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Community based occupational therapy for patients with dementia and their care givers: randomised controlled trial

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Abstract

Objective To determine the effectiveness of community based occupational therapy on daily functioning of patients with dementia and the sense of competence of their care givers.

Design Single blind randomised controlled trial. Assessors were blinded for treatment allocation.

Setting Memory clinic and day clinic of a geriatrics department and participants' homes.

Participants 135 patients aged ≥ 65 with mild to moderate dementia living in the community and their primary care givers.

Interventions 10 sessions of occupational therapy over five weeks, including cognitive and behavioural interventions, to train patients in the use of aids to compensate for cognitive decline and care givers in coping behaviours and supervision.

Main outcome measures Patients' daily functioning assessed with the assessment of motor and process skills (AMPS) and the performance scale of the interview of deterioration in daily activities in dementia (IDDD). Care giver burden assessed with the sense of competence questionnaire (SCQ). Participants were evaluated at baseline, six weeks, and three months.

Results Scores improved significantly relative to baseline in patients and care givers in the intervention group compared with the controls (differences were 1.5 (95% confidence interval 1.3 to 1.7) for the process scale; -11.7 (-13.6 to -9.7) for the performance scale; and (11.0; 9.2 to 12.8) for the competence scale). This improvement was still significant at three months. The number needed to treat to reach a clinically relevant improvement in motor and process skills score was 1.3 (1.2 to 1.4) at six weeks. Effect sizes were 2.5, 2.3, and 1.2, respectively, at six weeks and 2.7, 2.4, and 0.8, respectively, at 12 weeks.

Conclusions Occupational therapy improved patients' daily functioning and reduced the burden on the care giver, despite the patients' limited learning ability. Effects were still present at 12 weeks, which justifies implementation of this intervention.

Trial registration Clinical Trials NCT00295152.

Introduction

Dementia has far reaching consequences for patients and their primary care givers and is currently a major driver of costs in health care and social systems in developed countries.¹ Major problems are the losses in independence, initiative, and participation in social activities, decreasing the quality of life of patients and putting pressure on both family relationships and friendships. Care givers often experience feelings of helplessness, social isolation, and loss of autonomy.²⁻⁴ Unfortunately,

drugs are not yet effective in improving the symptoms of dementia, and non-pharmacological strategies are generally more time consuming and not widely available. A systematic review found non-pharmacological interventions to produce effect sizes in behaviour similar or larger to those seen with cholinesterase inhibitors, the currently available drug treatment, but without any side effects.⁵ Occupational therapy is also said to be effective in dementia.⁶⁻⁹ The primary focus of such a therapy is to improve patients' ability to perform activities of daily living and hence promote independence and participation in social activities^{4 7 9} and to reduce the burden on the care giver by increasing their sense of competence and ability to handle the behavioural problems they encounter.^{4 6-10} These outcomes are increasingly being considered equally or even more clinically relevant than measures of cognitive outcome.¹¹

Earlier studies have shown community occupational therapy given in the home can improve the functional independence of patients with dementia and decrease the burden on the care giver.⁶⁻⁹ We considered that community based occupational therapy in dementia would improve patients' daily functioning and care givers' sense of competence. As a systematic review questioned the methods of these earlier studies¹² we conducted a randomised controlled trial to study the effects of community based occupational therapy on the daily functioning of patients with dementia and on the sense of competence among their primary care givers.

Methods

Participants

From April 2001 to January 2005, we recruited 135 people from the memory clinic and the day clinic of a department of geriatrics. Patients were included if they were aged ≥ 65 , had been diagnosed with mild to moderate dementia, were living in the community, and had a primary care giver who cared for them at least once a week. The diagnosis of dementia was based on criteria from the *Diagnostic and Statistical Manual of Mental Disorder*, fourth edition.¹³ Severity of dementia was determined with the brief cognitive rating scale (BCRS),¹⁴ with a score of 9-24 indicating mild dementia and a score of 25-40 indicating moderate dementia.

We excluded patients with a score >12 on the geriatric depression scale,¹⁵ severe behavioural or psychological symptoms in dementia (BPSD), and severe illnesses as judged by a



Details of the research protocol can be found on bmj.com

geriatrician and those in whom occupational therapy goals could not be defined or who were not on stable treatment of a dementia drug (that is, less than three months on the same dose of a cholinesterase inhibitor or memantine). We also excluded care givers with severe illnesses.

The geriatrician gave all eligible patients and primary care givers written and verbal information, and the researcher explained the assessment instruments and gave examples. After being given the time needed to make a decision and if they wanted to take part, the patient and care giver signed the informed consent form in a second meeting with the researcher.

Randomisation and procedures

Patients were randomly assigned by blocked randomisation (block size 4) to the intervention (10 sessions of occupational therapy at home over five weeks) or control group (no occupational therapy), which was stratified by level of dementia (mild or moderate). A statistician not involved in the study carried out randomisation. Concealed envelopes were used to allocate the patients to either the occupational therapy or the control group and these envelopes were opened by an independent secretary. In this single blind randomised controlled trial, patients and care givers were aware of the treatment assigned. The assessors (MT or MJLG) were blinded to group allocation. Patients and care givers were asked before each assessment not to inform the assessors about the intervention. To check the success or failure of the blinding after each measurement the assessors were asked if they had been told or knew for sure to which group each patient had been allocated. The total study period per patient was 12 weeks from the moment of inclusion. The control group received occupational therapy after completion of the study (12 weeks later). Participants left the study period if they started another possibly effective treatment, were admitted to a nursing home, home for the elderly, or hospital, withdrew, or died. We carried out a process analysis evaluating the steps of the occupational therapy that were followed in each case.

Intervention

The study intervention was developed in a consensus process and was implemented by experienced occupational therapists who had been trained (for about 80 hours) and were experienced (for at least 240 hours) in delivering treatment according to a client centred occupational therapy guideline for patients with dementia.^{9 16} Treatment consisted of 10 one hour sessions held over five weeks and focused on both patients and their primary care givers. In the first four sessions of diagnostics and goal defining, patients and primary care givers learnt to choose and prioritise meaningful activities they wanted to improve. To this end, the occupational therapist used three narrative interview instruments: the occupational performance history interview¹⁷ directed at the patient; the ethnographic interview¹⁸ for the primary care giver; and the Canadian occupational performance measure (COPM)¹⁹ for both patient and primary care giver. The occupational therapist evaluated the possibilities for modifying patients' homes and environment and observed patients' ability to perform relevant daily activities and to use compensatory and environmental strategies. Compensatory strategies are used to adapt activities of daily living to the disabilities of patients, and environmental strategies are used to adapt the patients' environment to their cognitive disabilities. Therapists also observed primary care givers' supervision skills.

In the remaining six sessions, patients were taught to optimise these compensatory and environmental strategies to improve their performance of daily activities. Primary care givers

were trained, by means of cognitive and behavioural interventions, to use effective supervision, problem solving, and coping strategies to sustain the patients' and their own autonomy and social participation.

The total time spent for the intervention, including the time spent for treatment at home (10 hours), narrative analysis, reports, and multidisciplinary briefing, was about 18 hours per patient and care giver together. Detailed description of the intervention has been published elsewhere.⁴

Outcome assessments and measures

We assessed patients and their primary care givers at baseline before the intervention and six weeks (effect measurement) and 12 weeks (follow-up measurement) later. Our primary outcome measure for patients was daily functioning assessed with the process scale of the assessment of motor and process skills,²⁰ in which scores range from -3 to 4 (higher scores indicate better process skills), and with the performance scale of the interview of deterioration in daily activities in dementia,²¹ in which scores range from 0 to 44 (lower scores indicate less need for assistance). The outcome for primary care givers was sense of competence assessed with the sense of competence questionnaire,²² in which scores ranged from 27 to 135 (higher scores denote greater sense of competence).

We collected information on the age, sex, and educational level of the patient and care giver at baseline. In patients we assessed co-morbidity (cumulative illness rating scale for geriatrics²³), depressive mood (geriatric depression scale¹⁵), cognition (mini-mental state examination²⁴), and behaviour (revised memory and behavioural problems checklist^{21 25}). We also assessed the relationship between care givers and patients and depression in care givers (Center for Epidemiologic Studies depression scale²⁶).

Statistical analysis

We used analyses of covariance of the primary outcome measures (process scale, performance score, and competence at six weeks) to determine the main effects based on an intention to treat analysis of all available data, applying the last observation carried forward method for dropouts. Treatment differences between baseline and six weeks were computed by analysis of covariance, with age, sex, relation to patient, other care givers, and baseline scores on the comorbidity, depression, cognition, and behaviour scales and the outcome variable as covariates. We carried out secondary analyses on the primary outcome measures at 12 weeks (conditional analysis: only in case of positive effects at six weeks).

The study was powered to detect a clinically relevant difference in change over time of 0.5 points on the process scale between the two groups, 20% improvement on the performance scale, and a 5 point difference on the competence scale, with a power of 80% on the basis of one sided testing, a standard deviation of 0.8 on the process scale, and $n \geq 100$. The power calculation was based on earlier data⁹ and on the minimal clinically relevant differences in the primary outcomes as defined in the measurement guideline for the process scale, which describes 0.5 points as clinically relevant,²⁰ and the measurement guideline for the performance interview.²¹ We used one sided tests in this power calculation because we previously found highly significant improvements after occupational therapy at $P < 5\%$.⁹ For ease of comparability we have presented two sided test results throughout, with $P < 0.05$ as significant. We computed the proportion of patients and care givers who achieved a clinically relevant improvement for each of the primary outcome measures and calculated the numbers needed to treat with 95% confidence

intervals for each of these outcome measures separately and for all three together. We also carried out per protocol analyses. The treatment effect sizes were computed as $d' = \Delta E / SD_e$ (ΔE = adjusted treatment effect, SD_e = residual standard deviation).

Results

We evaluated 275 consecutive patients diagnosed with dementia and living in the community for eligibility (fig 1). Of the 135 patients randomised, three (one in intervention group, two in the control group) stopped the trial immediately after randomisation because they did not want to continue and they did not receive the study intervention. Six patients in the intervention group (three admitted to hospital, one to a nursing home, one to a residential home, and one started other treatments that influenced cognition and behaviour) and six patients in the control group (one died, one admitted to hospital, one to a residential home, two withdrew themselves, and one primary care giver died) stopped the trial immediately after baseline data were recorded. Three patients in the intervention group (one admitted to a nursing home, one to hospital, one withdrawal) and three patients in the control group (one admitted to a nursing home, two did not complete assessments) dropped out just before the six week assessment. At six weeks the per protocol analyses included 114 patients.

The baseline characteristics of patients and care givers were well matched between the two groups. We corrected for age differences (mean ages were lower by 2.0 (patients) and 4.7 (care givers) years in the control group) in the analysis of covariance (table 1).

Outcomes at six weeks

There were significant differences between the groups on all primary outcome variables at six weeks. Patients who received occupational therapy functioned significantly better in daily life than

Table 1 Baseline characteristics of patients and care givers

	Occupational therapy (n=68)	Control (n=67)
Mean (SD) age (years):		
Patient	79.1 (6.2)	77.1 (6.3)
Primary care giver	66.0 (15.3)	61.3 (15.4)
Sex (M/F):		
Patient	29/39	31/36
Primary care giver	22/46	18/49
Relation of care giver to patient:		
Partner	41	38
Daughter	22	21
Other	5	8
Mean (SD) scores on assessment scales:		
Mini-mental state	19.0 (5.7)	19.0 (4.0)
CIRS-G	10.7 (3.5)	11.6 (4.3)
Geriatric depression scale	6.9 (3.0)	7.5 (3.0)
RMBPC frequency	5.6 (5.3)	5.0 (6.0)
AMPS-motor	1.0 (1.1)	1.1 (1.0)
AMPS-process	0.2 (0.8)	0.3 (0.8)
IDDD-performance	23.5 (7.9)	24.5 (8.7)
Cornell depression scale	8.3 (6.2)	8.1 (4.6)
Brief cognitive rating scale	27.3 (5.1)	27.1 (4.2)
Sense of competence	89.7 (14.9)	90.4 (13.6)
CES-D	11.7 (8.3)	11.4 (7.2)

CIRS-G=cumulative illness rating scale for geriatrics; RMBPC=revised memory and behavioural problems checklist; AMPS=assessment of motor and process skills (higher scores indicate better skills); IDDD=interview of deterioration in daily activities in dementia (lower scores indicate less need for help); BCRS=brief cognitive rating scale; CES-D=Center for Epidemiologic Studies depression scale.

those who did not (for intervention *v* control, mean process scores were 1.2 (SD 0.7) *v* 0.2 (SD 0.8), fig 2), and mean performance interview scores were 14.4 (SD 6.1) *v* 25.3 (SD 8.6), fig 3). The difference between the groups was significant (1.5 (95% confidence interval 1.3 to 1.7) for the process scale; - 11.7

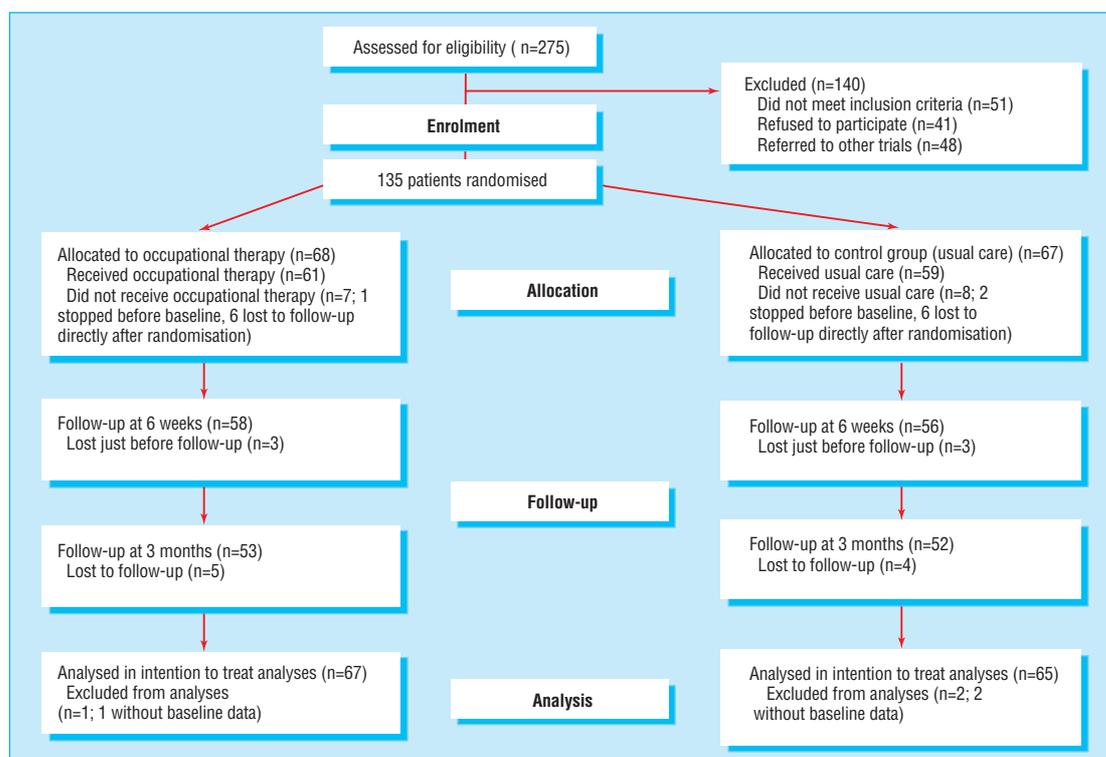


Fig 1 Flow of participants through the trial

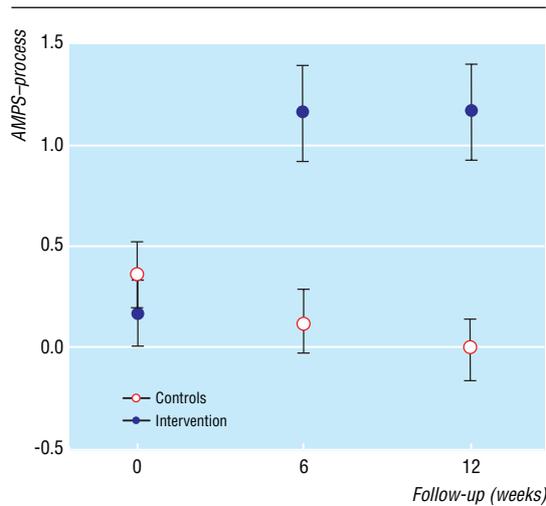


Fig 2 Mean (95% confidence interval) scores on assessment of motor and process skills (AMPS) at baseline, six, and 12 weeks in intervention and control groups

(-13.6 to -9.7) for the performance interview; table 2). Primary care givers who received occupational therapy felt significantly more competent than those who did not (mean competence score 104.6 (SD 13.4) v 88.4 (SD 13.7), fig 4). The difference in competence scores was significant (11.0, 9.2 to 12.8; table 2).

Overall, 84% in the intervention group and 9% in the control group achieved a clinically relevant improvement on the process outcome, the figures being 78% v 12% for the performance interview. For the care givers 58% and 18% had a clinically relevant improvement in sense of competence. For all three outcomes together 47% in the intervention group and 2% in the control group achieved a clinically relevant difference. The number needed to treat was 1.3 (1.2 to 1.4) for the process outcome, 1.5 (1.4 to 1.6) for the performance outcome, and 2.5 (2.3 to 2.7) for competence outcome (table 2). The number needed to treat for all three primary outcomes together was 2.2 (2.1 to 2.3). The effect sizes at six weeks were 2.5, 2.3, and 1.2, respectively (table 2). The per protocol analyses at six weeks showed effect sizes of 3.2, 2.3, and 1.2, respectively. In 82% of the cases blinding was successful, and in 18% (n=21) the assessors knew the treatment allocation.

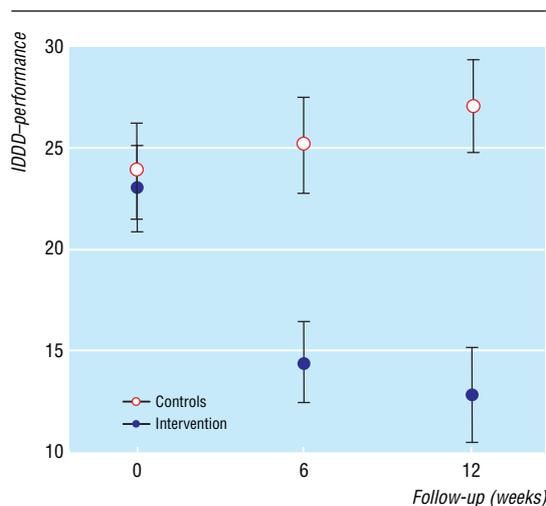


Fig 3 Mean (95% confidence interval) scores on performance interview (IDDD) at baseline, six, and 12 weeks in intervention and control groups

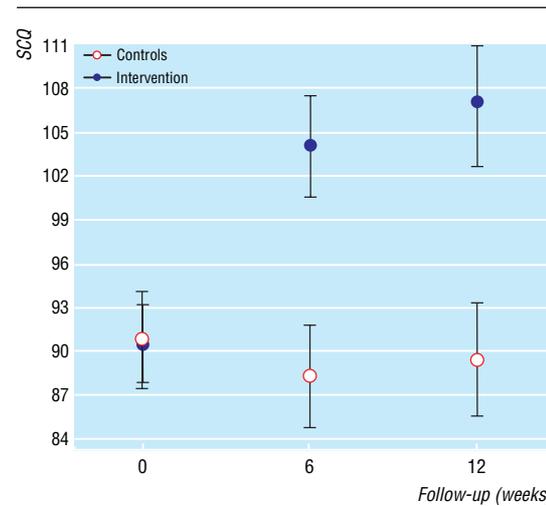


Fig 4 Mean (95% confidence interval) sense of competence scores (SCQ) in care givers at baseline, six, and 12 weeks in intervention and control groups

Outcomes at 12 weeks

At 12 weeks, 53/68 (78%) patients in the intervention group and 52/67 (78%) in the control group remained in the study (fig 1). The daily functioning of patients who had received occupational therapy was still much better than that in the control group: for the intervention v the control group the mean process score was 1.2 (SD 0.8) v -0.02 (SD 0.7) and the mean performance interview score was 13.6 (SD 6.0) v 27.2 (SD 8.9) (figs 2 and 3). Analysis of covariance of the intention to treat population (n=132) showed that the difference in groups at 12 weeks compared with baseline was significant for the process scores (1.6, 1.3 to 1.8; table 3) and the performance interview (-13.6, -15.8 to -11.3; table 3). Care givers' sense of competence was significantly better at 12 weeks than at baseline (mean 107.3 (SD 13.6) v 89.4 (SD 14.4); fig 4), the difference between the groups being significant (9.6, 4.7 to 14.5; table 3).

The proportion of patients still having a clinically relevant improvement at 12 weeks for the process and the performance interview outcomes were 75% and 82% in the intervention group and 9% and 10% in controls. Nearly half (48%) of the care

Table 2 Outcomes in patients with dementia and care givers in intention to treat population at six weeks

	AMPS-process	IDDD-performance	Competence (SCQ)
Occupational therapy group			
Observed mean (SD) score	1.2 (0.7)	14.4 (6.1)	104.6 (13.4)
Clinically relevant improvement	84%	78%	58%
Control group			
Observed mean (SD) score	0.2 (0.8)	25.3 (8.6)	88.4 (13.7)
Clinically relevant improvement	9%	12%	18%
Occupational therapy v control group			
Covariate adjusted treatment difference (95% CI)	1.5 (1.3 to 1.7)	-11.7 (-13.6 to -9.7)	11.0 (9.2 to 12.8)
Difference in clinically relevant improvement	75%	66%	40%
Number needed to treat (95% CI)	1.3 (1.2 to 1.4)	1.5 (1.4 to 1.6)	2.5 (2.3 to 2.7)
Statistics			
P value	<0.0001	<0.0001	<0.0001
Effect size	2.5	2.3	1.2

AMPS=assessment of motor and process skills (higher scores indicate better skills); IDDD=interview of deterioration in daily activities in dementia (lower scores indicate less need for help); SCQ=sense of competence questionnaire (higher scores indicate greater competence).

Table 3 Outcomes in patients with dementia and care givers in intention to treat population at 12 weeks

	AMPS-process	IDDD-performance	Competence (SCQ)
Occupational therapy group			
Observed mean (SD)	1.2 (0.8)	13.6 (6.0)	107.3 (13.6)
Clinically relevant improvement	75%	82%	48%
Control group			
Observed mean (SD)	0.0 (0.7)	27.2 (8.9)	89.4 (14.4)
Clinically relevant improvement	9%	10%	24%
Occupational therapy v control group			
Covariate adjusted treatment difference (95% CI)	1.6 (1.3 to 1.8)	-13.6 (-15.8 to -11.3)	9.6 (4.7 to 14.5)
Difference in clinically relevant improvement	66%	72%	24%
Number needed to treat (95% CI)	1.5 (1.4 to 1.6)	1.4 (1.3 to 1.5)	4.2 (4.0 to 4.4)
Statistics			
P value	<0.0001	<0.0001	<0.0001
Effect size	2.7	2.4	0.8

AMPS=assessment of motor and process skills (higher scores indicate better skills); IDDD=interview of deterioration in daily activities in dementia (lower scores indicate less need for help); SCQ=sense of competence questionnaire (higher scores indicate greater competence).

givers in the intervention group still felt more competent to care compared with 24% in the control group. A clinically relevant difference was reached on all three outcome measures in 37% of the intervention group and 2% of the control group. The number needed to treat was 1.5 (1.4 to 1.6) for the process outcome, 1.4 (1.3 to 1.5) for the performance outcome, and 4.2 (4.0 to 4.4) for the competence outcome (table 3). For all three outcomes together the number needed to treat was 2.8 (2.7 to 2.9). The effect sizes at 12 weeks were 2.7, 2.4, and 0.8, respectively (table 3). The per protocol analyses at 12 weeks showed effect sizes of 2.3, 2.4, and 0.8, respectively. In 20% of the cases (n=21) the assessors knew the treatment allocation. No adverse events were reported in intervention or control group.

Discussion

In this randomised controlled trial we found evidence that 10 sessions of community occupational therapy, given over five weeks, improves the daily functioning of patients with dementia and diminishes the burden of care on their primary care givers. The process skills and need for assistance in performing daily activities improved in patients, and their care givers felt more competent at six weeks (one week after completion of occupational therapy), and these beneficial effects remained so at 12 weeks (seven weeks after completion of the occupational therapy programme). A similar positive effect of occupational therapy was reported earlier in stroke patients.²⁷ The improvement was also clinically relevant, meeting predefined criteria for clinical relevance and highly effective with low numbers needed to treat. At six weeks, the process outcome score of patients was higher than that associated with independent functioning (cut-off score of 1.0) and remained so at 12 weeks. Moreover, the effect sizes of all primary outcomes were higher than those found in trials of drugs or other psychosocial interventions for people with dementia.⁵ We believe that the benefit was sustained because a component of the intervention was to train care givers in providing the supervision patients needed to sustain their performance of daily activities. The intervention also provided individualised support to care givers, which earlier studies have also shown to be effective.²⁸⁻³⁰

Strengths and weaknesses

Two earlier studies evaluated occupational therapy in patients with dementia^{6,7} but their methodological quality was poor.¹² A recent study by Gitlin et al had similar results on care giver outcome after a community occupational therapy programme for patients with dementia and their primary care givers.⁸ The outcomes of our study were also expressed in effect sizes as recommended by Luijpen et al,⁵ which enables comparison with drug and non-drug interventions. Our design was based on a pilot study of the intervention protocol.⁹ The occupational therapy intervention was based on a guideline developed on the basis of consensus among a national panel of qualified and experienced occupational therapists.^{4,16} We had a high follow-up rate at 12 weeks, possibly because our study was directly relevant to the daily lives of patients and their care givers. According to our process, all stages (diagnostics, goal defining, and treatment) of the intervention could be carried out.

A limitation of our study design is that, as with some other types of treatment, we could not carry out a double blind study because the patients and their care givers knew which therapy they received, nor was it possible to blind occupational therapists to treatments. We tried to maintain masked conditions for assessment, however, which succeeded for 80% of the cases.³¹ For this reason, we believe that our results are not greatly affected by observer bias. Another potential limitation is that our sample might not be representative of all patients with mild to moderate dementia in our health region as participants were recruited primarily from the outpatient clinics of the university hospital and not from other institutions or directly from general practices. We chose this recruitment strategy because we wanted to achieve uniformity in terms of screening and diagnosis to facilitate comparison with other national and international studies. The size of the effects is promising for implementation in other settings as well.

Because outcomes such as improvement in activities of daily living and sense of competence are associated with a decrease in need for assistance,²¹ we believe that, in the long term, occupational therapy will result in less dependence on social and healthcare resources and less need for institutionalisation.²⁹ The training in effective use of the intervention (at least 80 hours) and the intervention itself is quite comprehensive (time spent for treatment at home, narrative analysis, reports, and multidisciplinary briefing is about 18 hours per patient and care giver). We believe, however, that it is worth implementing in clinical practice because of its relevant effects and high efficacy, which makes it reasonable to expect cost effectiveness in clinical practice.

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Contributors: MJLG was the lead investigator, developed the study design, carried out data-acquisition, analysis, interpretations, and wrote the paper. MJMV-D, JD, MGMOR, and WHLH were responsible for design, project supervision, and writing. MGMOR was also involved in data acquisition and is guarantor. MT carried out data acquisition and was involved in preparing the study design and in writing the manuscript.

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What is already known on this topic

Effective treatment for patients with dementia and their care givers should lead to improvement in activities of daily living and diminished burden on the care giver

Drugs are not effective in improving the symptoms of dementia and non-pharmacological strategies have similar effect sizes and no side effects but are generally more time consuming

What this study adds

Ten sessions of community occupational therapy over five weeks improved the daily functioning of patients with dementia, despite their limited learning abilities, and reduced the burden on their informal care givers

The effect sizes of all primary outcomes were higher than those found in trials of drugs or other psychosocial interventions, and these effects were still present at three months