occupational therapist will evaluate the possibilities to modify patients’ homes and environment, observes patient’s ability to perform relevant daily activities and uses compensatory and environmental strategies. Compensatory strategies will be used to adapt activities of daily living to the disabilities of the patients, and environmental strategies will be used to adapt the patients’ environment to their cognitive disabilities. The primary caregivers’ supervision skills will also be observed. In the occupational therapy treatment phase that consists of six treatment sessions, patients will be taught to optimize these compensatory and environmental strategies to improve their performance of daily activities. Primary caregivers will receive practical and emotional support. They will be trained, by means of cognitive and behavioural interventions, to use effective supervision, problem-solving, and coping strategies to sustain patients’ and their own autonomy and social participation. For a detailed description of the intervention, see Melick & Graff, 1998, 2000; Graff & Melick, 2000).

3.5 Outcome assessments and measures

Patients and their primary caregivers will be assessed at baseline directly after randomisation (T0), at 6 weeks directly after the intervention group is completed (effect measurement, T1) and after 3 months after baseline (follow-up measurement).
**Primary outcome measures**

THE ASSESSMENT OF MOTOR AND PROCESS SKILLS (AMPS, FISHER, 2000)
The process scale of the AMPS, the AMPS process, will be used as a primary outcome measure of the patients’ daily performance. With this scale process skills in performing daily activities are observed in two activities of daily living the patient is used to. Scores range from -3 to 4 (higher scores indicate better process skills).

THE INTERVIEW OF DETERIORATION IN DEMENTIA (IDDD, Teunisse, 1997)
The performance scale of the IDDD, will be used as the other primary outcome measure of the patients’ daily performance. It is a questionnaire assessed at the primary caregiver about the need for assistance in 11 activities of daily living of the patients. Scores range from 0 to 44 (lower scores indicate less need for assistance).

THE SENSE OF COMPETENCE QUESTIONNAIRE (SCQ, Vernooij-Dassen, 1996)
The primary caregiver primary outcome measure outcome will be sense of competence assessed with the SCQ. It is a questionnaire of 27 items. Scores range from 27 to 135 (higher scores denote a greater sense of competence).

**Secondary outcome measures**

THE MOTOR SCALE OF THE ASSESSMENT OF MOTOR AND PROCESS SKILLS (AMPS motor, FISHER, 2000)
The AMPS motor, will be used to measure the patients’ motor skills in performing daily activities. In two familiar daily activities the motor skills of the patients will be observed. Scores range from -3 to 4 (higher scores indicate better motor skills).

Quality of life of the patients and primary caregivers will be assessed with the DQOL. The questionnaire is directed at the client and can be used for both the patients’ and for the caregivers’ quality of life. We will use the instrument to evaluate the patients.
and the caregivers’ quality of life. It is divided into 3 categories and 6 subscales: A) Aesthetics (scores from 5-25); B) frequency of feelings: B1: positive affect (5-30); B2: negative affect (5-55); B3: self esteem (5-20); B4: feelings of belonging (5-15); and C) overall quality of life (1-5) (higher scores indicate better quality of life, except for subscale B2).

GENERAL HEALTH QUESTIONNAIRE (GHQ-12, Goldberg, 1988, in Dutch: Koeter, 1991)
Health status of the patients and of the caregivers will be assessed with the GHQ-12. The questionnaire contents of 12 items and scores range from 0-36 (lower scores indicate a better health status).

CORNELL SCALE FOR DEPRESSION (CSD, Alexopoulos, 1988; Dutch version: Droës, 1992)
Mood of the patients will be assessed on their caregivers with the CSD. Scores range from 0-38 (lower scores indicate less depressive characteristics).

CANADIAN OCCUPATIONAL PERFORMANCE MEASUREMENT (COPM, Law 1994; Dutch version Duijn et al., 1998)
The self-perception in occupational performance of the patients and of the caregivers will be assessed by the COPM. With this instrument 5 problem areas in daily functioning can be defined and judged by the patients or caregivers. They judge their own level of performance and their satisfaction with this performance by giving notes from 0 to 10 for the performance and for their satisfaction with this performance on each problem area.

CENTER FOR EPIDEMIOLOGIC DEPRESSION SCALE (CES-D, Beekman, 1994, 1997, Radloff, 1977)
Mood of the caregivers will be assessed with the Center for Epidemiologic Depression Scale (CES-D, Beekman, 1994, 1997, Radloff, 1977), in which scores range from 0-60 (lower scores indicate less depressive complaints).

MASTERY SCALE (Smits, 1998)
Caregivers’ sense of mastery will be assessed with the Mastery Scale in which scores range from 5-25 (lower scores indicate a better sense of mastery).

Coping skills of the primary caregivers in dealing with the stress caused by the caring for patients with dementia will be measured by the JCS of 60 items. Scores range from 0 to 180. The questionnaire is divided into 7 coping styles: analyzing, finding support, avoiding, optimistic attitude, fatalistic attitude, finding diversions of the mind, expression of feelings. The higher the score, the better use of coping strategies.

Control measures

Information on age, sex, educational level of the patient and caregiver and information on caregiver’s relationship to the patient will be collected at baseline and used as control measures or covariates in the analyses. Other control measures will be:

CUMULATIVE ILLNESS RATING SCALE FOR GERIATRICS (CIRS-G, ) (Miller, e.a., 1991)
Information on patients’ co-morbidity will be assessed with the CIRS-G. The CIRS-G contents of 14 categories of organ systems. Each category contents illnesses that must be judged and scored by a medical doctor and all categories should be summarized for the total score on this instrument.

THE GERIATRIC DEPRESSION SCALE (GDS, Brink, 1982; Kok, 1994)
To determine depression the GDS will be used. The GDS is a screeningsinstrument for depression in geriatric patients. The GDS will be assessed by the geriatrician at baseline. Scores above 12 indicate depression. The lower the score the better and less depressive complaints.

THE MINI MENTAL STATE EXAMINATION (Folstein, 1975)
The MMSE will be assessed to examine the memory of the patient by a geriatrician. The higher the score the better the memory of the patient.

THE REVISED MEMORY AND BEHAVIORAL PROBLEMS CHECKLIST (RMBPC, Teri et al, Dutch version, Teunisse, 1997)

Behavioral problems and memory will be assessed with the RMBPC. There are two scales: frequency and irritation of behavior of each 23 items. The frequency scale ranges from 0 to 92, the irritation scale from 0 to 69. The higher scores on the frequency scale the more behavioral problems and the higher scores on the irritation scale the more irritation the caregiver experiences as a reaction on the behavioral problems of the patient.

3.6 Statistical analysis

For the data-analysis SPSS for windows will be used. The main effect of the study will be determined by analyses of covariance of the primary outcome measures (AMPS process, IDDD performance, and SCQ at 6 weeks) based on an intention-to-treat analysis of all available data, applying the last observation carried forward method for drop-outs. Treatment differences between baseline and 6 weeks will be computed by analysis of covariance, with age, sex, relation to patient, other caregivers and baseline scores on the MMSE, GDS, CIRS-G, RMBPC, and outcome variable at baseline as covariates. Secondary analyses will be done with the primary outcome measures at 12 weeks (conditional analysis, only in case of positive effects at 6 weeks). The study is powered to detect a clinically relevant difference in change over time of 0.5 points on the AMPS process scale between the intervention and control groups, 20% improvement on the IDDD performance scale, and a 5-point difference on the SCQ, with a power of 80% on the basis of one-sided testing and n ≥100. The power calculation was based on pilot data (Graff, 1998), and on the minimal clinically relevant differences in the primary outcomes as defined in the AMPS measurement guideline, which describes 0.5 points as clinically relevant and the IDDD measurement guideline, which describes 20% improvement as clinically relevant difference. We will test one-sided, because we found in our pilot study highly significant improvements after occupational therapy at a significance level of 5%.
Per-protocol-analyses will also be carried out. The treatment effect sizes will be computed as: \( d' = \frac{\Delta E}{s_{d_r}} \) (\( \Delta E \) = the adjusted treatment effect, \( s_{d_r} \) = the residual standard deviation).
### CONSORT Checklist of items to include when reporting a randomized trial

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