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Cross-national transfer of Community Occupational Therapy in Dementia

Sebastian Voigt-Radloff

Cross-national transfer
of Community Occupational Therapy
in Dementia

Een wetenschappelijke proeve
op het gebied van de Medische Wetenschappen

Proefschrift

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te Schwelm, Duitsland

Contents

Papers

British Medical Journal, BMJOpen (published)	A multi-centre RCT on community occupational therapy in Alzheimer's disease: Ten sessions are not better than one consultation
British Medical Journal, BMJopen (published)	Why did an effective Dutch complex psycho-social intervention for people with dementia not work in the German health care context? Lessons learned from a process evaluation alongside a multi-centre RCT
International Psychogeriatrics (accepted)	Interview for Deterioration in Daily Living Activities in Dementia - Construct and Concurrent Validity in Patients with mild to moderate Dementia
International Psychogeriatrics (accepted)	Reliability of the Perceive, Recall, Plan and Perform Assessment in Community Dwelling Dementia Patients: Test Consistency and Inter-Rater Agreement
European Journal of Neurology (published)	Dementia Quality of Life Instrument - Construct and Concurrent Validity in Patients with mild to moderate Dementia

1

Introduction

Dementia

Dementia is a chronic clinical syndrome characterized by a progressive deterioration of capabilities that affects a person's ability to function independently. Symptoms of dementia are the loss of memory, judgement and reasoning, changes in mood and behaviour, and progressive difficulties in the performance of complex daily activities such as managing medication or finances and later on also in simple tasks performances such as eating or toileting.[1]

Worldwide an estimated 24 million people suffered from dementia in 2001. It is predicted that this number will rise to over 80 million people by 2040.[2] The numbers of people with dementia are predicted to be 16 million in the year 2050 in Europe[3], 2.3 million in Germany[4], and 0.5 million in The Netherlands.[5] In Germany, the majority of people with dementia (60%) live in the community and receive care by their family members.[6] Direct and indirect dementia costs are estimated to be 43,767 Euro per year and patient, divided into 2 % medical costs, 30 % nursing care costs and 68 % costs borne by the patients' families[7]. About one third of patients with mild or moderate dementia receive informal care of 4 to 10 h per day and one third more than 10 h per day.[8] The deterioration of patients' daily functioning caused by deficits in cognition and affective behaviour is an increasing burden for the family caregiver.[9-11]

So far, neither an effective causal treatment nor disease-modifying drugs are available for the treatment of dementia. The systematic review of Luijpen et al.[12] concluded that improvements in cognition and affective behaviour by non-pharmacological interventions (d = 0.32) and by cholinesterase inhibitors (d = 0.31) were of similar effect-size. However, daily functioning was not subject of the analysis. The review of Smits et al.[13] on combined intervention programmes identified some studies demonstrating positive impact on the mental health of patients and carers. But no consistent positive effects on the patient's activities of daily living could be found. A synopsis of four systematic reviews analysing 73 RCTs on the efficacy of pharmacological and psychosocial interventions regarding everyday functioning in dementia concluded that positive effects of drugs on activities of daily living (ADL) are small (pooled effect sizes < 0.28) and heterogeneous regarding safety and that high quality multi-centre randomised trials on the effects of psychosocial interventions are missing[14]. In summary, literature shows consistent small effects of drugs regarding patient's daily functioning and inconsistent effects with largely varying outcomes and lack of high quality trials for psycho-social interventions.

Occupational Therapy in Dementia

Guidelines for dementia management recommend occupational therapy.[15-17] Occupational therapy specialises in supporting independence in ADL and uses a complex approach including activity simplification, environmental modification, adaptive aids, problem-solving strategies, skill training and carer training.[18 19] The assumed mechanism of how occupational therapy affects the daily functioning of people with dementia is corresponding with the bio-psycho-social health model of the World Health Organization. The negative impact of cognitive deficits on activities can be diminished by improving the patient's physical and social environment and by tailoring the intervention to the patient's capability.[20] The task performance of people with dementia can be improved by reducing

distraction and arranging clear structures in the physical environment.[21] Research on caregiver interventions provides evidence that educational and psychosocial approaches targeting at the optimisation of the social environment have the potential to delay nursing home placement.[22-24] Tailoring the activities planned to patients' capability may enhance activity engagement and reduce challenging behaviour.[25] Parker et al.[26] advocated well-designed multi-component psycho-social interventions directed to both patients and carers and encouraging the carer's active participation.

In the absence of systematic reviews on community occupational therapy for people with Alzheimer's disease, evidence is based on the work of two research groups who conducted mono-centre RCTs in this subject. The USA study group found beneficial effects on patients' challenging behaviour.[25 27 28] The Dutch group also found positive effects on patients' ADL, mood, health status and quality of life and on carers' sense of competence, mood, quality of life and costs of informal care.[29-32] The Dutch programme demonstrated promising positive effects on daily functioning and costs of care and was the starting point of a research proposal from the University of Freiburg, Germany, which was funded by the German Federal Ministry of Health.

The Dutch Community Occupational Therapy in Dementia programme (COTiD) aims at the improvement of daily functioning of both the patients and their primary caregivers.[33-35] The treatment of the patient focuses on enabling the successful performance of highly meaningful daily activities. The intervention focus for the caregiver is on enhancement of successful interaction with the person with dementia by improving the caregiver's skills in communication, supervision and problem solving. A manual comprising a detailed description of the intervention is available.[33 35] The process, in which this guideline for the treatment of older people with cognitive impairments has been developed, was evaluated systematically over the last ten years. This process included a literature review, theoretical modelling, an advisor panel of international experts, draft manuals, pilot testing in practice, case study analyses, a pilot study and a mono-centre RCT on effectiveness and on cost-effectiveness.[29-34]

Cross-national transfer

The planned transfer included changes in three ways. (1) The transfer across nations from the Netherlands to Germany. (2) Changes in trial design from mono-centre waiting control group design with 12 week follow up to a multi-centre active control group design with 26 weeks follow up period. (3) A shift in the expertise of the interventionists from two highly motivated experts with several years of treatment experience to 14 newly introduced therapists working in routine care setting.

Ad (1): In Europe, cross-national dementia research is recently concerned with the issues of timely recognition and diagnosis and with cross-sectional comparisons of care status.[36-39] International literature on the cross-national transfer of psychosocial interventions in dementia is scarce.[40] The only multi-centre RCT analysing cross-national differences in the impact of a psychosocial intervention in dementia found that changes in the treatment group did not significantly differ among the study sites in New York, Manchester and Sydney.[41] Guidelines on successful cross-national transfer of complex interventions in dementia are missing. However, the European group "Early detection and timely INTERven-

tion in DEMentia" (www.interdem.org) achieved consensus on a set of measurement instruments to be used in international psychosocial intervention research. Our project was supported by members of the INTERDEM group and carefully considered their recommendations on the use of instruments.

Ad (2): The shift from a specific mono-centre design to a multi-site trial in seven different regions with less restrictive exclusion criteria represents the step from an explanatory RCT on efficacy to a pragmatic RCT on effectiveness. In this step we very closely followed the recommendations of the *CONSORT and Practihc groups*[42], in order to avoid any poor planning and reporting of our pragmatic RCT design. Furthermore, we performed the power calculation very conservatively to address the expectation of effect size reduction in such a pragmatic setting.

Ad (3): From the perspective of our newly introduced trial interventionists, the application of the Dutch COTiD programme can be considered as uptake of an innovation. Consequently, we brought our project plan in line with the guidance of implementation research as far as possible within the given frame conditions. According to the defined ADAPTE process[43], we (a) determined our research question, (b) searched and screened structured and manualised programmes of community occupational therapy in dementia, (c) systematically assessed the identified guidelines regarding currency, consistency and applicability and (d) decided for the COTiD. However, we could not realize all recommended steps. We missed the customisation of the guideline to the different local contexts of the seven study sites and the incorporation of the interventionists who would use the guideline in the process of guideline assessment. This could not be realized otherwise, because the trial had to be planned before all interventionists at the different study sites could be named. However, we have arranged that occupational therapists translate the manual from Dutch to German and thus avoid misunderstandings in taxonomy.

Objective and outline of this thesis

The primary aim of the research project was to determine whether the Dutch COTiD programme still has positive effects on patients' daily functioning when occupational therapists who were newly introduced in this complex psychosocial intervention apply it in a routine care context of another country. The PhD thesis is a synopsis of five publications reporting the background, objectives, methods and results of a pragmatic multi-centre RCT as well as the accompanying cross-national process evaluation and trans-cultural validation efforts of three measurement instruments.

Chapter 2 presents a randomised controlled trial at seven German study sites testing the hypothesis that the Dutch ten-session Community Occupational Therapy in Dementia Programme would significantly improve the daily functioning of people with mild or moderate dementia, more so than a one-session Community Occupational Therapy Consultation.

Chapter 3 describes the process evaluation exploring possible bias within the German study and differences between the Dutch and German RCT.

Chapter 4 reports the translation process and the construct and concurrent validity of the Interview for Deterioration in Daily Living Activities in Dementia.

Chapter 5 provides results on the test consistency and inter-rater agreement of the Perceive, Recall, Plan and Perform Assessment.

Chapter 6 describes the construct and concurrent validity of the Dementia Quality of Life Instrument in patients with mild to moderate dementia.

Chapter 7 discusses the implications of the findings for future practice and research regarding to cross-national transfers of complex intervention programmes.

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2

A multi-centre RCT on community occupational therapy in Alzheimer's disease: Ten sessions are not better than one consultation

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Abstract

Objective: To compare the benefits and harms of a Dutch 10-session Community Occupational Therapy programme for patients with Alzheimer's disease with the impact of a one session consultation at home in German routine health care.

Design: A seven-centre, parallel group, active controlled randomised controlled trial. Patients and carer were not masked. Assessors were fully blind for treatment allocation for one of two primary-outcome measures.

Setting: Patients' homes.

Participants: Patients with mild to moderate Alzheimer's disease (Mini-Mental State Examination 14-24), living in the community with primary carer available and without severe depression or behavioural symptoms, were eligible.

Interventions: *Experimental* 10 home visits within 5 weeks by an occupational therapist, educating patients in the performance of simplified daily activities and in the use of aids to compensate for cognitive decline; and educating carers in coping with behaviour of the patient and in giving supervision to the patient. *Control* one home visit including individual counselling of patient and carer and explanation of a leaflet on coping with dementia in daily life.

Outcome measures: The primary outcome was the patient's daily functioning measured with the Interview of Deterioration in Daily activities in Dementia and the Perceive, Recall, Plan and Perform System of Task Analysis. Assessments were at baseline, 6, 16, and 26 weeks, with a postal assessment at 52 weeks.

Results: 141 patients were 1:1 randomised to the experimental (N=71) and control group (N=70). Data for 54 and 50 participants were analysed. Patients' daily functioning did not differ significantly between experimental and control group at week 6, 16, 26 or 52 and remained stable over 26 weeks in both groups. No adverse events were associated with the interventions.

Conclusions: In German health care, a Dutch 10-session community occupational therapy was not better than a one-session consultation for the daily functioning of patients with Alzheimer's disease. Further research on the transfer of complex psychosocial interventions is needed.

Introduction

Alzheimer's disease causes high health care costs and burdens patients and carers with severe problems in activities of daily living (ADL).[1][2] Consequently, the improvement or the preservation of ADL is evaluated as a patient-related outcome in clinical trials related to dementia.[3] ADL, burden of care, ability to stay in the community and quality of life issues are probably much more relevant to patients and carers than the deceleration of cognitive decline, another patient-related outcome.[4] A synopsis of four systematic reviews analysing 73 RCTs on the efficacy of pharmacological and psychosocial interventions regarding everyday functioning in dementia concluded that positive effects of drugs on ADL are small (pooled effect sizes < 0.28) and heterogeneous regarding safety. In contrast to the well documented results for pharmacological interventions, evidence for psychosocial interventions on ADL is lacking.[5] However, a recent Dutch mono-centre RCT demonstrated significant positive effects of occupational therapy on ADL (effect sizes of 2.4, p<0.0001).[6] Therefore, the purpose of our multi-centre RCT was to transfer the Dutch community occupational therapy programme in a broader context of German routine healthcare and to evaluate its effectiveness and safety in comparison with an active-control-group intervention.

Occupational therapy specialises in supporting independence in ADL and is recommended in several guidelines for dementia management.[7-9] Occupational therapy uses a combined approach including activity simplification, environmental modification, adaptive aids, problem-solving strategies, skill training and carer training.[7][10][11] According to the bio-psycho-social health model of the WHO, the negative impact of cognitive deficits on activities can be diminished by improving the patient's physical and social environment and by tailoring the intervention to the patient's capability.[12-15]

Until July 2011, there was no systematic review on community occupational therapy for people with Alzheimer's disease, but two research groups had conducted RCTs in this subject. In the USA study, occupational therapy demonstrated beneficial effects on patients' challenging behaviours but not on ADL. No information on adverse events were given.[14][16-18] In the Netherlands, occupational therapy, tailored to the needs of patients and carers, showed benefits in the patient's ADL, mood, health status and quality of life and in the carer's sense of competence, mood, quality of life and costs of informal care. No adverse events were reported in either intervention or control group.[6][19][20]

In the current randomised trial, we tested the hypothesis that the Dutch 10-session Community Occupational Therapy in Dementia Programme (COTiD) would significantly improve the daily functioning of people with mild or moderate dementia, more so than a one-session Community Occupational Therapy Consultation (COTC). Secondary research questions were whether these interventions would show any difference in their effect on patient's and primary carer's quality of life and mood; on the carer's sense of competence in the interaction with the patient; and on long-term nursing home placements.

Methods

Design

In order to evaluate the superiority of COTiD, we used a seven-centre single-blind, active-controlled design with a 1:1 randomisation for two parallel groups. There was no modification in design or eligibility criteria from the study protocol available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761388/. The study was registered at the German register of clinical trials, which is connected to the International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/ => DRKS00000053). The Medical Ethics Committee of the University Hospital Freiburg gave ethical approval (no. 110/08).

Participants and Setting

Patients were eligible to participate in the study if they had mild to moderate dementia (Mini-Mental State Examination (MMSE) 14-24) and were diagnosed as having Alzheimer's disease or mixed type dementia, according to the Tenth Revision of International Classification of Disieases criteria, by physicians with more than 5 years of experience in dementia diagnosis. Participants had to live in the community either together with their primary carer or with involvement of a carer providing care at least twice a week. Patients with a score above 12 on the 30-items Geriatric Depression Scale or a major need of physical nursing care of more than 120 min per day (level 2 or higher according to the German Long-Term Care Insurance Act) were excluded. Unstable medical conditions or severe behavioural disturbances, which did not allow participation in the study as judged by the study physicians, were criteria for exclusion as well as for discontinuation. Long-term nursing-home placements of the patients during the treatment phase or death of patient or primary carer were criteria for discontinuation. The patient gave written informed consent and the carer consented by written format to join and support the treatment procedures.

Patients were recruited from five outpatient memory centres at university hospitals (in Bonn, Freiburg, Mainz, Marburg and Tübingen); one municipal hospital in Karlsruhe specialising in geriatric medicine; and one neurological private practice in Berlin specialising in neuropsychiatry and collaborating with an occupational therapy private practice. The seven participating centres are located throughout Germany in urban regions with catchment areas of about 70,000 to 700,000 inhabitants. They had all provided outpatient dementia care for 3-15 years. Their standard service comprised diagnostic work-up for dementia and related diagnoses as well as recommendation of risk reduction, dementia medication and non-pharmacological treatments. Principal investigators of the centres were psychiatrists, neurologists or geriatricians with 6-13 years of experience in dementia care.

Interventions

The experimental intervention (COTiD) was designed to improve the patient's and the primary carer's daily functioning, and was based on an evidence-based treatment manual.[6, 19-23] COTiD consisted of 10 occupational therapy sessions of 1 hour's duration held over five weeks at each patient's home. In the diagnostic phase, comprising three of four sessions, the occupational therapist explored (1) the patient's preferences and history of daily activities; (2) their ability to perform activities and to use compensatory strategies within the familiar environment; (3) the possibilities of modifying the patient's home; (4) the carer's activity

preferences, problems in care giving, coping strategies and abilities to supervise; and (5) the interaction between carer and patient. In a shared decision-making process during the goal setting session, the patient and the carer selected the one or two most meaningful activities out of a list of their preferences for daily activities to work on in occupational therapy. During the treatment phase of five to six sessions, the occupational therapist defined, together with the patient and the carer, more effective compensatory and environmental strategies to adapt both the environment and the selected activities to the patient's habits and cognitive abilities. Patient and carer were taught how to use these suggested adaptations within strategies, activities and the environment in order to improve their performance of daily activities. In addition, the carer received practical and emotional support and was coached in effective supervision, problem solving and coping strategies by means of cognitive-behavioural interventions. Detailed description of the experimental intervention has been published elsewhere.[23]

For the German RCT, MG taught the content of the translated treatment manual to 14 study-participant occupational therapists in 16 hours of seminars using presentation, videos and role play with feedback and group discussion. After the seminar and before the study started, they needed to complete a full treatment series for at least one pilot dyad of patient and carer. In the study phase, the interventionists spent about 20 hours per patient for a full treatment series including 10 treatment sessions, travel, reports and a multidisciplinary briefing. In Germany, a series of 10-30 sessions is within the normal range of time that occupational therapists use for the treatment of older outpatients diagnosed with other diseases, such as stroke or rheumatoid arthritis.

The control group received 1 h of COTC at the patient's home conducted by the same study interventionists. Based on material of the German Alzheimer Society, two occupational therapists with more than 5 years of experience in dementia care had prepared a leaflet of 10 pages.[24 25] The semistructured consultation was an explanation of 30 min of this leaflet and a talk of 30 min on individual problems that arose from the patient's and carer's needs. This included encouragement to stay active in everyday life, to maintain social contacts and to use dementia services in the region for which local addresses were listed in the leaflet. Occupational therapists were taught the control intervention within a 4 h seminar. Consultations of 30 min up to 1 h duration about such issues are common in German dementia care. A detailed description of the control intervention as well as means of quality assurance in experimental and control intervention has been published elsewhere.[26]

Outcome measures

The primary endpoint was the patients' change of daily functioning from baseline to follow-up time points at week 6, 16 and 26 measured with the performance scale of the Interview for Deterioration in Daily Living Activities in Dementia (IDDD).[27] This scale records carer rating of the patient's need for assistance in the performance of (1) washing oneself, (2) making tea or coffee, (3) dressing, (4) combing one's hair and brushing one's teeth, (5) eating, (6) using the toilet, (7) shopping, (8) using the telephone, (9) preparing a meal, (10) cleaning the house or doing minor repair work and (11) handling finances. Each item is rated never=0, seldom=1, sometimes=2, often=3 or always=4. The sum of scores ranged from 0 to 44. Higher scores indicated higher need for assistance. Since carer rating could not be 'masked', daily functioning was additionally

evaluated by external raters fully 'blind' to the group assignment. They rated video tapes of a challenging daily living task and used the Perceive, Recall, Plan and Perform System of Task Analysis (PRPP).[28] For the PRPP, raters had to define single steps of the performed activity, and they identified any activity step in which errors of accuracy, omission, repetition or timing occurred. The number of activity steps rated as incorrectly performed was divided by the total number of activity steps, resulting in an independence score indicated in a percentage (100%=all steps are error-free).

Table 1: Measurements of secondary endpoints[26]

Endpoint	Measurement
Patient's initiative in daily activities	Interview for Deterioration in Daily Living Activities in Dementia (IDDD), initiative scale
Patient's mood	Cornell Scale for Depression in Dementia (CSDD)
Carer's mood	Center for Epidemiologic Depression Scale (CES-D)
Patient and carer's quality of life	Dementia Quality of Life Instrument (DQoL), overall item
	SF-12 physical
	SF-12 mental
Carer's interaction with patient	Sense of Competence Questionnaire (SCQ)
Care by primary carer	Resource Utilization in Dementia (RUD), hours per day
Nursing home placement	RUD, nights in nursing home (except respite care)
Harms	Number of adverse events
	RUD, nights in hospital

Secondary endpoints included mood, quality of life, resource utilisation and possible harms (table 1). Assessors 'blind' for the group assignment, completed measurements at the patient's home at baseline, week 6, 16 and 26 and arranged a postal survey of carer questionnaires at week 52. The assessors had a minimum of one year's professional experience with older or cognitively impaired people. They attended an introductory seminar of 8 h. The complete assessment was applied during a 2 h visit at each patient's home including (1) handing out and explaining the questionnaires to the carer; (2) interviewing the patient (Dementia Quality of Life Instrument and Short-Form 12 Health Survey Questionnaire) in a separate room; (3) videotaping the patient; and (4) receiving back the carer questionnaires, checking it and clarifying answers if necessary. Seminar descriptions and means of quality management for assessment as well as detailed scheme and psychometric properties of all measurement instruments have been reported recently.[26]

All measurement instruments are validated and used in dementia research.[29 30] For the present study, we translated the IDDD into German according to high methodological standards with two independent forward and backward translations, analysis of discrepancies and final agreement by discussion with all translators. There was no need to translate the PRPP because, because it was established in The Netherlands and applied by Dutch raters. There was one protocol amendment before recruitment started. The Assessment of Motor and Process Skills was replaced by the PRPP, because the Assessment of Motor and Process Skills was not available in the German language within the planned schedule.

Indicators of harm were defined as patient or carer death, number of patients with admission to hospital and number of nights in hospital. These indicators were recorded in interviews with the carer at intervals of 5-7 weeks over 52

weeks. Study sites had to report severe adverse events to the study centre immediately when each occurred. We did not assume a direct association between the defined harms and either the experimental or the control intervention. However, increased daily activities in the interventions group might have resulted in a higher risk of falls or accidents and thus may indirectly have led to more nights in hospital or, in the worst case, to death.
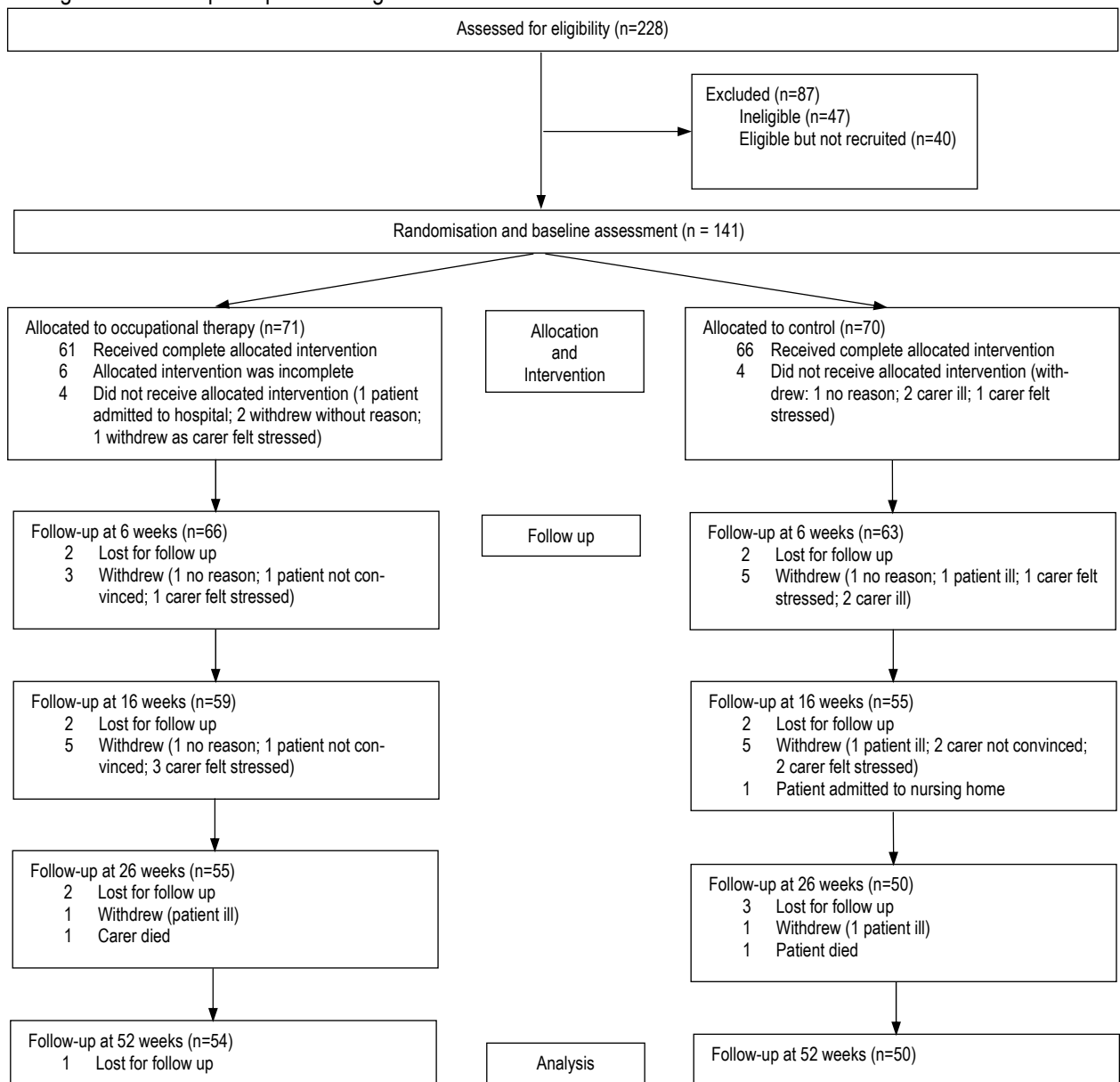
Sample size calculation
A sample size of 42 participants per group was calculated to be necessary to detect an effect size of f=0.10 on the IDDD performance scale in an analysis of variance of two groups and four time points, using a two-sided 5% significance level, a power of 80%, and a correlation of 0.7 between the measurement time points.[31] According to the Dutch original RCT, we expected a dropout rate of 10% at week 16, which was extrapolated to 40% at week 52. A 9-month inclusion period was anticipated as necessary in order to recruit the 140 patients. Our assumed effect size of f=0.10 is based on a group-by-time interaction and compatible with Cohen's d=0.20, which corresponds to a small effect size, and any d over 0.8 is large. Although the Dutch original RCT found effect sizes of d=2.4 in the IDDD performance scale at week 12, for this study the power was calculated much more conservatively. This was because we (1) introduced an active control group, (2) investigated the programme effects under varying care conditions in seven centres with interventionists who were introduced in this new treatment and were not as experienced as the Dutch study therapists and (3) prolonged the follow-up period. Interim analyses were not planned.

Randomisation and masking
The random allocation sequence was computer-generated with blocking by centre and groups of two persons, without stratification and in a ratio of 1:1 by a statistician from a distant site. After enrolment, study site physicians requested randomisation via email. The statistician emailed the individual allocation to COTiD or COTC exclusively to the site interventionist and stored the allocation list at his distant site which was not available to any study site staff. The interventionist scheduled treatment sessions, faxed records to the distant coordinating study centre and kept all documents strictly separated from any other site staff. This was in order to avoid contamination. Since the numbers of home visits differed in the experimental and control groups, masking of patients and carers was not possible. However, study information did not include any preference for a special treatment 'arm'. Patients and carers were asked to give no information about their treatment package to assessors or study physicians. All study personnel were 'blind' for group assignment, except the interventionists. Agreement between the assessors' estimation of group assignment and the actual group assignment was 61%, and thus slightly over the expected 50% of agreement by chance. The procedure of external video rating ensured the full 'blinding' of the external raters for the PRPP primary outcome measure. Independent research assistants cleaned the videotapes of any hint of group assignment before they were rated by two Dutch raters not involved in the trial treatment. In order to establish the inter-rater reliability, we tested 10 double ratings of the same video by the two raters and found an intraclass correlation coefficient of 0.9. Data analysts were not 'blind' for the group assignment. However, measurement time points and outcomes had been published before data

were available for analysis[26] and any decision to remove patients from the analyses is reported in the present publication.

Figure 1: Flow of participants through the trial

Assessed for eligibility (n=228)

Excluded (n=87)
    Ineligible (n=47)
    Eligible but not recruited (n=40)

Randomisation and baseline assessment (n = 141)

Allocation and Intervention

Allocated to occupational therapy (n=71)
  61 Received complete allocated intervention
  6 Allocated intervention was incomplete
  4 Did not receive allocated intervention (1 patient admitted to hospital; 2 withdrew without reason; 1 withdrew as carer felt stressed)

Allocated to control (n=70)
  66 Received complete allocated intervention
  4 Did not receive allocated intervention (withdrew: 1 no reason; 2 carer ill; 1 carer felt stressed)

Follow up

Follow-up at 6 weeks (n=66)
  2 Lost for follow up
  3 Withdrew (1 no reason; 1 patient not convinced; 1 carer felt stressed)

Follow-up at 6 weeks (n=63)
  2 Lost for follow up
  5 Withdrew (1 no reason; 1 patient ill; 1 carer felt stressed; 2 carer ill)

Follow-up at 16 weeks (n=59)
  2 Lost for follow up
  5 Withdrew (1 no reason; 1 patient not convinced; 3 carer felt stressed)

Follow-up at 16 weeks (n=55)
  2 Lost for follow up
  5 Withdrew (1 patient ill; 2 carer not convinced; 2 carer felt stressed)
  1 Patient admitted to nursing home

Follow-up at 26 weeks (n=55)
  2 Lost for follow up
  1 Withdrew (patient ill)
  1 Carer died

Follow-up at 26 weeks (n=50)
  3 Lost for follow up
  1 Withdrew (1 patient ill)
  1 Patient died

Analysis

Follow-up at 52 weeks (n=54)
  1 Lost for follow up

Follow-up at 52 weeks (n=50)

Statistical methods

Data were entered via special MS Access entry masks automatically controlling for data plausibility. In addition, sections of entered data were checked for typing errors by hand, in order to ensure an error rate lower than 0.2%. The primary intention-to-treat analysis included all allocated participants with valid data whether they did or did not receive the complete intervention. For the IDDD and the PRPP measurements of the primary outcome, we performed a multivariate analysis of variance (MANOVA) with repeated measures with two groups and four measurement time points at baseline, week 6, 16 and 26. A univariate ANOVA with five measurement time points (+ postal assessment in week 52) was carried out for the secondary outcomes and the IDDD. We did not adjust for baseline values, because we found no marked group differences. In order to

deal with missing data occurring not in the primary but in the secondary outcomes, we performed secondary intention-to-treat analyses with multiple data imputation using the Full Information Maximum Likelihood (FIML) method.[32] We imputed data for all secondary outcome measurements and all time points using SPSS (V.19). All statistical tests were two-sided on an α level of 0.05. Subgroup analyses were not planned.

Results

Recruitment and participant flow

We prolonged the planned recruitment period from August 2008 to April 2009 by one additional month, up to May 2009. This was in order to recruit the intended sample size. The 52-week follow-up was closed in May 2010.

One hundred and forty-one participants were recruited (Berlin: 19; Bonn: 21; Freiburg: 26; Karlsruhe: 15; Mainz: 24; Marburg: 21; Tübingen: 15). The flow chart (Figure 1) shows that attrition following randomisation did not lead to significant group differences.

Baseline Characteristics

Randomisation did avoid imbalances in baseline characteristics (Table 2) and pre-treatment assessment data (Table 3) except in one item. Participants in the control group had more moderate to severe limitations in their financial situation (14% v 2%; p=0.027). Because the financial situation is not known as predictive factor for functional decline, we did not adjust for this imbalance.[33]

Table 2: Demographic and clinical characteristics						
	COTiD			**Control**		
	analysed (n=54)	dropouts (n=17)	total (n=71)	analysed (n=50)	dropouts (n=20)	total (n=70)
Age, years (SD)	78.0 (7.1)	77.2 (8.5)	77.8 (7.4)	78.7 (6.0)	78.3 (7.1)	78.5 (6.3)
Sex, female	29 (54 %)	12 (71 %)	41 (58 %)	30 (60 %)	10 (50 %)	40 (57 %)
MMSE (SD)	20.4 (3.1)	19.0 (3.3)	20.2 (3.2)	20.7 (2.7)	20.3 (2.9)	20.7 (2.7)
GDS (SD)	6.9 (3.0)	5.6 (2.9)	6.5 (3.0)	5.2 (2.8)	6.1 (2.6)	5.5 (2.8)
Education						
no school graduation	2 (4 %)	1 (6 %)	3 (4 %)	1 (2 %)	0 (0 %)	1 (1 %)
middle school graduation (9 or 10 years)	41 (76 %)	13 (76 %)	54 (76 %)	37 (74 %)	15 (75 %)	52 (74 %)
high school graduation (12 or 13 years)	11 (20 %)	3 (18 %)	14 (20 %)	12 (24 %)	5 (25 %)	17 (24 %)
Financial situation as perceived by the carer						
no limitation	40 (74 %)	14 (82 %)	54 (76%)	38 (76 %)	13 (65 %)	51 (73 %)
minor limitation	12 (22 %)	1 (6 %)	13 (18 %)	3 (6 %)	3 (15 %)	6 (9 %)
moderate or severe limitation	1 (2 %)	2 (12 %)	3 (4 %)	7 (14 %)	4 (20 %)	11 (16 %)
no data	1 (2 %)	0 (0.0 %)	1 (1 %)	2 (4 %)	0 (0 %)	2 (3 %)
Primary carer						
Age, years (SD)	65.4 (16.3)	63.1 (14.0)	64.9 (15.7)	65.9 (13.0)	61.4 (17.4)	64.5 (14.4)
Sex, female	38 (70 %)	9 (53 %)	47 (66 %)	35 (70 %)	18 (90 %)	53 (76 %)
Spouse	32 (59 %)	8 (47 %)	40 (56 %)	31 (62 %)	9 (45 %)	40 (57 %)
Daughter or son (in law)	20 (37 %)	7 (41 %)	27 (38 %)	16 (32 %)	9 (45 %)	25 (36 %)
Others	2 (4 %)	2 (12 %)	4 (6%)	3 (6 %)	2 (10 %)	5 (7 %)
Living together (%)	41 (76 %)	11 (65 %)	52 (73%)	33 (66 %)	14 (70 %)	47 (67 %)

Intervention delivery

61 of 71 (86%) allocated patient-carer dyads received complete sessions in the COTiD group, 66 of 70 (94%) in the control group. In each group, 4 pairs were lost before intervention. Six patient-carer dyads in the COTiD had less than 10 sessions. Interventionists rated the delivery of 20 pre-defined treatment sub-processes, ranging from interviewing patient and carer to training of simplified activities or supporting the carer in supervision. They scored treatment delivery as 78% in the COTiD group and 80% in the control group. Interventionists rated the patient's adherence in 67 cases of the COTiD group, from 15 as hindering the delivery of treatment; 26 as neutral and 26 as facilitating. Rating criteria were the patient's cooperation during interview, goal setting and training; the daily changing mental capacity; collaboration with the carer; and the acceptance of innovations. Ratings of carers' adherence were 5 hindering; 15 neutral; and 47 facilitating. The carer adherence was assessed with regard to the cooperation during scheduling, interview, goal setting and training to supervise; the encouragement of the patient; the acceptance of support service; and the implementation of innovations. The adherence of the participants in the control group could not be rated, because interventionists had no further contact after the consultation.

Outcomes

The MANOVA in 104 completers (COTiD: n=54; control: n=50) revealed no significant group time interaction effect in the primary outcome measurements of patients' daily functioning (Figures 2 and 3). Using the arcsine transform [34] for the PRPR percentage did not change results (original: p = 0.243; arcsine-transform: p = 0.216). An additional mixed models analysis of all randomised patients (N=141) as recommended by Coley and colleagues [35] did reveal no significant interactions for the IDDD (p=0.340) and the PRPP (p=0.785). Tables 3 and 4 show mean, standard deviation and group difference including 95%-confidence intervals of an ANOVA for all outcomes. Patients' daily functioning did not significantly change over 26 weeks in either the experimental and control group. In the postal 52 weeks follow up, the patients' need for assistance increased in both groups, and accordingly the carer's hours of care for basic ADL were higher. Two patients of the COTiD group were placed to nursing homes 33 and 44 weeks after baseline and one patient of the control group after 33 weeks.

To address the problem of missing data in single measurement instruments, we performed a multiple data imputation. We calculated a MANOVA over four measurement time points for all primary and secondary outcomes for all 104 completers. Ten different data imputations did not reveal any significant time group interaction effects.

We also tested for study sites differences at baseline and found no significant differences in a MANOVA with the factors *study sites* and *intervention groups* ($F(66, 432)=1.079$, p=0.323). Furthermore, no study site effect was found in the primary outcome analysing IDDD and PRPP data of baseline, week 6, 16 and 26 (IDDD: $F(6, 90)=0.724$, p=0.631; PRPP: $F(6, 90)=1.758$, p=0.117).

Harms

There were no differences between intervention and control group, neither in the number of adverse events nor in their severity. The study site physicians judged all adverse events as unrelated to trial treatment or assessment con-

tacts. In the total sample of all randomised participants (n=141), two deaths of patients (both in the control group) and one death of carer (in the COTiD group) were reported. In the COTiD group, 14 patients were admitted to hospital for an average of 15 nights; and 10 patients in the control group, for an average of 18 nights. There was no difference between the two groups in average number of nights admitted to hospital (F(1, 97)=2.785, p=0.1). All events were unrelated to the occupational therapy sessions.

Figure 2: ADL task performance of Alzheimer patients following intense occupational therapy compared with a single session control intervention; means and 95%-confidence intervals of the PRPP independence scale (N=104 completers; range: 100=no errors to 0=all errors)
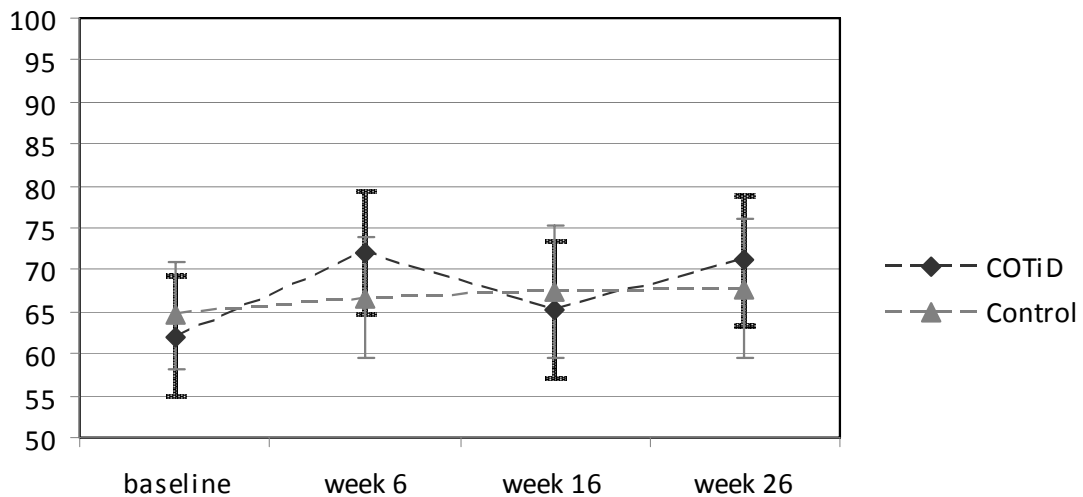

Figure 3: Need for assistance in ADL of Alzheimer patients following intense occupational therapy compared with a single session control intervention; means and 95%-confidence intervals of the IDDD performance scale (N=104 completers; range: 0=never needed assistance to 44=always needed assistance)
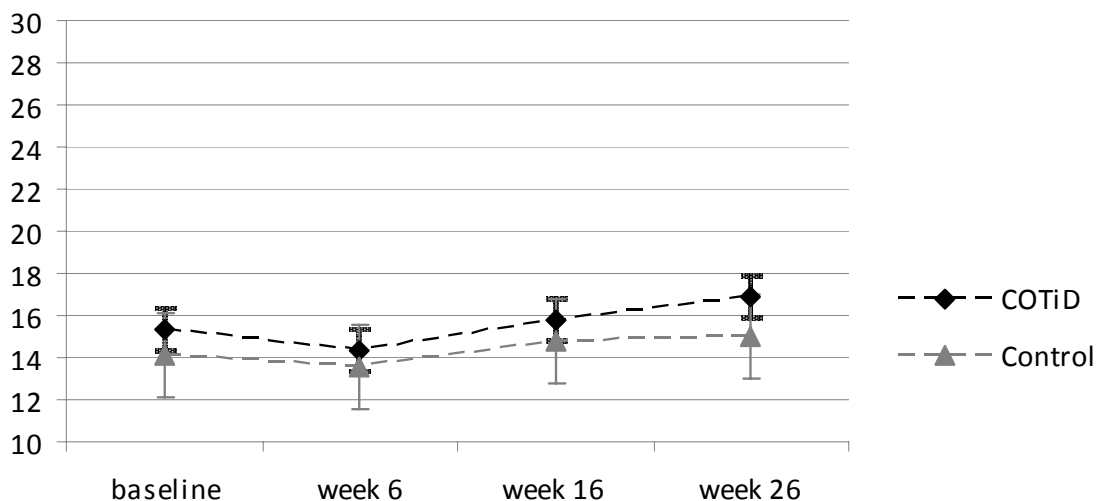
Table 3: Patients' outcomes following intense occupational therapy compared with a single session control intervention in Alzheimer patients and their carers

	Sample size		Baseline		6 weeks			16 weeks			26 weeks			52 weeks (postal carer rating)		
	COTiD N	Control N	COTiD mean (SD)	Control mean (SD)	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]
PRPP independence 100 to 0*	54	50	62.1 (26.8)	64.6 (23.1)	72.0 (27.1)	66.7 (26.1)	-5.3 [-15.7 to 5.1]	65.2 (30.3)	67.4 (28.2)	2.2 [-9.2 to 13.6]	67.8 (30.1)	71.1 (29.4)	3.3 [-8.3 to 14.9]	-	-	-
IDDD performance 44 to 0*	54	50	15.4 (9.9)	14.1 (10.1)	14.3 (9.5)	13.5 (10.3)	-0.8 [-4.6 to 3.1]	15.8 (10.1)	14.8 (10.1)	-1.0 [-5.0 to 2.9]	16.9 (10.1)	15.0 (10.3)	-1.9 [-5.8 to 2.1]	21.1 (11.9)	18.7 (11.6)	-2.4 [-7.1 to 2.3]
IDDD initiative 0 to 36*	54	50	16.0 (8.7)	15.9 (8.4)	15.0 (8.1)	14.4 (8.7)	-0.6 [-3.9 to 2.7]	15.5 (8.2)	16.4 (9.1)	0.9 [-2.5 to 4.3]	16.1 (8.6)	16.7 (9.3)	0.6 [-2.9 to 4.1]	20.1 (9.9)	19.1 (10.1)	-1.0 [-5.0 to 3.0]
CSDD 0 to 38*	41	37	13.2 (7.6)	10.4 (6.3)	12.7 (7.8)	10.3 (6.1)	-2.4 [-5.5 to 0.8]	11.4 (7.2)	11.3 (6.6)	-0.1 [-3.2 to 3.0]	12.3 (6.8)	10.9 (6.3)	-1.3 [-4.3 to 1.6]	13.8 (6.7)	11.7 (6.7)	-2.0 [-5.1 to 1.0]
DQoL overall 5 to 1*	49	45	2.8 (0.8)	3.1 (0.8)	2.9 (0.9)	3.1 (0.6)	0.3 [-0.04 to 0.6]	2.8 (0.8)	3.1 (0.9)	0.3 [-0.02 to 0.6]	2.9 (0.8)	3.0 (0.8)	0.2 [-0.1 to 0.5]	-	-	-
SF-12 physical 100 to 0*	47	45	42.7 (10.0)	45.0 (9.4)	42.4 (11.4)	45.4 (11.0)	3.0 [-1.7 to 7.6]	41.8 (9.2)	45.1 (11.6)	3.3 [-1.0 to 7.6]	41.8 (11.3)	44.8 (11.1)	3.0 [-1.6 to 7.6]	-	-	-
SF-12 mental 100 to 0*	47	45	49.3 (11.0)	52.2 (9.3)	50.3 (12.3)	51.2 (9.9)	0.9 [-3.7 to 5.6]	51.8 (10.1)	52.8 (9.5)	1.1 [-3.0 to 5.1]	53.1 (9.0)	52.3 (10.6)	-0.8 [-4.9 to 3.3]	-	-	-

*Range: positive to negative, COTiD: Community Occupational Therapy in Dementia Programme, PRPP: Perceive, Recall, Plan and Perform System of Task Analysis, IDDD: Interview for Deterioration in Daily Living Activities in Dementia, CSDD: Cornell Scale for Depression in Dementia, DQoL.: Dementia Quality of Life Instrument

Table 4: Carers' outcomes following intense occupational therapy compared with a single session control intervention in Alzheimer patients and their carers

	Sample size		Baseline		6 weeks			16 weeks			26 weeks			52 weeks (postal carer rating)		
	COTiD N	Control N	COTiD mean (SD)	Control mean (SD)	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]	COTiD mean (SD)	Control mean (SD)	Group Diff. mean [95%CI]
SCQ 135 to 27*	50	47	100.8 (17.4)	107.0 (16.4)	103.0 (18.7)	108.6 (17.2)	5.7 [-1.6 to 12.9]	102.7 (18.2)	107.3 (17.8)	4.6 [-2.6 to 11.9]	104.7 (17.0)	107.9 (17.4)	3.2 [-3.7 to 10.1]	99.8 (17.8)	103.6 (18.6)	3.8 [-3.5 to 11.2]
CES-D 0 to 60*	52	46	12.1 (7.7)	11.3 (5.9)	10.6 (7.1)	10.9 (6.9)	0.3 [-2.6 to 3.1]	10.6 (7.7)	10.8 (7.3)	0.3 [-2.8 to 3.3]	10.0 (7.9)	10.0 (6.9)	0.0 [-3.0 to 3.0]	14.3 (10.3)	12.9 (7.7)	-1.4 [-5.1 to 2.3]
DQoL overall 5 to 1*	51	48	3.1 (0.8)	3.1 (0.7)	3.0 (0.6)	3.1 (0.7)	0.0 [-0.2 to 0.3]	3.1 (0.7)	3.0 (0.8)	0.0 [-0.3 to 0.3]	3.0 (0.7)	3.2 (0.8)	0.2 [-0.1 to 0.5]	2.8 (0.8)	3.0 (0.8)	0.2 [-0.1 to 0.5]
SF-12 physical 100 to 0*	40	38	42.4 (11.5)	43.5 (11.3)	45.8 (10.0)	44.0 (10.0)	-1.8 [-6.3 to 2.7]	44.1 (10.8)	46.2 (9.2)	2.1 [-2.5 to 6.6]	45.4 (10.7)	45.0 (10.5)	-0.4 [-5.2 to 4.4]	42.7 (10.7)	41.6 (11.7)	-1.0 [-6.1 to 4.0]
SF-12 mental 100 to 0*	40	38	50.9 (9.1)	49.8 (10.7)	50.6 (11.0)	50.0 (8.7)	-0.6 [-5.1 to 3.9]	52.3 (8.6)	48.5 (11.8)	-3.9 [-8.5 to 0.8]	50.2 (9.1)	50.1 (10.7)	0.0 [-4.5 to 4.4]	49.5 (11.9)	47.7 (10.7)	-1.7 [-6.9 to 3.4]
Basic ADL-care by primary carer (hours per day)	52	43	0.5 (0.8)	0.8 (1.3)	0.8 (1.8)	0.9 (1.4)	0.1 [-0.5 to 0.8]	0.7 (1.2)	1.0 (1.4)	0.2 [-0.3 to 0.7]	0.8 (1.2)	1.0 (1.5)	0.2 [-0.3 to 0.8]	1.6 (2.2)	1.8 (2.2)	0.1 [-0.8 to 1.0]
IADL-care by primary carer (hours per day)	52	45	2.1 (2.7)	2.5 (2.6)	1.9 (2.5)	2.9 (3.0)	1.1 [-0.04 to 2.2]	2.3 (2.6)	2.9 (2.8)	0.6 [-0.5 to 1.7]	2.2 (2.2)	3.2 (2.8)	1.0 [0.0 to 2.0]	2.7 (2.2)	3.2 (2.8)	0.5 [-0.6 to 1.6]

*Range: positive to negative, COTiD: Community Occupational Therapy in Dementia Programme, SCQ: Sense of Competence Questionnaire, CES-D: Center for Epidemiologic Depression Scale, DQoL.: Dementia Quality of Life Instrument, ADL: Activities of Daily Living, IADL: Instrumental Activities of Daily Living

Discussion

In the results of this study, a ten-session community occupational therapy in dementia programme (COTiD) was found to be no more beneficial than a one-session consultation concerning short- and middle-term effects on patients' daily functioning. In both groups, the need for assistance in basic and instrumental activities of daily living and the performance of a self-chosen daily living task remained stable up to six months after baseline. No significant group differences could be found on secondary outcomes, which were quality of life and mood of patient and primary carer; patient's initiative in daily activities; carer's sense of competence in interaction with the patient; carer's hours of daily care; and the patient's nursing home placement. There were no adverse events associated with experimental or control intervention.

Limitations
Despite an elaborate study design, there are some limitations in this study. We analysed only 104 completer dyads from 141 recruited pairs (74 %). However, (1) baseline data of completers and non-completers did not show imbalance; (2) dyads were maintained, whose data were valid, and for whom treatment was intended but not received in the complete ITT-analysis; (3) an additional mixed model analysis of all randomised patients did also not reveal significant differences; and (4) the analysis of the reduced patient sample with valid data did not show even a tendency towards significant group differences. Thus the hypothesis of group differences must be rejected, because the analysis of completers usually favours results in the direction of group differences.
A second shortcoming was that following the common introductory seminar the start of the study differed amongst the sites owing to different time lines in administrative matters and approval of the local ethic commissions. Therefore, a common repetition seminar for the interventionists could not be arranged after the pilot training. This may have led to some heterogeneity in the intervention, especially because in Germany eleven newly introduced interventionists performed the treatment compared to two experienced experts in the original Dutch trial. We addressed this problem with feedback on videos of treatment sessions the interventionists sent in. Furthermore, we arranged telephone supervision on demand.
We consider the contamination of the control intervention with knowledge from the experimental intervention to be low, because any specific intervention such as activity selection, simplification or training was precluded by the limited time to carry out the control intervention.

Comparison
The Dutch RCT on the COTiD with waiting-control-group design showed large effect sizes in the IDDD performance scale at six and twelve weeks after baseline (d=2.3 and 2.4, respectively).[6] The Dutch and the German sample did not differ remarkably in cognition at baseline (MMSE: 19 v 20), but did differ in the need for assistance (IDDD performance: 24 v 15). The German patients showed a low need for assistance at the beginning of the study. This was comparable to the IDDD values of the Dutch patients at the end of the treatment. This may have caused a floor effect on the IDDD. Another mono-centre RCT in the USA compared community occupational therapy and a less intensive telephone consultation in patients with probable dementia (MMSE: 13).[36] The authors found a small effect size in daily functioning (d=0.21). The initial need for

assistance in both studies was higher than in the German sample. A systematic review of community programmes in dementia [37] reported one study on exercise and behavioural management with beneficial effects on daily functioning of patients with moderate dementia (MMSE: 17); one trial on occupational therapy with heterogeneous effects; and two studies on occupational therapy and music therapy with no significant effects. A current German health technology assessment on non-drug therapies in Alzheimer's disease did not identify further community occupational therapy trials [38]. The comparison of community intervention trials reveals that study samples with a lower MMSE and a higher need for assistance benefit more than those with initial higher cognitive and daily functioning. Similarly, a standardized synopsis of ADL outcomes in pharmacological dementia trials indicated that samples with an MMSE between 17 and 10 benefit most in ADL while samples with higher MMSE scores showed less effects.[39] However, different baseline scores of cognitive and daily functioning alone cannot explain the major difference between the findings in this German study and the positive results of the Dutch RCT. Detailed process evaluation and exploratory analyses of the study data might show whether variations in study site context and treatment performance influenced the intervention's effectiveness.

Clinical and research implications
Published evidence for the effectiveness of community occupational therapy in dementia is heterogeneous as indicated by a Dutch trial with large positive effects on daily functioning; a few USA trials with no or small positive effects on ADL and this German study showing that ten sessions were not better than one consultation. A preventative one-session consultation might be hypothesised as beneficial for people with mild dementia and an improved 10-session programme more specifically adapted to the German health care system as beneficial for dementia patients with moderate need for assistance in ADL, as was shown in the Dutch study in which most people with dementia had moderate to high need for assistance at baseline.

Although we had expected smaller effect sizes than in the Dutch original trial owing to changed study design with (1) the introduction of an active control group, (2) a variance in treatment performance in several centres, (3) a prolonged follow up time and (4) rigorous reduction of the analysed sample to participants with valid data, it remains surprising that significant group difference could not be found in any of the primary or secondary outcomes.

This study has shown that careful cross-national comparisons are greatly needed, especially in complex interventions, before they can be considered evidence based and implemented effectively in other health care systems. Therefore, further analyses must investigate the role of interventionists' expertise and treatment performance, and the role of participants' needs and utilisation of health care resources, before conclusions on international implementation of this intense occupational therapy intervention can be drawn.

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3

Why did an effective Dutch complex psycho-social intervention for people with dementia not work in the German health care context? Lessons learned from a process evaluation alongside a multi-centre RCT

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Abstract

Background: The positive effects of the Dutch Community Occupational Therapy in Dementia programme on patients' daily functioning were not found in a multicentre RCT in Germany.

Objectives: To evaluate possible effect modification on the primary outcome within the German RCT with regard to (1) participant characteristics, (2) treatment performance, and (3) healthcare service utilisation; and (4) to compare the design and primary outcome between the German and the original Dutch study.

Methods: (1) The impact of participant baseline data on the primary outcome were analysed in exploratory ANCOVA and regression analyses. (2) Interventionists completed questionnaires on context and performance problems. The main problems were identified by a qualitative content analysis and focus group discussion. Associations of the primary outcome with scores of participant adherence and treatment performance were evaluated by regression analysis. (3) Utilisation rates of healthcare services were controlled for significant group differences. (4) Differences of the Dutch and German study design were identified and primary outcome was contrasted at the item level.

Results: (1) Participant characteristics could not explain more than 5 % of outcome variance. (2) The treatment performance of some active intervention components was poor but not significantly associated with the primary outcome. (3) There were no significant group differences in the utilisation of health care resources. (4) In contrast to the Dutch waiting-control group, the active intervention in the German control group may have reduced group differences in the current RCT. The German patients demonstrated higher independence at baseline and less improvement in instrumental activities of daily living.

Conclusion: The differences in outcome may be explained by a more active control treatment, partially poor experimental treatment and less room for improvement in the German sample. Future cross-national transfers should be prepared by pilot studies assessing the applicability of the intervention and patient needs specific to the target country.

Introduction

New guidance from the British Medical Research Council states that developing and evaluating complex interventions can be a lengthy process. All steps should sufficiently be addressed. These steps include (1) the development of the intervention, (2) a pilot study on feasibility, (3) a randomised controlled trial (RCT) on effectiveness and (4) an evaluation of implementation in health care practice.[1] Cross-national transfer of complex intervention can speed up the uptake of innovative and effective programmes from one country to another. Time and resources might be saved when an intervention programme which was already developed, piloted and evaluated on effectiveness in one country can directly be proven regarding effectiveness in the healthcare context of another country. We followed this approach by transferring the Dutch evidence-based Community Occupational Therapy in Dementia Programme (COTiD)[2] to the German health care system and testing its effectiveness in a seven-centre RCT.[3] However, the highly positive effects of the Dutch COTiD on patients' daily functioning could not be found. Process evaluation is recommended as highly valuable in RCTs to provide insight into unexpected intervention failure.[4] Differences in participants as well as aspects of treatment performance and contextual factors should be assessed with regard to their associations with the primary outcome.[5-7] Based on these recommendations, our process evaluation investigated four research questions. We evaluated both possible bias within the German study (question 1-3) and differences between the Dutch and German RCT (question 4).

1. Did specific patient or carer characteristics influence a patient's outcome after the intervention?
2. What problems and variations in experimental treatment performance could be identified in the study context and did they influence the daily functioning of patients?
3. What differences in the utilisation of further healthcare resources during the treatment period could be identified and did they influence the daily functioning of patients?
4. What differences between the Dutch and the German study could be identified in terms of design and primary outcome?

Methods

1. Specific participant characteristics of the German sample
The outcome of interest was daily functioning indicated by two measurement instruments, the Interview for Deterioration in Daily Living Activities in Dementia (IDDD) and the Perceive, Recall, Plan and Perform System of Task Analysis (PRPP). The IDD performance scale records the patients' need for assistance in 11 basic and instrumental activities of daily living.[8] In the PRPP, the number of errors occurring during the performance of a self-chosen daily living task is measured.[9] An ANCOVA was used to investigate the mean changes from baseline in the IDDD and PRPP between the COTiD and control group controlling for (1) the patient's age, gender, education and financial limitation; and the daily activities, mood and cognition at baseline; and (2) the carer's gender, education, relationship to the patient; and the sense of competence and mood at baseline. Data were collected with standardised measurement instruments as de-

scribed in the study protocol and were in line with a recent health-technology assessment of risk or protective factors for Alzheimer's disease.[10, 11] Percentage variance explained in mean changes from baseline in the IDD and PRPP was assessed using multiple regression.

Table 1: Statements by interventionists stating main performance problems within the therapeutic subprocesses	
Setting therapy goals	*"Priorisation by the patient was difficult, because he was very uncritical".*
	"The carer wants immediately to talk about problem solving. I again and again had to suggest the procedure [of systematic shared goal setting]*"*.
Educating patient in new skills	*"Patient needs much guidance. Concentration and endurance* [are] *very limited. Assistance for simple tasks* [is needed]*"*.
	"Activities agreed on could not be carried out twice owing to apathy and depressive mood".
	"In addition, patient had dyspraxia, which made training difficult".
	"[There was a] *lack of training owing to the negative attitude of the carer".*
	"It is difficult for the patient to accept the disease. Therefore a high degree of convincing is needed in each session".
Adapting physical or social environment	*"The carer is the house owner and refuses any adaptation".*
	"[Adapting physical environment] *does not succeed because the carer is ostensibly open for intervention, but in reflective talks reluctant and negative".*
	"An adaptation [of the physical environment] *seems not reasonable to the patient, although* [it is] *necessary".*
	"[Adapting physical environment] *is possible only step by step, because the patient reacts on it with reluctance".*
	"The patient lives rather reclusively, wishes no changes [in the social environment]*"*.
	"The patient is very anxious and avoiding [change]*"*.
	„*The son strongly adheres to old patterns of interaction*".
	"The family dynamic is very fixed. Both daughters seem to have difficulty in just letting the mother [patient] *simply do … Changes take place, but very slowly.* [It is] *questionable, whether there will be work on the goals after the intervention is finished".*
	"In the community, there is no day care and no care centre for people with dementia".
Training of carer's competence	*"The son* [is] *often not or only temporary present at the sessions".*
	"[The carer is] *many a time overstrained and tries to give away* [the responsibility] *to the therapist"*
	"It is difficult for the carer to get used to something new. He quickly falls back into old patterns [of behaviour] *without being aware of it".*
	"[The carer] *seems to be very overstrained and burdened by the disease. He needs additional professional support e.g. from a psychologist".*
	"The carer has need for support, but refuses any offer of support for himself."
	"The carer mostly sees only his own problems. He can not or only very rarely empathises with the patient. Offers of support are refused".
	„*There are difficulties in the interaction between the family and the patient. The patient plays off the caring family members against each other".*

2. COTiD performance in the German experimental group

Interventionists completed semi-structured questionnaires during and after the treatment period. (Questionnaires are available in German from the corresponding author.) During the treatment phase, they reported reasons for a problematic performance of 20 sub-processes for each experimental case. The sub-processes were defined according to the study protocol (table 1 and 4). After the treatment period, interventionists described and rated their professional experience in the field and their valuation of introduction, pilot phase and supervision, as well as inhibiting and facilitating processes at the study site. A qualitative content analysis with inductive category development was used to identify the main performance problems from the comments given in the question-naires.[12-16] A focus-group discussion served as a member check, in order to achieve consensus among the interventionists about the main performance problems.[17-21] Furthermore, the interventionists dichotomously scored the 20 treatment sub-processes as performed either with or without problems. These scores were used to operationalise the quality of performance for each case. The best quality was indicated by 100% when all sub-processes were performed without any problems.

The interventionists also rated patient adherence regarding the cooperation during the interview, the goal setting and the training; as well as regarding the patient's daily changing mental capacity, their collaboration with the carer and regarding the acceptance of innovations. Additionally, the carer adherence was assessed with regard to their cooperation during the scheduling, the interview, the goal setting and the training of supervision, as well as with regard to their encouragement of the patient, the acceptance of support service and the implementation of innovations. Interventionists rated these indicators for adherence on a five-point-Likert scale ranging from *'very facilitating for the treatment performance'* (=1) to *'very hindering for the treatment performance'* (=5).

Correlations between the mean changes from baseline in the IDDD and PRPP and scores of the performance quality and the participant adherence were calculated (Pearson coefficient). An exploratory regression analysis was deemed to be appropriate for smaller samples, and this was to evaluate whether such scores could explain variance in the mean changes from baseline in the IDDD and PRPP.[22]

3. Utilisation of healthcare resources in the German study

The Resource Utilisation in Dementia[23] was applied to collect patient data during the treatment period on (1) the number of consultations with general practitioners, neurologists/psychiatrists and other medical specialists; (2) the time for individual therapy such as physio-, speech- or psychotherapy; (3) the time for group therapy such as cognitive stimulation or exercise groups; (4) times of receiving nursing or domestic home care; (5) the number of technical aids implemented within the patient's home; and (6) increasing, decreasing, constant or no intake of acetyl cholinesterase inhibitors. Furthermore co-morbidity indicating a possible need for further healthcare services was rated using the Cumulative Illness Rating Scale.[24] These data were tested for the significance of group differences between the experimental and the control arm (nonparametric two-tailed Mann-Whitney-U test owing to the negative skewness of the data distribution).

4. Comparison between the Dutch and the German study

Regarding the patient characteristics and change from baseline to follow-up on the primary outcome, we compared the single IDDD items of the Dutch and the German sam-

ple within the identical measurement period of five weeks from baseline to the first follow up measurement at week 6. This was in order to assess whether both samples had the same room for improvement in items which indicate the need for assistance in daily activities. Furthermore, we compared the expertise of the Dutch and German interventionists in terms of pre-experience with the experimental intervention and intensity of treatment delivery (patients per interventionist) and the study designs regarding the control-group intervention. [2][3]

Results

1. Specific participant characteristics of the German sample

The mean changes to baseline in the IDDD and the PRPP were neither associated with carers' socio-demographic or baseline assessment data nor with patients' socio-demographic data or baseline mini mental state (table 2). We found a minor correlation of mean changes to baseline in the IDDD with patients' mood at baseline (Cornell Scale for Depression in Dementia, CSDD[25]; r=0.21; p=0.044).

	N	Perceive, Recall, Plan and Perform System of Task Analysis[9] change to baseline	Interview for Deterioration in Daily Living Activities in Dementia[8] change to baseline
Table 2: Pearson correlation coefficient of specific participant characteristics and mean changes to baseline in the IDDD and the PRPP (German completers of the Community Occupational Therapy in Dementia Programme and control group)			
Patient			
Age	104	-0.02	0.11
Gender	104	-0.16	-0.11
Education	104	-0.13	-0.02
Financial limitation	93	0.07	0.14
Mood, Cornell Scale for Depression in Dementia[25] baseline	95	0.16	0.21*
Cognition, MMSE baseline	104	0.02	0.10
Carer			
Gender	104	0.08	-0.11
Education	104	-0.12	0.11
Relationship to patient	104	0.15	0.09
Sense of competence, Sense of Competence Questionnaire (SCQ)[26] baseline	103	-0.06	-0.02
Mood, Center for Epidemiologic Depression Scale [27] baseline	103	0.09	0.09
*p<0.05 (two-tailed)			

A stepwise regression analysis using patient and carer characteristics as listed in table 2 could not explain more than 5 % of variance in change over time of patient's daily functioning. Adjusted ANCOVA using patient's baseline values of the CSDD, the PRPP and the IDDD as independent variables did not yield any significant group differences in the dependent variables, which were the mean changes to baseline in the IDDD and the PRPP (results not shown). This indicated that after correction for baseline scores of mood and daily functioning, there were still no significant differences on the primary outcome in the German sample with moderate to good daily functioning at baseline.

2. COTiD performance in the German experimental group

Eleven interventionists from seven study sites delivered the COTiD to 54 patients. The interventionists' characteristics (table 3) varied in previous years in dementia care from 1 year part time to 11 years full time, in perceived facilitators from quite facilitating to slightly hindering and in the quality of treatment performance from 52 to 90% of optimal performance. The data did not provide stable patterns in the sense that many previous years in dementia care and high values of perceived facilitators did lead to a high quality of treatment performance or vice versa.

Table 3: Characteristics of the 11 interventionists who delivered Community Occupational Therapy in Dementia Programme (COTiD) to 54 patients with Alzheimers (German completers of the COTiD group)

Basic data				Perceived facilitators§				Treatment performance	
Age	Gender	Years in occu-pational therapy	Years in dementia care	Pre-existing knowledge	Study preparation	Site support	Total	Cases	Quality (%)&
27	Male	3	3	2.2	2.0	1.1	1.8	3	86
31	Female	8	5	1.6	2.0	1.2	1.6	3	89
45	Female	9	7	1.8	2.5	2.2	2.2	5	94
44	Female	7	1*	3.2	1.7	1.8	2.2	2	64
40	Male	13	13*	3.8	3.0	2.4	3.1	10	81
34	Female	5	3	3.8	2.5	2.8	3.0	10	90
54	Male	11	11	2.0	3.5	2.7	2.7	4	73
36	Female	11	9	2.3	2.7	2.6	2.5	1	52
39	Female	18	12*	2.4	2.5	2.9	2.6	2	74
40	Female	6	3*	2.4	3.3	2.9	2.9	2	59
32	Female	9	9*	4.2	3.3	3.4	3.4	12	84

*part-time; §scored by interventionists with 1=very facilitating, 2=facilitating, 3=neutral, 4=hindering, 5=very hindering; &100%=all treatment sub-processes were performed without problems

The quality of the subprocess performance (table 4) did also vary from receiving full medical information in 52 of 54 cases (96%) to successfully adapting physical environment in 24 cases (44 %). Subprocesses relating to therapeutic active agents as identified by Graff et al.[15] were performed with no problems at only a low frequency with 76 % for setting therapy goals, 46 % for training of patient's skills, 44 and 46 % for adapting physical and social environment and 59 and 54 % for training of carer's competence in instruction and problem-solving. In the questionnaires, the interventionists gave comments representing the main performance problems in these subprocesses (table 4).

Table 4: Quality of sub-processes of Community Occupational Therapy in Dementia Programme (COTiD) performance in 54 Alzheimer's disease patients (German completers of the COTiD group)

| Sub-processes | Performance* | | Main problems |
	Good (%)	Poor	
01 Receiving medical information	52 (96)	2	Received wrong phone number or no detailed medical information
02 Making appointments with participants	49 (91)	5	Participants had other appointments
03 Travelling to participants	46 (85)	8	Long travel to patient's home (some > 40 km)
04 Meeting the participants	50 (93)	4	Participants forgot to cancel the date and were late or not at home
05 Contacting and providing confidence	50 (93)	4	Patient was sceptic or abrasive
06 Informing about the procedure	50 (93)	4	Patient could not understand procedure, misunderstood procedure as test for nursing home placement
07 Observing the timeframe	42 (78)	12	Participants (mainly carer) had a great need to tell and talk
08 Explaining clearly, responding to questions	50 (93)	4	Patient could not understand explanation owing to communication deficits or mood swings
09 Mastering conflicts and problematic situations	39 (72)	15	Patient had severe mood swings or additional cognitive deficits or was not aware of deficits; carer was overstrained, abrasive or placed sole responsibility on therapist; family conflicts existed for a long time
10 Interviewing patient with OPHI	38 (70)	16	Patient was not or hardly able to tell, had anomia or severe deficits in biographic memory or was disoriented
11 Observing patient activity with Volitional Questionnaire, if OPHI not done	5 (71*)	2	Patient not motivated to demonstrate activities; *Volitional Questionnaire not necessary in 47 cases, because OPHI was done
12 Interviewing carer with Ethnographic Interview	47 (87)	7	Carer had only little understanding of dementia or felt very burdened
13 Observing activities of patient and carer	43 (80)	11	Patient did activity incompletely, was very passive or was fraught when being observed; carer was demanding or inpatient
14 Setting therapy goals with patient and carer	41 (76)	13	Participants negated need for change or could not specify goals
15 Defining occupational therapy problems	43 (80)	11	Patient had no activity limitations; participants could not understand the relevance of problems; problems were very complex or became clearer only later during intervention or were not related to dementia but depression or physical limitations.
16 Educating patient in new skills and compensation capability	25 (46)	29	Patient was not or hardly motivated in training, additional symptoms such as dyspraxia, depression, apathy, attention deficit disorder hampered the training; carer or family were not supportive
17 Adapting physical environment	24 (44)	30	Participants refused or hesitantly accepted necessary adaptations
18 Adapting social environment	25 (46)	29	Participants were reluctant to change social environment; informal social support or care services were lacking
19 Training of carer's competence in instruction and interaction	32 (59)	22	Carer could not change behaviour as being very burdened or inpatient or bound in firm habits; was not willing to take responsibility or was missing sessions
20 Training of carer's competence in problem solving	29 (54)	25	Carer was not willing to undertake the responsibility of problem solving or not able to do so owing to high burden; carer would have needed more time or further support to undertake the responsibility for independent problem solving.

* Number of cases, in which the performance of this sub-process was rated as *unproblematic* (=good) or *problematic* (=poor). OPHI, Occupational Performance History Interview

Association between COTiD performance and primary outcome
We found no significant associations between the scores of COTiD performance and changes to baseline in the IDDD and in the PRPP (detailed data not shown). Since there was a poor performance of those subprocesses which were related to active therapeutic agents (nos 14 to 20; table 4), we further analysed the association between the performance score of these subprocesses and the changes to baseline in the IDDD and in the PRPP. A minimal correlation was found, r=0.268 (p=0.05) only with the PRPP. No association was found between carer adherence and the changes to baseline in the IDDD and in the PRPP. The score of patient adherence and the change to baseline in the PRPP demonstrated a moderate correlation of r=-0.317 (p=0.02). The subsequent regression analysis revealed that patient adherence could explain 10 % of the variance (p=0.02) in the PRPP change to baseline. The IDDD change to baseline could not be explained by patient or carer adherence, or by the quality of treatment performance.

Table 5: Utilisation of further healthcare resources of patients with Alzheimers during the intervention period of intense occupational therapy compared with a single session control intervention (German completers of the Community Occupational Therapy in Dementia Programme (COTiD) and control group)

Healthcare resources	COTiD (n=54)			Control (n=50)		
	Mean (SD)	Range	Skewness	Mean (SD)	Range	Skewness
Medical consultations per week						
General practitioner	0.28 (0.40)	0 - 2.33	3.211	0.18 (0.17)	0 - 0.67	0.828
Neurologist or psychiatrist	0.04 (0.09)	0 - 0.33	2.092	0.03 (0.09)	0 - 0.50	3.508
Other medical expert	0.14 (0.26)	0 - 1.33	2.778	0.15 (0.24)	0 - 1.00	1.825
Hours for therapy per week						
Individual therapy	0.14 (0.32)	0 - 1.00	2.029	0.11 (0.29)	0 - 1.00	2.597
Group therapy	1.05 (2.92)	0 - 14.00	3.064	0.88 (3.32)	0 - 16.00	4.163
Hours for nursing or domestic home care per week	1.33 (3.23)	0 - 15.08	3.074	1.87 (5.32)	0 - 25.54	3.173
Number of technical aids provided at home	0.15 (0.49)	0 - 3.00	4.306	0.06 (0.24)	0 - 3.00	3.821
Comorbidity (Cumulative Illness Rating Scale[24])	3.15 (3.20)	0 - 13	1.101	2.42 (2.60)	0 - 11	1.374
No of patients with acetylcholinesterase-inhibitor medication						
De-novo treatment or increased dose	4 (7%)			3 (6%)		
Decreased dose or medication ceased	2 (4%)			1 (2%)		
Constant level	34 (63%)			26 (52%)		
No AchE-inhibitors	14 (26%)			20 (40%)		

3. Utilisation of healthcare resources in the German study
The COTiD group had a somewhat higher co-morbidity index, slightly more visits to general practitioners and somewhat less hours for nursing or domestic home care. Negative skewness in the data distribution indicated that many participants had a low utilisation rate and only a few participants had a high intensity of resource utilisation (table 5). However, we found no significant differences on group level within the German trial in any resource utilisation or co-morbidity. The subgroups of patients with decreasing or increasing acetylcholinesterase inhibitor medication were too small to detect any significant group differences. However, the daily functioning in the COTiD group was not better than in the control group, although more COTiD patients received acetylcholinesterase inhibitors at a constant level (COTiD, 63 % vs control, 52 %).

Table 6: Responsiveness of specific activities of daily living after an identical treatment period of 5 weeks in the Dutch and the German sample

		Dutch COTiD				Dutch control				German COTiD				German Control			
		N	Mean	T0-T1	SD	N	Mean	T0-T1	SD	N	Mean	T0-T1	SD	N	Mean	T0-T1	SD
IDDD items with low responsiveness in the Dutch sample																	
Washing oneself	T0	55	1.42	0.67	1.37	57	2.04	-0.07	1.63	54	0.74	0.15	1.20	50	0.78	-0.12	1.27
	T1	55	0.75		0.95	57	2.11		1.58	54	0.59		1.00	50	0.90		1.30
Dressing	T0	55	1.73	0.71	1.47	57	2.09	-0.17	1.49	54	0.98	0.07	1.34	50	1.06	-0.06	1.32
	T1	55	1.02		1.24	57	2.26		1.51	54	0.91		1.26	50	1.12		1.44
Combing one's hair and brushing one's teeth	T0	55	0.67	0.29	1.11	57	1.04	-0.05	1.40	54	0.70	0.00	1.16	50	0.60	-0.06	1.14
	T1	55	0.38		0.87	57	1.09		1.43	54	0.70		1.19	50	0.66		1.15
Eating	T0	55	0.18	0.03	0.67	58	0.43	0.03	0.98	54	0.28	0.02	0.74	50	0.40	0.04	1.07
	T1	55	0.15		0.45	58	0.40		0.95	54	0.26		0.78	50	0.36		0.92
Using the toilet	T0	55	0.42	0.17	0.88	57	0.96	0.12	1.48	54	0.37	0.07	0.85	50	0.58	0.22	1.09
	T1	55	0.25		0.65	57	0.84		1.39	54	0.30		0.74	50	0.36		0.94
Handling finances	T0	47	3.89	0.10	0.60	55	3.87	0.00	0.39	54	3.09	0.00	1.35	50	2.78	0.12	1.66
	T1	47	3.79		0.69	55	3.87		0.61	54	3.09		1.35	50	2.66		1.60
Overall mean	T0	55	1.33	0.34	0.73	57	1.73	-0.01	0.92	54	1.03	0.05	0.77	50	1.03	0.02	0.85
	T1	55	0.99		0.59	57	1.74		0.88	54	0.98		0.78	50	1.01		0.84
IDDD items with high responsiveness in the Dutch sample																	
Making tea or coffee	T0	55	2.05	**1.14**	1.39	57	2.18	-0.26	1.45	54	1.33	0.13	1.66	49	1.04	0.20	1.46
	T1	55	0.91		0.91	57	2.44		1.31	54	1.20		1.59	49	0.84		1.21
Shopping	T0	53	3.62	**1.19**	0.71	57	3.33	-0.06	1.19	54	2.00	-0.15	1.70	50	2.08	0.08	1.64
	T1	53	2.43		1.17	57	3.39		1.18	54	2.15		1.71	50	2.00		1.60
Using the phone	T0	55	2.04	**1.04**	1.53	54	2.28	-0.26	1.46	54	1.43	0.26	1.51	50	1.18	-0.24	1.29
	T1	55	1.00		1.23	54	2.54		1.53	54	1.17		1.34	50	1.42		1.54
Preparing a meal	T0	54	3.22	**1.26**	1.16	55	3.09	-0.18	1.44	54	2.15	0.11	1.80	50	1.92	0.30	1.77
	T1	54	1.96		1.32	55	3.27		1.37	54	2.04		1.74	50	1.62		1.68
Cleaning the house or doing minor repair work	T0	54	3.15	**1.43**	1.24	56	3.18	-0.36	1.22	54	2.31	0.43	1.65	50	1.62	0.06	1.50
	T1	54	1.72		1.27	56	3.54		0.93	54	1.89		1.64	50	1.56		1.59
Overall mean	T0	55	2.81	**1.21**	0.78	57	2.81	-0.22	0.96	54	1.84	0.16	1.29	50	1.56	0.08	1.56
	T1	55	1.61		0.74	57	3.04		0.86	54	1.69		1.24	50	1.50		1.19

COTiD: Community Occupational Therapy in Dementia, IDDD: Interview for Deterioration in Daily Living Activities in Dementia. In each item the need for assistance is rated from 0=never to 4=always. T0: IDDD score on entry to the study, T1: IDDD score at week 6 after 5 weeks treatment. T0-T1: 20 % improvement (≥ 0.8; shown in bold) is defined as clinically relevant change.

4. Comparison between the Dutch and the German study

Differences in the room for improvement in the IDDD
Table 6 shows that the COTiD group in the Dutch sample did notably improve in household instrumental activities of daily living (IADL), only marginally in basic activities of daily living and not at all in handling finances. Graff et al.[2] defined 20% improvement as being clinically relevant, which is indicated by a pre-post-treatment difference of 0.8 on item level. The household IADL items demonstrated such differences and, therefore, a high responsiveness to the COTiD programme. Thus, the household IADL items can be presumed to be a therapeutic window basically providing room for improvement given a sufficient need for assistance in these items at baseline. Comparing the Dutch and the German COTiD groups, the baseline values in these IADL items differed considerably more than in the other IDDD items.
The German patients showed much less need for assistance in this area. The limited room for improvement in the German sample is obvious when regarding the baseline differences between the Dutch and the German sample. Analysis of a German sub-sample matched to the Dutch sample with comparable need for assistance in these household IADL-items at baseline was not possible owing to the low number of German patients with such baseline values.

Differences in design
The German trial design included a comprehensive consultation as active control intervention which approximately represents the non-pharmacological standard care in Germany. This was in order to evaluate possible benefits of COTiD additional to standard care. Compared to the waiting-control-group design of the Dutch original trial, the German active control intervention may have reduced the group differences in daily functioning after the treatment. Compared with the Dutch therapists, the interventionists in Germany had less experience with COTiD before their study involvement (NL: 240 h vs GER: 0 h), less seminar and training time in the study preparation phase (80 vs 40 h) and fewer COTiD patients per interventionist during the treatment period (34 vs 5).

Discussion

The process evaluation of our multi-centre RCT on community occupational therapy in Alzheimer's disease revealed that the characteristics of the German participants at baseline did not mediate patients' daily functioning after treatment as indicated by the mean change to baseline in the IDDD and PRPP. Some sub-processes, which deemed to be active components of the applied complex psycho-social experimental intervention, were performed poorly. However, variances in the performance were not associated with patients' mean change to baseline in the IDDD and PRPP. The utilisation of further health care resources was equal in the experimental and control groups. Based on exploratory analyses of process data, we can reject the hypothesis that group differences in participant characteristics, variances in the treatment performance or in the utilisation of further health care resources had a confounding influence on the primary outcome within the German study sample. The analyses were limited by the restriction of range in the IDDD baseline data within the German sample. However, the variance of the IDDD baseline data in the German sample was higher than in the Dutch sample (German sample: experimental group, mean 15.4

(SD 9.9); control group, 14.1 (10.1); Dutch sample: experimental group 23.5 (7.9); control group, 24.5 (8.7)).

Using the same eligibility criteria, the German sample showed much less room for improvement in daily functioning than the Dutch sample. In Germany, patients' daily functioning at baseline was much better. Most German patients still performed better at the end of the study irrespective of group assignment than the successfully treated Dutch group, in which patients had lower baseline scores and improved significantly. This underlines the importance to pay attention to the needs of the patients and care givers specific to the target country.

In the German study, the self reported performance of active intervention components was not associated with the primary outcome. The small sample size and the method of self-rating are limitations for detecting such associations. Although an exploratory regression analysis is vulnerable to missinterpretation[22], we also performed this type of analysis, in order to detect any signs of an influence of treatment performance on the primary outcome. However, we found only minor rates of correlation and explanation, which makes any meaningful association between variances in the treatment performance and the primary outcome unlikely. Self-rating can be a feasible approach for adherence evaluation in dementia research[28], in order to deal with limited resources.[29] However, interventionists tend to overestimate their own performance.[30] Although the interventionists were explicitly asked to be critical when judging their own performance, for further studies it is recommended that there be an additional external monitoring of treatment performance. This may reduce possible bias introduced by over-estimation or over-criticism in self-rating. Furthermore, it might help to find appropriate onsite coaching strategies. These strategies should aim at high quality treatment performance even though the complexity of psycho-social interventions induces variances – especially in multi-centre RCTs.

Data on the association of treatment performance and primary patient outcomes, although encouraged,[5, 31] are scarce in RCTs studying complex interventions. Teri et al.[25] implemented an external video rating of therapists' adherence to protocol but found no associations between this rating and any outcome variable. Similar studies in the field[29, 30] did not operationalise the impact of treatment performance on the primary outcome as the British Medical Research Council had strongly recommended.[1] Within the original Dutch RCT, the large number of patients treated by two highly motivated interventionists from the same study site suggests an excellent quality of treatment performance.[2] However, its association with the patients' outcome was not quantified. The experiences with the subsequent Dutch implementation of the guidelines revealed that novices had difficulties in adapting to this highly complex intervention in a concrete treatment setting. Prior to cross-national implementation of complex interventions, a successful national transfer from a single-centre setting with highly motivated specialists to a multi-centre routine setting with therapists varying in competence and motivation seems to be appropriate.

Conclusion

Our process evaluation revealed that the participants in the study may have had insufficient need for the applied treatment and that active components of the complex psycho-social intervention were poorly performed. Also, an interaction can be considered in the sense that little need for assistance can make a less intensive, one-session treatment appropriate, as applied to the control group. These recent experiences suggest that cross-national transfers are best prepared by a pilot study in the target country exploring specific patient needs, the feasibility of inclusion criteria, the

usability of measurement instruments and the applicability of the complex intervention by therapists in routine care settings.

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4

Interview for Deterioration in Daily Living Activities in Dementia: Construct and Concurrent Validity in Patients with mild to moderate Dementia

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Abstract

Background: The purpose of the study was to translate the Interview of Deterioration in Daily Living Activities in Dementia (IDDD) into German and to evaluate the construct and concurrent validity in people with mild to moderate dementia.

Methods: IDDD data of two pooled samples (n=301) were analysed regarding ceiling and bottom effects, internal consistency, factor reliability and correlations with corresponding scales on cognition and activities of daily living.

Results: We found minimal bottom (< 5 %) and ceiling (≤ 2 %) effects, good internal consistency (Cronbachs α > 0.7) and moderate to good factor reliability (0.66 to 0.87). Low correlations with cognition (Pearson coefficient: < 0.17) confirmed the differences between cognitive testing and activities of daily living (ADL). Minor correlations with other ADL scores (r < 0.2) indicated that different scores cover a different range of ADLs. The original two factor model could not be confirmed. A suggested four factor model distinguishing initiative and performance of basic and instrumental ADL demonstrated better indices of fit and higher correlations with corresponding scales.

Conclusion: A four factor model of the IDDD can be used in dementia research for assessing initiative in and performance of basic and household activities of daily living. The findings suggest that ADL scales correlate only poorly and that further development of the IDDD is needed to cover a broader range of ADLs.

Introduction

The independent performance of daily activities is one of the most relevant outcomes for people with dementia. Family carers claimed that dementia research should focus more on the outcome of daily functioning than on cognition (Georges et al., 2008). International guidelines demand the assessment of activities of daily living (ADL) in dementia research (European Medicines Agency, 2008; National Collaborating Centre for Mental Health, 2007; Institute for Quality and Efficiency in Health Care, 2009; Work Group on Alzheimer's Disease and other dementias, 2007). A recent synopsis of four Health Technology Assessments reporting the results of 27 pharmacological and 13 psychosocial intervention RCTs regarding the endpoint daily functioning revealed that very heterogeneous ADL scales were used (Voigt-Radloff and Hüll, 2011). For harmonisation, the INTER-DEM group sought for a consensus on appropriate outcome measures (Moniz-Cook et al., 2008). Although the group stated that an adequate dementia-specific measure for the endpoint ADL is not available at present, they considered the Interview of Deterioration in Daily Living Activities in Dementia (IDDD; Teunisse and Derix, 1997) among several other scales to be appropriate when metric properties will be confirmed through further validation studies.

The IDDD consists of two scales recording the carers' rating of patients' initiative and performance of daily living activities. The *Initiative Scale* measures the initiative for (1) washing oneself, (2) making tea or coffee, (3) dressing, (4) combing one's hair and brushing one's teeth, (5) shopping, (6) using the phone, (7) preparing a meal, (8) cleaning the house or doing minor repair work and (9) handling finances. The *Performance Scale* records the need of assistance in the performance of the same nine activities plus eating and using the toilet. Both domains of the IDDD are constructed as five-point-Likert-scales with the ratings never=0, seldom=1, sometimes=2, often=3, always=4. Scores of the *Initiative Scale* range from 0 to 36. Higher scores indicate higher initiative. The *Performance Score* ranges from 0 to 44. Higher scores indicate higher need for assistance. In a sample of 451 persons, the IDDD demonstrated great internal consistency (Cronbach's alpha=0.99), reproducibility (intraclass correlation coefficient ICC=0.94) and significant differences between groups of patients with mild cognitive impairment and patients with dementia (Böhm et al., 1998). In a sample of 25 primary and secondary carer pairs, the IDDD interrater reliability was high (ICC: 0.85 for the *Initiative Scale* and 0.74 for the *Performance Scale;* Teunisse and Derix, 1997). In an RCT on psychosocial intervention, the *Performance Scale* demonstrated high responsiveness by indicating clinically relevant improvement in 78% of cases in the intervention group and 12 % of cases in the control group 6 weeks after baseline and 82 % and 10 % respective after 12 weeks (Graff et al., 2006).

While these results provide evidence for the reproducibility, interrater reliability and responsiveness of the IDDD, studies on its construct and concurrent validity are missing. Therefore the purpose of the present validation study was to translate the IDDD into German and to evaluate the internal consistency, construct validity and correlation with corresponding scales of this translated version in two samples of people with mild to moderate dementia.

Methods

Design

Two independent RCTs funded by the Federal German Health Ministry set the frame for data collection. These multi-site randomised trials evaluated the effectiveness of community occupational therapy on daily functioning of people with mild to moderate dementia.

The WHEDA trial from Freiburg included seven study sites and 141 participants. Inclusion criteria were the diagnose Alzheimer's disease or mixed type and a MMSE score between 14 and 24. Patient had to live in the community and a carer had to be available twice a week. Participants with major depression and severe behavioural disturbances were excluded.

The ERGODEM trial from Dresden comprised three sites and 160 patients. The criteria for the eligibility to participate in the study were the same as in the WHEDA trial with two exceptions. Patients with vascular dementia according to DSM-IV were also included and the range of the MMSE score was broader (12-26).

Measurement Instruments

Two assessment instruments on activities of daily living and two measurements on cognition were applied assuming a possible association with the IDDD.

Table 1: Measurement scheme		
Variables	**Freiburg**	**Dresden**
Demographics		
Age	x	x
Gender	x	x
Relation to carer	x	x
Activities of Daily Living		
IDDD, carer-rated	x	x
ADCS-ADL, carer-rated		x
PRPP, performance test	x	
Cognition		
MMSE, performance test	x	x
ADAS-cog, performance test		x

The WHEDA trial used the *Perceive, Recall, Plan and Perform System of Task Analysis (PRPP)* to evaluate a patient's common daily activity (Chapparo and Ranka, 2006). In this assessment, a trained rater defines single steps of a performed activity to be analysed and identifies any activity step in which errors of accuracy, omission, repetition or timing occur. The number of activity steps rated as incorrectly performed is divided by the total number of activity steps, resulting in an independence-score indicated in percent (100 % = all steps are error-free). Content validity was shown in a comparative analysis of the same activities of daily living of 25 healthy adults and 20 persons with brain injury. Variations of performance but no errors occurred within the healthy sample. Clearly observable errors within the sample with brain injury could be catalogued in the four main categories accuracy, omission, repetition or timing. Interrater reliability of three raters in a sample of 15 adults with schizophrenia was moderate (ICC: 0.77; Chapparo and Ranka, 2006). Nott et al. (2008) found fair test-retest reliability and high internal consistency (ICC>0.8).

The informant-based *Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL)* was applied in the ERGODEM trial. It assesses 17 instrumental and 6 basic ADL. The scoring categories differ between 0 to 3 and 0 to 5 depending on the item. The total score of the *ADCS-ADL* ranges from 0 (positive, highly independent) to 78 (negative, highly dependent). In a sample of community dwelling older people with mild to moderate Alzheimer's Disease, each of the 27 items was tested for correlation with the MMSE (Spearman R: 0.28-0.70) and for test-retest-reliability after 1 and 2 months (Kappa: 0.40-0.73; Galasko et al., 1997).

The *Mini Mental State Examination (MMSE)* and the *Alzheimer's Disease Assessment Scale cognitive (ADAS-cog)* are established tests of cognitive performance (Demers et al., 2000).

Procedures

Our procedures followed the latest guideline on cross-cultural translation and validation (Sousa and Rojjanasrirat, 2010). We used Dutch as source and German as target language. English was the common language in all phases to explore the meaning of terms in the source and target languages and to resolve inconsistencies by using descriptions of intended meanings.

Forward translations: Two native German speakers, excellent in Dutch and fluent in English independently translated the instructions, items and response format. One of them is living in the Netherlands and working in Germany. The second translator is living in Germany, but studied psychology in the Netherlands for five years.

Synthesis of forward translations: The project manager of the WHEDA-study compared the forward-translated versions and achieved an agreement with the translators by discussing ambiguities and discrepancies in a synthesised version.

Backward translations: Two native Dutch speakers, excellent in German and fluent in English, independently translated the preliminary German version back to Dutch. One translator published on language issues in qualitative research (Van Nes et al., 2011).

Synthesis of backward translations: The Dutch translators compared the two backward-translated Dutch versions and transferred the Dutch discrepancies to the German version and explained it with English comments using single Dutch words when necessary. The project manager moderated the discussion of all four translators about the synthesised version considering all highlighted ambiguities and discrepancies of the forward and backward versions. Agreement on the final version was achieved by discussion.

Pilot-testing: The assessors involved in the WHEDA trial attended a seminar on the IDDD application and applied it to carers of patients with mild to moderate dementia. The assessors listed aspects facilitating or hindering the IDDD application within a written cognitive debriefing on the response process (Frost et al., 2007; Cook and Beckman, 2006). The assessors involved in the ERGODEM trial attended a training comprising detailed instructions for the application of the instrument.

Full psychometric testing: Patients of the participating centres with mild to moderate dementia were informed during a routine visit or via an invitation letter. The study physician informed both patient and carer and received written informed consent and full agreement with the contents and procedures of the study also from both patient and primary carer. The primary carer had to be a family member or friend living together with or providing informal care for the patient at least twice a week. Trained physicians, psychologists or study nurses collected data of the MMSE and ADAS-cog at the study site. The assessors handed over the IDDD and the socio-demographic

questionnaires to the primary carer, received it back and clarified questions and unclear answers with the carer within the same session. In the Dresden trial, the primary carers completed the ADCS-ADL contemporaneous with the other questionnaires. In the Freiburg trial, the assessors videotaped the patient's performance of a selected activity of daily living, which was rated by external raters using the PRPP. The patient, the carer and the assessor jointly selected one out of 20 defined everyday activities considering that the task must be meaningful for this patient and that he must not be able to demonstrate an effective and fully independent task performance, so that room for improvement of the performance is given. At the coordinating study centres, questionnaires were checked for completeness and plausibility, typed in, checked again for typing errors and analysed.

Statistical analysis

Descriptive statistics: IDDD scales were reported with means, standard deviation, and frequency of best and worst possible values (ceiling and bottom effects).

Construct validity and internal consistency: We applied confirmatory factor analyses, in order to evaluate whether the scale structure of the IDDD can be replicated in other samples. Internal consistency was indicated by Cronbach's alpha.

Concurrent validity: Pearson correlation coefficients were calculated for both IDDD scales and scores of the PRPP, ADCS-ADL, MMSE, and ADAS-cog.

Results

Translation

There was a discussion on how to call the patient, when the relative is addressed in the questionnaire: *your relative* vs *patient* vs *the ill person* vs *person with dementia*. We decide for *the ill person* because this term is in German a single word and has the connotation of someone who is cared for, but not only medically. The use of the term *your relative* would have excluded non family carers.

Two misinterpretations could be prevented due to the comparison of the forward and backward translations. (1) The item *using the toilette without soiling* was not meant as *without soiling oneself*, but *without soiling the toilette*. (2) The forward translation of the item *doing tasks in and around the house such as cleaning, repairing something or gardening* could be misleading, because the carer might associate also bigger tasks such as renovating and caring for the whole garden. To avoid such misinterpretation we agreed on the amendment *doing <u>minor</u> tasks.*

Pilot-testing

14 Assessors provided data of 21 IDDD questionnaires. All carers could complete the IDDD, except of one who felt that he did not know the patient well enough. No item response was missing in the provided 20 questionnaires. Of 400 possible response items, 7 (<2%) were answered with "do not know" and 28 (7%) with "activity was never done" indicating that the carers could rate most of the daily activities and that these activities were relevant to the patients. The assessors observed that motivation, sufficient cognitive ability and diligence of the carer facilitate the completion of the IDDD. Furthermore, the fact that the carer was asked to mark any unclearness or open question directly on the form was very supportive, as well as the assessor's check of each response directly when he received back the questionnaire. We concluded that a change in the wording was not necessary and that the data collection

will be optimised, when trained assessors ask the carer to note unclear points and directly check the responses for completeness and plausibility.

Table 2: Baseline characteristics				
	Freiburg (FR)	Dresden (DD)	p	Total sample
N	141	160		301
MMSE, mean (SD)	20.5 (2.9)	20.8 (3.9)	0.401	20.7 (3.5)
Age, years (SD)	78.2 (6.9)	76.5 (7.3)	0.039	77.3 (7.2)
Gender, female (%)	81(57.4%)	92 (57.9%)	0.942	173 (57.7%)
Spouse as primary carer (%)	100 (62.9%)	80 (56.7 %)	0.277	180 (60.0 %)

Descriptive results

We pooled the data from both samples, Freiburg (N=141) and Dresden (N=160). Baseline characteristics were similar and differed only in age, which however was still in a typical range for people with mild to moderate dementia (table 2). Descriptive data indicate that on average patients only sometimes showed initiative to perform activities of daily living but seldom needed assistance (table 3). Minimal bottom effects were found in the *performance scale* (4.3 % with best scale values).

Table 3: IDDD descriptive data (Freiburg and Dresden sample, N=301)						
	No. of Items	Mean	SD	Median	Bottom effects$	Ceiling effects$
IDDD performance (0-44)§	11	16.8	10.9	16.1	13 (4.3%)	2 (0.7%)
IDDD initiative (36-0)§	9	17.5	9.0	17.1	3 (1.0%)	6 (2.0%)

IDDD= Interview of Deterioration in Daily Living Activities in Dementia
§ Range: positive to negative; $ No. of cases with worst/best scale values

Construct validity

The IDDD scales demonstrated good internal consistency with Cronbachs α=0.878 for the *performance scale* and α=0.764 for the *initiative scale* (table 4). Only for the item *handling finances*, we found low corrected item-to-scale-correlations in both scales. However, the factor analysis of the IDDD model revealed a significant chi-square ($\chi2$ =1396, df=169, $\chi2$/df=8.261, p<0.001) indicating a difference between empirical and estimated data and a bad fit for the model. Further indices (Kline 1998) confirmed an insufficient model fit (Root Mean Square Error of Approximation, RMSEA=0.156 [good fit: <0.08]; Tucker-Lewis Index, TLI=0.574; [good fit: >0.9] Comparative Fit Index, CFI=0.657 [good fit: >0.95]). The *initiative scale* showed low factor reliability (r=0.66, table 5). Especially items of instrumental activities of daily living (*shopping*, *using telephone*, *preparing a meal*, *cleaning house or doing repair work* and *handling finances)* demonstrated very low correlations (r<0.2, table 5). Considering this, we developed a four factor model based on the clinically relevant distinction between basic and instrumental activities of daily living. The new model demonstrated an acceptable fit according to the indices recommended by Kline (1998; $\chi2$=431, df=160, $\chi2$/df=2.696, p<0.01; RMSEA=0.075; TLI=0.911; CFI=0.925) and an excellent internal consistency with Cronbachs alpha as follows:

α = 0.897 for IDDD performance of basic ADL (01 washing oneself, 03 dressing, 04 combing hair and brushing teeth, 05 eating, 06 using the toilet)

α = 0.838 for IDDD performance of instrumental ADL (02 making tea or coffee, 07 shopping, 08 using the telephone, 09 preparing a meal, 10 cleaning house or doing repair work, 11 handling finances)

α = 0.967 for IDDD initiative for basic ADL (01 washing oneself, 03 dressing, 04 combing hair and brushing teeth)

α = 0.820 for IDDD initiative for instrumental ADL (02 making tea or coffee, 05 shopping, 06 using the telephone, 07 preparing a meal, 08 cleaning house or doing repair work, 09 handling finances).

Table 4: Interview of Deterioration in Daily Living Activities in Dementia - internal consistency

Scale	N	Cronbachs alpha	Items	Mean item	SD	Corrected item-to-scale-correlation	Cronbachs alpha without item
Performance	290	0.878	01 Washing oneself	0.96	1.38	0.678	0.862
			02 Making tea or coffee	1.53	1.66	0.725	0.857
			03 Dressing	1.16	1.41	0.709	0.860
			04 Combing hair and brushing teeth	0.84	1.31	0.655	0.864
			05 Eating	0.46	1.10	0.429	0.877
			06 Using the toilet	0.68	1.18	0.585	0.868
			07 Shopping	2.30	1.68	0.562	0.870
			08 Using the telephone	1.63	1.53	0.636	0.864
			09 Preparing a meal	2.17	1.75	0.592	0.868
			10 Cleaning house or doing repair work	1.96	1.54	0.660	0.862
			11 Handling finances	3.02	1.48	0.273	0.887
Initiative	295	0.764	01 Washing oneself	1.91	1.78	0.482	0.736
			02 Making tea or coffee	2.01	1.71	0.694	0.702
			03 Dressing	1.81	1.86	0.360	0.757
			04 Combing hair and brushing teeth	1.87	1.77	0.456	0.740
			05 Shopping	2.08	1.64	0.510	0.732
			06 Using the telephone	2.01	1.46	0.501	0.735
			07 Preparing a meal	1.93	1.67	0.462	0.739
			08 Cleaning house or doing repair work	1.82	1.52	0.611	0.719
			09 Handling finances	2.04	1.75	0.023	0.804

Table 5: Interview of Deterioration in Daily Living Activities in Dementia - Confirmatory factor analysis

Scale	N	Factor reliability	Average variance extracted	Items	Squared multiple correlation
Performance	301	0.87	0.40	01 Washing oneself	0.661
				02 Making tea or coffee	0.519
				03 Dressing	0.697
				04 Combing hair and brushing teeth	0.660
				05 Eating	0.376
				06 Using the toilet	0.522
				07 Shopping	0.215
				08 Using the telephone	0.353
				09 Preparing a meal	0.257
				10 Cleaning house or doing repair work	0.335
				11 Handling finances	0.021
Initiative	301	0.66	0.39	01 Washing oneself	0.840
				02 Making tea or coffee	0.236
				03 Dressing	0.876
				04 Combing hair and brushing teeth	0.923
				05 Shopping	0.000
				06 Using the telephone	0.003
				07 Preparing a meal	0.001
				08 Cleaning house or doing repair work	0.051
				09 Handling finances	0.196

Concurrent validity

We found no correlations between the IDDD scales and cognition performance scores (r<0.17 for MMSE and ADAS-cog, table 6). Furthermore, the IDDD performance and initiative scale both correlated very weakly with the carer-rated ADCS-ADL score (r<0.24) and were not associated with the PRPP performance test of a daily activity (r<0.1). In addition, we found no association between the ADCS-ADL and the ADAScog. Correlations of the MMSE were moderate with the PRPP and weak with the ADCS-ADL (table 6).

Table 6: Correlations between activities of daily living scales and related scores (Pearson coefficient)

	Study	IDDD-Performance		IDDD-Initiative		ADSC-ADL		PRPP	
Activities of Daily Living		N	r	N	r	N	r	N	r
ADCS-ADL, carer-rated	DD	154	-0.230*	154	-0.231*				
PRPP, performance test	Fr	107	-0.016	107	0.099				
Cognition									
MMSE, performance test	Fr/DD	278	-0.167*	279	-0.050	148	0.290*	120	0.378*
ADAS-cog, performance test	DD	149	0.099	150	0.015	140	-0.134		

IDDD= Interview of Deterioration in Daily Living Activities in Dementia
ADCS-ADL=Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory
PRPP=Perceive, Recall, Plan and Perform System of Task Analysis
MMSE=Mini Mental State Examination
ADAS-cog=Alzheimer's Disease Assessment Scale cognitive
*p<0.01

Discussion

Following standardised procedures of translation, we could provide a German IDDD version equivalent to the Dutch instrument. Piloting revealed that carers did understand the questions well and that data collection can be optimised by checking the responses directly after administration.

Descriptive IDDD data indicated a moderate initiative to perform activities of daily living and a minor need of assistance in a pooled sample of 301 community dwelling people with mild to moderate dementia from two multi-centre trials including ten study-sites in total. For both IDDD scales, *initiative* and *performance*, bottom and ceiling effects were very low (< 5 %) and internal consistency was good (α>0.7).

Based on our findings on the construct validity of the IDDD, we advocate for a four factor solution, because even though each of the four new scales consisted of fewer items, the Cronbach alpha values were excellent. The indices for a better fit of the four factor model as well as the excellent internal consistency suggest that the clinically established differentiation between instrumental and basic ADL is confirmed by our factor analysis.

Cognition as measured with the MMSE or ADAS-cog did not correlate with the IDDD scales (r<0.17). These findings are in contrast to former studies. The first version of the IDDD correlated highly with the Cambridge Cognitive Examination (Roth et al. 1986) in a sample of 30 community dwelling person with mild to moderate dementia (r=-0.77, p<0.01; Teunisse and Derix, 1991). However, this former IDDD version included additional items of cognitive and communicational functions such as finding way in and outside the house, finding things, reading, writing, verbal expressing and starting conversation. Bouwens and colleagues (2009) found in a sample of 442 per-

sons with Alzheimer's disease (MMSE: 19) a moderate correlation (r=-0.60; p<0.01) between the MMSE and the Blessed Dementia Scale (BDS; Erkinjuntti et al., 1988). The BDS comprises only four ADL items (eating, dressing, continence and household tasks) and seven items of cognitive functioning in everyday life (coping with small sums of money, remembering short list of items, finding way about indoors and about familiar streets, interpreting surroundings, recalling recent events and tendency to dwell in the past). These results suggest that ADL constructs are heterogeneous. A precise definition is needed for a thorough evaluation of the association between cognition and daily functioning in AD.

The low correlations between the IDDD performance scale and the PRPP may have two reasons. (1) The PRPP measured the number of mistakes made in the performance of instrumental and not of basic activities of daily living. This was because patients never chose activities like dressing or bathing to demonstrate for video taping, while the original 11-items IDDD performance scale covered also these basic activities. However, the assumption that the PRPP would significantly correlate with the IDDD performance subscale limited to instrumental ADL could not be confirmed (r=0.008; p=0.932). (2) Also, the comparison of the IDDD and the PRPP performance scales included the contrast of a carer's estimation of the patient's need of assistance and an assessor's rating of a concrete task performance. The first can be influenced by the carer's mood, attitude, knowledge or memory. The second might be biased by the patient's mental capacity possibly changing day by day or by special motivation when being video taped. So the fact that the carer's rating of the need of assistance in everyday functioning for the last seven days is different to a patient's short-term performance of an everyday task when being videotaped seemed to be the main reason for the low correlations between the IDDD and the PRPP.
The IDDD scales demonstrated low correlations with the ADCS-ADL score (r<0.24), although both instruments are carer-rated. Reasons might be that the ADCS-ADL did not cover the IDDD item *handling finances* but additionally records items on communication (reading, writing, making conversation, discussing current events), on social interaction (watching TV, doing games or hobbies, keeping appointments, can be left alone, travelling outside home) and on two further items (walking and finding belongings). To test this assumption we selected the basic ADL items and the household ADL items of the ADCS-ADL and correlated these two new ADCS-subscales with the two new IDDD performance subscales. We found highly significant correlations between the ADCS-basic-ADL and IDDD-performance-basic-ADL scores (r=0.549; p<0.001) and between ADCS-household-ADL and IDDD-performance-instrumental-ADL scores (r=0.646; p<0.001).

Our findings are in line with reviews on assessment instruments in dementia research stating that ADL instruments are heterogeneous on item level and in their correlations with measures of cognition. Furthermore, ADL measurements differ in their responsiveness to drugs and psychosocial interventions depending on the state of dementia (Sikkes et al., 2009; Bouwens et al., 2009; Voigt-Radloff and Hüll, 2011; Gauthier et al., 2010; Desai et al., 2004). Low correlations of cognition not only with the IDDD but also with the other ADL measurements (PRPP; ADCS-ADL; table 6) emphasize the conceptual differences between these constructs. Cognitive decline can result in a reduced performance of cognitively challenging daily activities but must not directly lead to the deterioration of routine activities of daily living such as basic ADL and familiar household chores. On the other hand, a decline in initiative may drastically re-

duce ADLs in patients with good cognitive test results. We therefore advocate for a precision of ADL measurement in AD. The IDDD has been shown to be able to measure the impact of non-pharmacological treatment aiming at the stabilisation of familiar routine activities. The presented empirical data of the German IDDD support a four factor model distinguishing initiative and performance as well as basic and household activities of daily living. Separate analyses of these subscales seem to be appropriate in further trials of non-pharmacological interventions. A further broadening of the IDDD would be necessary to cover the full range of daily functioning.

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5

Reliability of the Perceive, Recall, Plan and Perform Assessment in community dwelling dementia patients: test consistency and inter-rater agreement

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Abstract

Background: The aim of this study is to evaluate aspects of inter-rater reliability of the Perceive, Recall, Plan and Perform (PRPP) System of Task Analysis for assessing daily functioning of home dwelling dementia patients.

Method: Videotaped recordings of 30 German patients with dementia performing a relevant daily task in their own homes were scored independently by 10 Dutch PRPP trained occupational therapists, randomly selected from a pool of 25. Intra-class correlations (ICC) (one-way single measure) were calculated for PRPP Stage One independence score, and PRPP Stage Two information processing scale, quadrant-scales, and sub-quadrant-scales from a total of 300 PRPP scores.

Results: ICCs for Stage One PRPP independence score are good to excellent (0,63; 0,94) for both individual rater and test reliability. The Stage Two PRPP total score shows moderate correlations (0.46) for the single rater absolute agreement and excellent agreement (0,90) for test reliability. The four quadrant scale scores of the PRPP show limited single rater absolute agreement (0,37-0,39) but excellent average test agreement (0,85-0,87). All sub quadrants of information processing show limited single rater absolute agreement (0,26-0,38) and good to excellent average test agreement (0,78-0,86). This suggests that the PRPP total is reliable in assessing information processing during activity performance in dementia patients.

Conclusions: The PRPP is a reliable measure to evaluate individual performances of routines and tasks in community living dementia patients by multiple raters. Future research should address reliability and validity features of the PRPP for dementia patients with incorporation of criterion referenced test characteristics.

Background

The world prevalence of dementia has recently been estimated at 24.3 million people. This is expected to double over the next 20 years [1]. Services that increase performance abilities and well-being in both patients and caregivers are required [2-4]. Decline in memory and executive functions are characteristics of the degenerative process in dementia. Disabilities in performing daily tasks are the most important reason for the need of care including nursing home placement and are a burden to caregivers and society [5].

Tailor-made, individualized, multi-component interventions that are aimed at improving daily functioning and quality of life for both patient and caregiver are shown to be most effective in the home setting [6-10]. To tailor interventions to individual needs it is important to know the client's ability to perform activities and their relationship to disturbances in the specific cognitive processes that underpin particular task performance. Neuro-psychological tests have a low ecological validity and do not adequately predict difficulty in daily functioning within the home context [11]. This is why sensitive instruments for measuring every day functional abilities are very important in dementia care [12-13]. Observation of the performance of daily activities within the home context gives unique information about the influence cognitive disturbances have on daily life. These assessments form the base for effective treatment interventions.

There are several reliable and valid observation instruments available to the occupational therapist for this purpose, such as the Assessment of Motor and Process Skills [14-17] and the Arnadottir OT-ADL neurobehavioral evaluation [18-20]. Usage depends on the type of activities a patient prefers to perform. The AMPS mainly consists of standardised household tasks and some other standardised instrumental activities of daily living, and measures quality of performance in motor and process skills. The A-ONE observes primary self care tasks, and measures levels of independence and related cognitive dysfunctions. The A-ONE has a ceiling-effect because of the lack of complexity in tasks. In both instruments the observed activities are standardised which may have the disadvantage that the whole task or the criteria to perform it do not fit to the clients' routines.

For dementia patients it is highly important to perform meaningful activities they are motivated for and in the routines and context they are familiar with. These components add to their quality of life [9-10, 21]. Therefore, the Perceive, Recall, Plan and Perform system (PRPP) seems an instrument with potential to assess dementia patients in the home environment because it enables the patient to choose activities individually based on preferences and needs [22]. The PRPP examines errors and the effectiveness of cognitive information processing in the performance of self-chosen tasks.

Psychometric properties of the PRPP for traumatic brain injury, learning difficulties, chronic pain and schizophrenia are evaluated in small groups and show adequate outcomes on content validity, construct validity, internal consistency, concurrent validity, inter-rater reliability, intra-rater reliability and responsiveness [23-26]. However, no data are available for the use of PRPP in older people with dementia, although this target group of patients needs a tailor made assessment to evaluate their performance in familiar daily activities in their own context. Inter-rater reliability is an important feature of measurings that assess performance of abilities in daily activities by observation. Criterion referenced measures incorporate the variability in three foci; the demands of the task, the capacity of the person to perform that task; and the con-

text of performance and therefore, have high ecological validity. However, they have the disadvantage that absolute inter-rater agreement is hard to achieve [24].

Hence, the objective of this study is to evaluate whether the PRPP assessment has reliable standardisation criteria that are consistently used for the assessment of performing familiar daily tasks in community dwelling dementia patients by multiple raters.

Methods

Patients

PRPP baseline data of the WHEDA trial were used in this study. This German multi-center randomised controlled trial evaluated the effectiveness of community occupational therapy for dementia patients and their caregivers. The design of the WHEDA study has been published in 2009 [26]. Inclusion criteria of participants were: Mild to moderate dementia of the type Alzheimer's disease or mixed type; MMSE ranging from 10 to 24; People dwelling at home either together with their primary caregiver or the primary caregiver provides care at least twice a week. People with a Geriatric Depression Scale score (GDS 30) > 12, in major need of nursing care, with unstable medical conditions or severe behavioural disturbances were excluded to establish a homogenous group with a focus on performance abilities [26].

Raters

All Dutch occupational therapists that had completed a PRPP assessment course (N=79) were asked by e-mail to participate in this inter-rater reliability study. 25 were motivated to participate and agreed to score independently the PRPP videos at home. No additional inclusion criteria for raters were used. Dutch PRPP trained occupational therapists were chosen as raters instead of German PRPP trained occupational therapists because of the availability of a PRPP alliance in the Netherlands and the use of the official translated (from English) Dutch PRPP scoring forms which are not available in German.

Measurements

Patient characteristics were measured within the WHEDA trial. The baseline characteristics regarding sex, age, education, years since onset dementia, and baseline outcomes measured with the interview of deterioration in daily living activities in dementia (IDDD), Dementia Quality of Life Instrument (DQoL), Short form of the SF-36 measuring health status (SF-12), Geriatric depression scale (GDS), and the Mini Mental State Examination (MMSE) will be presented.

The PRPP system of task analysis is a two-stage, criterion referenced measure instrument that examines the effectiveness of cognitive information processing in performing meaningful tasks according to individualized standards (the criterion) set by the client's particular situation. Stage One incorporates a task analyses procedure, in which an observed familiar task is subdivided into all relevant steps, and measures types of mistakes, e.g. being inaccurate, repeat steps, omit steps, and wrong timing, in the performance of steps in the chosen task. Level of independence in performing the task can be calculated in Stage One by dividing the amount of wrongly performed steps by the amount of all steps of the task. Stage Two consists of the analyses of information processing and incorporates 34 items divided in the subscales Perceive, Recall, Plan, and Perform. Items cover information processing aspects such as at-

tending; sensing; discriminating; recalling facts, schemes and procedures; mapping; programming; evaluating; initiating; continuating; and controlling. Each item is rated on a 3-point scale (inadequate, inconsistent, adequate). Both therapist and patient decide together which task is relevant to observe given the performance difficulties in meaningful activities as expressed by the patient.

The PRPP was scored using the Dutch PRPP assessment scoring form including Stage One independent score and Stage Two information processing items. For Stage One the activity steps to be scored were pre-set by the raters from the WHEDA trial based on individual performance of the filmed task according to the routines of the patient. Within the WHEDA trial each patient performed two self-chosen tasks out of 29 pre-set meaningful tasks. Scoring criteria were used according the PRPP manual which is instructed in the PRPP assessment course [23].

Procedures

30 video footages out of 258 baseline performances of two self chosen daily tasks in the home environment by a dementia patient were randomly selected by a research assistant who was blinded for patient identity and performance characteristics. Exclusion criteria for video footages were duration > 15 minutes, comments from WHEDA rater on insufficient visibility of the video and/or comments on therapist's inadequate influence on performance. An independent statistician randomized the videos by raters in such manner that each of the 25 raters scored 12 videos and that each of the 30 videos was scored by 10 different raters. This resulted in 300 cases and provides a good power to establish inter-rater test reliability (ICC > 0.70) [27].

Raters were provided with cd-roms with the 12 video films and scoring forms and were instructed to rate independently at home and not discuss findings with other raters. Independence of raters was enhanced by providing each rater with a unique set of 12 videos.

Statistical analyses

For Stage One independence score and Stage Two sub quadrant scales, quadrant scales and whole scale ICCs were computed with SPSS 18. A one way model was used for ICC calculation since both raters and video's were randomly assigned and no videos were rated by all raters. Average measure ICCs reflect the consistent use of the PRPP standardisation criteria by multiple raters. Scores ≥0.70 will be regarded as good inter-rater consistency.

Single measure ICCs reflect the absolute agreement between raters and are expected to be fair or moderate. ICC from 0,20 to 0,39 is regarded as fair inter-rater reliability, 0.40 to 0.59 as moderate inter-rater reliability, 0.60 to 0.79 as substantial, and 0.80 or above as outstanding [28].

Results

Patient characteristics

Table 1 summarizes the characteristics of the 28 dementia patients at the time of the video shoot. Recently diagnosed (mean 1.7 year, sd 1.5) mild dementia patients (mean MMSE score = 20, sd 2.5) with few to moderate need for assistance (IDDD performance mean = 14, sd 10.5) were included in this study.

All participating raters (N= 25) were occupational therapy practitioners or researchers who had been trained in PRPP use. The majority (N= 24 therapists) followed the as-

sessment course 3 to 1 year prior to this research, only one had been trained 11 years before. All were experienced occupational therapists in adult health care.

Table 1: Characteristics of included patients (N=28)			
Characteristic	**Mean**	**SD**	**Range**
Male N	12 (42.9%)	-	-
Female N	16 (57.1%)		
Age	76	9	56-87
Education			
Professional N	22 (78 %)	-	-
University N	6 (22 %)		
Years since onset dementia	1,7	1,5	0-5
MMSE	21,0	2,5	17-24
GDS	6,0	3,1	0-11
IDDD			
Initiative	19,7	10,1	0-36
Performace	14,0	10,5	0-38
SF-12			
Physical	42,4	10,8	24-62
Mental	46,6	10,2	16-64
DQOL overall	3,0	0,7	2-5

MMSE= Mini Mental State Examination
GDS= Geriatric Depression Scale
SF-12 = Short Form of the SF-36 measuring health-status
DQoL= Dementia Quality of Life Instrument
IDDD = Interview of Deterioration in Daily Living Activities in Dementia

Table 2: Inter-rater single measure and average measure reliability of the PRPP				
Items	**ICC single**	**95% CI**	**ICC average**	**95% CI**
Stage One independence score	0.63	0.50-0.76	0.94	0.91-0.97
Stage Two information processing: whole	0.46	0.33-0.63	0.90	0.83-0.94
Perceive Quadrant	0.37	0.24-0.54	0.85	0.76-0.92
Attending	0.32	0.20-0.49	0.83	0.72-0.91
Sensing	0.31	0.19-0.48	0.82	0.71-0.90
Discriminating	0.36	0.23-0.53	0.85	0.75-0.92
Recall Quadrant	0.38	0.25-0.54	0.86	0.77-0.92
Recalling facts	0.28	0.17-0.45	0.80	0.67-0.89
Recalling shemes	0.26	0.15-0.43	0.78	0.64-0.88
Recalling procedures	0.35	0.23-0.52	0.84	0.74-0.92
Plan Quadrant	0.39	0.26-0.56	0.86	0.78-0.93
Mapping	0.35	0.22-0.52	0.84	0.74-0.91
Programming	0.32	0.20-0.49	0.82	0.71-0.90
Evaluating	0.31	0.19-0.48	0.82	0.70-0.90
Perform Quadrant	0.39	0.26-0.56	0.87	0.78-0.93
Initiating	0.29	0.18-0.46	0.80	0.68-0.89
Continuing	0.31	0.19-0.48	0.82	0.70-0.90
Controlling	0.38	0.25-0.54	0.86	0.77-0.92

PRPP=Perceive, Recall, Plan and Perform System of Task Analysis
ICC= Intra-class correlations

Table 2 shows the ICC for Stage One and Stage Two: sub-quadrant scales, quadrant scales and whole scale. The ICC for Stage One independence score showed good outcomes both for absolute inter-rater agreement as for consistency of test criteria standardisation. Stage Two subscales, quadrants and whole scale show good inter-rater consistency of test criteria standardisation. Stage two subscales and quadrant shows fair inter-rater absolute agreement. The whole PRPP information processing scale shows moderate absolute agreement.

Discussion

This study shows that the PRPP system of task analysis has sufficient inter-rater reliability for the assessment of performance of familiar daily activities in the home context in mild dementia patients and who required little to moderate assistance in performing daily activities. Both the independence score and the information processing scale show consistent test use by multiple raters indicating reliable standardisation of the PRPP assessment of task analysis. Absolute inter-rater agreement is not expected to be high in ecologically valid, criterion referenced measures. This is confirmed for Stage Two. The absolute agreement between raters for the independence score is good.

The results of this study for Stage Two correspond in general with other studies that evaluated inter-rater reliability of the PRPP assessment for other diagnostic groups. Nott et al (2009) evaluated inter-rater reliability of Stage Two of the PRPP assessment in two studies with respectively 15 and 5 traumatic brain injury patients who had been scored by 3 and 9 raters respectively and found high reliability (single measure agreement ICC between 0,51-0,77; test consistency all ICC > 0,8). Nott et all used a three-way ICC analyses incorporating the three factors of variability; patients, tasks, and raters, which explains the higher ICCs in comparison with the current single absolute agreement outcomes of the current study [24]. Aubin et al (2009) reported good (for PRPP total score; 0,77) and moderate (for PRPP quadrant scale scores; 0,63-0,69) outcomes for inter-rater reliability of the PRPP assessment Stage Two in 15 schizophrenia patients who were scored by 3 raters on two tasks each using a two-way mixed effects model for absolute agreement [25]. This is the first study that also looked at inter-rater reliability for Stage One of the PRPP and showed good results on both absolute inter-rater agreement and standardisation.

The reliability outcomes for Stage One of the PRPP assessments do show the power of the instrument to assess individual performance of routine tasks of dementia patients in their home context. In the PRPP the necessity for individual choices regarding specific tasks and environmental demands is well recognised and therefore is an important tool in assessing ecological valid performance levels in the performance of daily tasks. The criterion referenced standardisation of scoring rules is applied consistently by multiple raters as shown in this study for both stages. Therefore, the PRPP is an important addition to the available assessment tools for occupational therapists treating home dwelling dementia patients.

A limitation of this study is that only patients with mild dementia who had been diagnosed in the last few years were included in the study. Therefore the results on reliability of this instrument cannot be generalised to all dementia patients. However, this sample is comparable for mood and quality of life with the Dutch study of Graff (2007) in which mild and moderate community dwelling dementia patients were included [10].

Another limitation of this study regarding Stage One is the use of pre-set task analyses by raters. This meant that the relevant steps of the task were already determined and not defined by the raters themselves. This was done to make the ratings comparable for the amount of the single steps of the rated tasks and for the equation of the independence score. In routine care each occupational therapist has to perform the task analyses for the individual situation and tasks observed which increases variability in scoring the PRPP. Future research into Stage One should also evaluate the consistency in task analyses standardisation applied by occupational therapists.

This study was not designed to establish absolute inter-rater agreement on Stage Two information descriptors (item) level. To look at inter-rater reliability on item level of the PRPP one should take into account all the variability that occurs in PRPP assessment. This means that the design should have enough statistical power, should use a nested design in which the variety in tasks, patients, environments, and raters are adequately addressed [24] and that all raters should rate all available cases. At this stage of PRPP implementation in the Netherlands the required amount of experienced raters were not available to perform such a large study.

The absolute agreement ICC outcomes for Stage Two are fair (subscales, scales) and tend to moderate (scales). These outcomes might be slight underestimates of real absolute agreement because of some specific study characteristics. The video footages were of German speaking dementia patients living in Germany and filmed in their home environments. Although all Dutch raters have sufficient knowledge of the German language and culture to rate these performances the influence of a different language and less familiar routines in performances need to be taken into account. The good consistency outcomes of the PRPP show that the PRPP is a reliable tool to be used by multiple raters in several and even less familiar tasks observations.

In conclusion, this study pertaining to inter-rater reliability of the PRPP for community dwelling dementia patients shows that the PRPP is consistent tool used by multiple raters and has potentiality to be a good measuring instrument to rate performance of patients with mild dementia in a variety of routines and tasks of meaningful daily activities in a variety of environments. The criterion referenced standardised PRRP can be used to reliably assess "real life" performances according individual standards. Future research should focus on other validity and reliability characteristics of the PRPP for dementia patients in different stages of the disease, with additional symptoms such as depression, and in different living environments. Rasch analyses procedures could be helpful to address the several variety issues that occur in criterion referenced measures.

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6

Dementia Quality of Life Instrument - Construct and Concurrent Validity in Patients with mild to moderate Dementia

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Abstract

Objective: to translate the Dementia Quality of Life Instrument (DQoL) into German and assess its construct and concurrent validity in community dwelling people with mild to moderate dementia.

Methods: DQoL data of two pooled samples (n=287) were analysed regarding ceiling and bottom effects, internal consistency, factor reliability and correlations with corresponding scales on quality of life (QoL-AD and SF-12), cognition (Mini Mental State Examination, Alzheimer's Disease Assessment Scale cognitive), depression (Cornell Scale for Depression in Dementia) and activities of daily living (Interview of Deterioration in Daily Living Activities in Dementia).

Results: We found no bottom effects (< 2 %), minor ceiling effects (1 to 11 %), moderate to good internal consistency (Cronbachs α: 0.6 to 0.8) and factor reliability (0.6 to 0.8), moderate correlations with self-rated scales of quality of life (Pearson coefficient: 0.3 to 0.6) and no or minor correlations with scores for cognition, depression or activities of daily living ($r < 0.3$). The original five factor model could not be confirmed.

Conclusion: The DQoL can be used in dementia research for assessing positive and negative affect, feelings of belonging and self-esteem. The findings suggest further research to improve the structure of the scales *aesthetics*, *feelings of belonging* and *self-esteem*.

Introduction

In dementia research, the assessment of quality of life (QoL) is recommended and valid instruments are needed in several languages for cross-national studies [1-5]. The debate on QoL for people with Alzheimer's disease refers to Lawton who claimed behavioral competence, positive and negative affect, the objective environment and subjective QoL as determinants of well-being in older adults [6-12]. Empirical data substantiate that QoL as perceived by people with dementia is moderately associated with depressive mood, slightly connected to activity participation but not consistently related to behavioral or cognitive disorders [13]. The Hierarchy Model of Needs in Dementia relates QoL to the fulfillment of needs in analogy to Maslow [14,15]. According to this an assessment of QoL should measure the grade of fulfillment of needs concerning basic physiology, safety, belongingness, esteem and self-actualization. Instruments measuring QoL in dementia research can be specified by (1) the number of measured dimensions, (2) its specificity (generic or disease-specific), (3) the information source (self-report, carer-rating or staff observation), (4) the severity of dementia in the target group (mild, moderate or severe) and (5) the housing situation (community or nursing home) [8]. Disease-specific instruments applied in the community and covering the perspective of patients with mild to moderate dementia are urgently needed to evaluate new psychosocial and drug therapies. We screened recent reviews on QoL measures [16-20] and found three instruments in this area: the Dementia Quality of Life Instrument (DQoL) in four different languages [21-26]; the Quality of Life-Alzheimer's Disease Scale (QoL-AD) in three versions [7, 27-30] and the DEMQOL in English [31].

Three reasons argue for applying the DQoL. (1) An international expert panel in dementia research gave a consented recommendation to use the QoL-AD or the DQoL for cross-national research [20]. (2) The DQoL was developed with a rigorous demand for the participation of people with dementia [21]. (3) It was already successfully used for randomised efficacy studies for psychosocial interventions [32] and may gain wide acceptance. This would allow more homogeneous meta-analyses of data on psychosocial interventions in Alzheimer's disease.

The *DQoL* consists of 30 items and five scales: *positive affect* (6 items), *negative affect* (11 items), *feelings of belonging* (3 items), *self-esteem* (4 items), *sense of aesthetics* (5 items) and one global item. Interviewees are asked to rate their frequency of affects in the last seven days with 1=never, 2=seldom, 3=sometimes, 4=often, and 5=very often. The enjoyment of experiences is to be rated with 1=not at all, 2=a little, 3=somewhat, 4=mostly, and 5=very [21]. The scores of the scales differ depending on the number of items. Higher scores indicate better QoL, except in the scale *negative affect*. The DQoL was developed specifically to be completed by people with mild to moderate dementia. The interview procedure includes three screening questions to test the patient's language comprehension. The patient must give at least two correct answers before the interview starts. 96 of 99 US-American people with dementia (MMSE ≥ 13) were able to respond appropriately to all DQoL questions with moderate to high internal consistency (0.67 to 0.89), with good two-week test-retest reliability (0.64 to 0.90) and without significant differences in patient groups with mild versus moderate dementia (cut off MMSE=17) [21].

The purpose of our study was to translate the DQoL into German and evaluate its construct validity including the internal consistency and concurrent validity in two samples of community dwelling older persons with mild to moderate dementia.

Methods

Design

Data were collected within two multi-centre RCTs on community occupational therapy for people with mild to moderate dementia funded by the German Federal Ministry of Health. The WHEDA trial was coordinated in Freiburg and included seven sites and 141 participants [33]. Eligible participants were diagnosed as having Alzheimer's disease; had a MMSE score between 14 and 24, no major depression and no severe behavioral disturbances; lived in the community; gave informed consent; and a primary carer was available at least twice a week. The ERGODEM trial from Dresden comprised three sites and 160 patients [34]. The criteria for the eligibility to participate in the study were the same as in the WHEDA trial with two exceptions. Patients with vascular dementia according to DSM-IV were also included and the range of the MMSE score was broader (12-26). Ethical approval was given by the Medical Ethics Committee of the University Hospital Freiburg and the Ethics Committee of the Faculty of Medicine at the Dresden University of Technology. Trials were registered at the German Trial Register.

Measurement Instruments

As constructs corresponding to the DQoL, we assessed the patient's generic health-related QoL, mood, activities of daily living, and cognition using established measurement instruments (table 1).

Table 1: Measurement scheme

Variables	Freiburg	Dresden
Demographics		
Age	x	x
Gender	x	x
Relation to carer	x	x
Quality of Life		
DQoL, disease-specific, self-rated	x	x
QoL-AD, disease-specific, self-rated		x
QoL-AD, disease-specific, carer-rated		x
SF-12, generic, physical subscale, self-rated	x	
SF-12, generic, mental subscale, self-rated	x	
Mood/depression		
CSDD mood/depression carer-rated	x	
Activities of Daily Living		
IDDD, carer-rated	x	x
Cognition		
MMSE, performance test	x	x
ADAS-cog, performance test		x

DQoL= Dementia Quality of Life Instrument
QoL-AD=Quality of life in Alzheimer's disease instrument
CSDD=Cornell Scale for Depression in Dementia
IDDD=Interview of Deterioration in Daily Living Activities in Dementia
ADAS-cog=Alzheimer's Disease Assessment Scale cognitive

The *Quality of life in Alzheimer's disease instrument* (*QoL-AD*) is a 13-item questionnaire designed for measuring the QoL of patients with dementia and their caregivers. It includes assessments of the individual's physical condition, mood, memory, rela-

tionships with friends and family, functional abilities, financial situation and an overall assessment of life quality. Individuals respond on a four point Likert-scale (1=poor, 4=excellent). The total score ranges from 13 to 52, with higher scores indicating greater QoL. Studies on psychometric properties demonstrated good reliability and validity of the QoL-AD for individuals with mild to moderate dementia [7, 35].

The *SF-12* is a broadly established generic self-assessment evaluating health-related QoL. The instrument generates a mental and a physical score from 12 weighted items with response categories varying from dichotomous to six-point scales using a complex algorithm. Higher scores indicate better health status. Metric properties are excellent [36].

The *Cornell Scale for Depression in Dementia (CSDD)* records 19 symptoms within the domains (1) mood and related signs, (2) behavioral disturbance (3) cyclic function and ideational disturbance and (4) physical signs [37]. Symptoms are rated as "absent", "mild or intermittent" or "severe". Scores range from 0 to 38. Lower scores indicate less depressive characteristics, values above 8 indicate a depressive disorder. Correlations with other depression measurements ranged from $r=0.70$ to 0.93. Internal consistency and inter-rater reliability were high (Cronbach's alpha=0.81; ICC=0.84) [38, 39].

The *Performance Scale of the Interview of Deterioration in Daily Living Activities in Dementia (IDDD)* records the need for assistance in the performance of 5 basic activities and 6 instrumental activities of daily living [40]. Items are rated from 0 to 4 with a sum score from 0 to 44. A higher score indicates higher need for assistance. The IDDD demonstrated great internal consistency (Cronbach's alpha=0.99), reproducibility (ICC=0.94), interrater reliability (ICC=0.74) and significant differences between groups of patients with mild cognitive impairment and patients with dementia [40, 41].

The *Mini Mental State Examination (MMSE)* and the *Alzheimer's Disease Assessment Scale cognitive (ADAS-cog)* are established tests of cognitive performance [16].

Procedures

Our procedures were in line with the latest guideline on cross-cultural translation and validation, which summarized relevant review studies and previous guidelines on this topic [42]. For two reasons we used the Dutch DQoL version [26] as source. Our Dutch-German research group investigated the impact of complex interventions on important patient-oriented outcomes when transferred from the Netherlands to Germany. So we were interested in broadening the Dutch and German understanding of the concepts underlying the DQoL construct. Furthermore, we deepened our understanding of the meaning and the conceptual equivalence of terms using primarily the Dutch source and secondarily the English original version [21]. In all phases, we used English as common language to explore the meaning of terms in the source and target languages and to resolve inconsistencies by using descriptions of intended meanings.

Forward translations: A psychologist and an occupational therapist independently translated the instructions, items and response formats from the Dutch source language to the German target language, additionally considering the English original version. Both translators were native German speakers, excellent in Dutch and fluent in English. One of them is living in the Netherlands and working in Germany. The second translator is living in Germany, but studied psychology in the Netherlands for five years.

Synthesis of forward translations: The project manager compared the forward-translated versions, highlighted ambiguities and discrepancies in a synthesised version and achieved an agreement with the translators by discussion.

Backward translations: Two Dutch occupational therapists independently translated the preliminary German version back to Dutch. The Dutch translators were excellent in German and fluent in English, one of them was formerly concerned with translation issues in research [43].

Synthesis of backward translations: The Dutch translators compared the two backward-translated Dutch versions and highlighted discrepancies. For the coordinating project manager, they transferred the Dutch discrepancies to the German version and explained it with English comments using single Dutch words when necessary. All four translators and the project manager discussed this synthesized version considering all highlighted ambiguities and discrepancies of the forward and backward translations. Again, agreement on the final version was achieved by discussion.

Pilot-testing: The assessors involved in the WHEDA trial attended a seminar on DQoL application and interviewed patients with mild to moderate dementia. In a written cognitive debriefing [44] on the response process, the assessors were asked to list aspects facilitating or hindering the DQol application.

Full psycho-metric testing: Patients were interviewed at home with the DQoL and the SF-12 (WHEDA-study) or with the DQoL and the QoL-AD at the study sites (ERGODEM-study). The primary caregivers completed the socio-demographic questionnaire, the QoL-AD-carer, the CSDD and the IDDD in a separate room. Trained study staff (psychiatrists, psychologists or study nurses) collected data of the MMSE and ADAS-cog at the study site in the same week. At the coordinating clinical trial centres questionnaires were checked for completeness and plausibility, typed in, checked again for typing errors and analysed.

Statistical analysis

The values of the DQoL scales were calculated and reported with means, standard deviation and frequency of best and worst possible values (ceiling and bottom effects). Internal consistency was indicated by Cronbach's alpha. Confirmatory factor analysis was applied to evaluate scale structures. Pearson correlation coefficients were calculated for scores of the DQoL scales and scores of the MMSE, ADAS-cog, CSDD, IDDD, SF-12 and QoL-AD. Because of the inflation of alpha-error, only correlations with high significance ($p < 0.01$) were considered.

Results

Translation

The introductory instructions for the patient were reformulated into a more plain language, e. g. we used the term *answers* instead of *response scale*. There were some minor discrepancies in the wording of questions such as "How much did you enjoy to *look at* vs *watch* vs *observe* birds"? Furthermore, it was a challenge to capture the meaning of affects represented by only one word. Examples were "How often did you feel *uneasily* vs *anxiously* vs *afraid*"? or "How often did you feel *irritated* vs *angry*"? We found agreement also through ranking the Dutch, German and English words by the intensity of the expression.

Pilot-testing

14 assessors provided cognitive debriefing data of 21 DQoL interviews. In one case one item response was missing. In 12 cases (57%), the assessors had to explain questions again or to encourage patients to continue, but all interviews could be completed, except one (5%) where the patient felt overstrained. The collection of DQoL data was feasible in patients with mild to moderate dementia, when trained interviewers adapted to the patients' individual capability. We concluded that the interviewers should be well trained and used to interviewing people with cognitive impairments, but that a change in the wording of instructions, questions or response formats was not necessary.

Descriptive results

Data could be pooled because analyzed samples of Freiburg (N=136) and Dresden (N=151) did not differ significantly (table 2). Consistently on each scale, descriptive data demonstrate values in the direction of positive QoL (table 3). This indicates that the majority of patients seldom experienced negative affects, often positive affects and mostly enjoyment. Minor ceiling effects were found in the scales *negative affect* (8.7 % with best scale values) and *feeling of belongings* (10.8 %).

Table 2: Baseline characteristics

	Freiburg (FR)	Dresden (DD)	p	Total sample
N	136	151		287
MMSE, mean (SD)	20.5 (2.9)	21.0 (3.9)	0.320	20.8 (3.5)
Age, years (SD)	78.4 (6.3)	76.5 (7.4)	0.051	77.3 (7.2)
Gender, female (%)	77 (57 %)	86 (57 %)	0.954	163 (57 %)
Spouse as primary carer (%)	78 (57 %)	97 (65 %)	0.205	175 (61 %)

MMSE=Mini Mental State Examination

Table 3: Dementia Quality of Life Instrument - descriptive data

	N	No. of items	Mean of items	Scale values				
				Mean	SD	Median	Bottom effects[b]	Ceiling effects[b]
Overall (1-5)[a]	287	1	3.05	3.05	0.73	3	4 (1.4%)	11 (3.8%)
Aesthetics (5-25)[a]	287	5	3.70	18.52	4.07	19	0 (0.0%)	13 (4.5%)
Positive affect (6-30)[a]	287	6	3.56	21.36	4.61	22	2 (0.7%)	3 (1.0%)
Negative affect (55-11)[a]	287	11	1.91[c]	20.97	7.29	20	0 (0.0%)	25 (8.7%)
Self Esteem (4-20)[a]	287	4	3.50	14.01	2.99	14	0 (0.0%)	5 (1.7%)
Feelings of belonging (3-15)[a]	287	3	3.89	11.68	2.23	12	0 (0.0%)	31 (10.8%)

[a] Range: negative to positive; [b] No. of cases with worst/best scale values; [c] item with reverse polarity

Construct validity

Cronbach's alpha indicated good internal consistency for the scales *positive affect* and *negative affect* ($\alpha > 0.8$) and moderate consistency for *aesthetics*, *self esteem* and *feelings of belonging* ($\alpha > 0.6$ and < 0.7). Cronbach's alpha > 0.7 were found for the scale *aesthetics* when eliminating the item *listening to music* and for the scale *self esteem* when eliminating the item *makes own decisi*ons (table 4). These items also showed the least correlations with scale values within the confirmatory factor analysis (table 5). Furthermore the factor analysis revealed that factor reliability for *positive*

affect and *negative affect* is higher (0.84) than for the other scales (<0.7). Average variance extracted is < 0.4 for all scales, except for *positive affect* (0.47). Overall, the confirmatory factor analysis found a bad fit indicated by a significant difference between the original five factor model of the DQoL and the correlations actually found in our sample (χ^2 = 888.6, df = 391, p<0.001).

Table 4: Dementia Quality of Life Instrument - internal consistency

Scale	N	Cronbachs alpha	Items	Mean item (SD)	Corrected item-to-scale-correlation	Cronbachs alpha without item
Aesthetics	285	0.669	01 Listening to music	3.58 (1.24)	0.205	0.711
			02 Listening to sounds of nature	3.61 (1.28)	0.575	0.543
			03 Watching animals or birds	3.78 (1.30)	0.479	0.591
			04 Looking at colourful things	3.82 (1.19)	0.454	0.605
			05 Watching clouds or sky	3.76 (1.17)	0.423	0.619
Positive affect	285	0.843	13 Found something that made them laugh	3.34 (1.10)	0.548	0.832
			15 Happy	3.63 (1.04)	0.659	0.809
			18 Cheerful	3.53 (1.00)	0.733	0.795
			21 Content	3.89 (0.97)	0.587	0.823
			23 Hopeful	3.54 (1.07)	0.579	0.826
			28 Jokes and laughs with others	3.43 (1.01)	0.634	0.814
Negative affect	285	0.843	07 Embarrassed	1.64 (0.93)	0.370	0.841
			14 Afraid	1.61 (1.03)	0.533	0.829
			16 Lonely	1.80 (1.11)	0.444	0.836
			17 Frustrated	1.84 (1.04)	0.588	0.824
			19 Angry	1.99 (0.99)	0.595	0.824
			20 Worried	2.41 (1.19)	0.489	0.833
			22 Depressive	1.87 (1.05)	0.556	0.827
			24 Nervous	2.18 (1.21)	0.529	0.829
			25 Sad	2.11 (1.10)	0.657	0.818
			26 Irritated	1.80 (0.98)	0.441	0.836
			27 Anxious	1.75 (1.05)	0.547	0.828
Self Esteem	286	0.678	09 Feels confident	3.52 (1.09)	0.580	0.526
			10 Satisfied with self	3.57 (1.06)	0.541	0.557
			12 Accomplished something	3.41 (0.95)	0.438	0.627
			29 Makes own decisions	3.51 (1.11)	0.304	0.715
Feelings of belonging	286	0.617	06 Felt useful	3.56 (1.08)	0.343	0.652
			08 Felt lovable	3.97 (1.04)	0.489	0.420
			11 Felt people liked you	4.14 (0.80)	0.478	0.477

Concurrent validity

The analysis of concurrent validity revealed moderate correlations (r > 0.43) for the DQoL *overall item*, *positive affect* and *self-esteem* with both the SF-12 mental scale and the QoL-AD score (table 6). *Negative affect* was moderately associated only with the SF-12 mental scale (r > -0.63); and *feelings of belonging* only with the QoL-AD score(r > 0.53). Carer-rated scales of patient's QoL, depression or activities of daily living demonstrated no or minor correlations with DQoL scales (r < 0.25). Performance tests of patient's cognition did not correlate with the DQoL (r < 0.18).

Discussion

In our cross-national validation study on the Dementia Quality of Life Instrument (DQoL), the standardised procedure of forward and backward translation resulted in a German version equivalent to the Dutch and the English DQoL. Piloting revealed good feasibility of the new version, when applied as interview by experienced assessors. However, in the study phase assessors reported that (1) sometimes patients with mild dementia perceived questions of the scale *aesthetics* as inappropriate because they were too narrowed to the experience with nature and that (2) a few patients with moderate dementia had a reduced understanding for some questions though they correctly answered the screening questions.

Table 5: Dementia Quality of Life Instrument - Confirmatory factor analysis

Scale	N	Factor reliability	Average variance extracted	Items	Squared multiple correlation
Aesthetics	285	0.69	0.33	01 Listening to music	0.081
				02 Listening to sounds of nature	0.512
				03 Watching animals or birds	0.409
				04 Looking at colourful things	0.357
				05 Watching clouds or sky	0.263
Positive affect	285	0.84	0.47	13 Found something that made them laugh	0.321
				15 Happy	0.586
				18 Cheerful	0.614
				21 Content	0.515
				23 Hopeful	0.413
				28 Jokes and laughs with others	0.413
Negative affect	285	0.84	0.34	07 Embarrassed	0.162
				14 Afraid	0.318
				16 Lonely	0.249
				17 Frustrated	0.406
				19 Angry	0.393
				20 Worried	0.290
				22 Depressive	0.427
				24 Nervous	0.297
				25 Sad	0.560
				26 Irritated	0.247
				27 Anxious	0.335
Self Esteem	286	0.69	0.37	09 Feels confident	0.470
				10 Satisfied with self	0.576
				12 Accomplished something	0.343
				29 Makes own decisions	0.119
Feelings of belonging	286	0.64	0.38	06 Felt useful	0.336
				08 Felt lovable	0.442
				11 Felt people liked you	0.342

However, the original five factor model of the DQoL could not be confirmed. Only the scales *positive affect* and *negative affect* demonstrated high factor reliability and internal consistency (r > 0.8). This is partly congruent to the factor analysis of Ready et al. confirming a three-factor solution corresponding to *positive affect*, *negative affect* and *aesthetics* [45]. In our sample, *aesthetics* was weakly correlated to QoL instruments (QoL-AD: r = 0.27; SF-12 mental: r = -0.102). The item *listening to music* nei-

ther statistically fits to *aesthetics* nor is the content consistent to the other items which record the enjoyment of nature (table 4 and 5). The scales *feeling of belongings* and *self esteem* were associated with other QoL instruments (table 6) and demonstrated a moderate internal consistency and factor reliability (tables 4 and 5).

Table 6: Dementia Quality of Life Instrument and related scores at baseline - Pearson correlations coefficient

	Study	N	DQoL-Scales					
			Overall	Aesthetics	Positive affect	Negative affect	Feelings of belonging	Self-esteem
Quality of Life								
QoL-AD, self-rated (13-52)[a]	DD	150	0.595**	0.270**	0.575**	-0.384**	0.530**	0.567**
QoL-AD, carer-rated (13-52)[a]	DD	147	0.139	0.150	0.220*	-0.240*	0.221*	0.226*
SF-12-physical, self-rated (0-100)[a]	FR	112	0.391**	-0.009	0.229**	-0.213	0.250*	0.277*
SF-12-mental, self-rated (0-100)[a]	FR	112	0.435**	-0.102	0.464**	-0.625**	0.267*	0.489**
Depression								
CSDD, carer-rated (38-0)[a]	FR	122	-0.252*	0.135	-0.263*	0.170	-0.225	-0.183
Activities of Daily Living								
IDDD, carer-rated (0-44)[a]	FR/DD	285	0.010	-0.084	-0.027	-0.083	-0.083	-0.119
Cognition								
MMSE, performance test (0-30)[a]	FR/DD	267	-0.007	-0.091	0.054	-0.012	0.026	0.173*
ADAS-cog, performance test (85-0)[a]	DD	151	-0.103	-0.098	-0.166	-0.030	-0.122	-0.125

DQoL= Dementia Quality of Life Instrument
QoL-AD=Quality of life in Alzheimer's disease instrument
CSDD=Cornell Scale for Depression in Dementia
IDDD=Interview of Deterioration in Daily Living Activities in Dementia
MMSE=Mini Mental Stat Examination
ADAS-cog=Alzheimer's Disease Assessment Scale cognitive
[a] Range: negative to positive; * p<0.01; ** p<0.001

Descriptive DQoL data indicated good QoL in our sample of 287 community dwelling people with mild to moderate dementia. We found only minor ceiling effects in the scales *negative affect* and *feeling of belongings.*

Correlations between DQol scales and depressive symptoms as reported by Suzuki et al. [23, 24] (r = 0.4 to 0.6) could not be found in our sample (r < 0.27, table 6). However, in the Japanese sample depression was self-rated. In contrast in our sample, all carer ratings on patient's QoL, depression and activities of daily living were poorly correlated with DQoL scores as self-rated by the patient (table 6) confirming findings of low associations between self- and carer-rated QoL [13].
Several limitations in the measurement of QoL are discussed in dementia research. Patient self-reports can be biased by depression and anosognosia and by disturbances of attention, language skills or orientation [6, 8-10, 46, 47]. Carer reports can also be biased. Carers with increased burden or depression rated the patients' QoL lower than the patients themselves did. Furthermore, carers rated the QoL of patients with challenging behaviours worse than the patients themselves did [13]. Consequently, measurement schemes of QoL in dementia should control for possibly confounding influences. The limitation of our study was that we could not provide enough data to control for such rating bias. However, our data showed that self-rated DQoL scales were higher correlated with self-rated than with carer-rated QoL-AD scores and not associated with performance tests of cognition (table 6).

Conclusion

Our validation study revealed that the DQoL sufficiently measures the self-rated QoL of patients with mild to moderate dementia in the domains positive and negative affect, and fairly assesses feelings of belongings and self-esteem. Researchers should consider that according to the Hierarchy Model of Needs in Dementia [14] the DQoL does not represent basic physiological and safety needs and insufficiently covers social contacts and enjoyment of activities.

The bad fit of the five factor model substantiate the need of further research for the improvement of the DQoL in general. Our findings suggest the following precisions:

1. The scale *aesthetics* should be renamed and restructured in order to cover the enjoyment of a broader range of activities.
2. The scale *feeling of belongings* could be improved to cover the full domain of social contacts.
3. The scale *self esteem* might be expanded with items fully representing needs of esteem and self-actualisation.

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7

General Discussion

This research project intended to evaluate whether positive effects of complex psychosocial interventions in dementia can be transferred from one country to another. Our randomised trial at seven German study sites revealed that a community occupational therapy programme could not travel from the Dutch source to the target context. A half year after baseline, the German active controlled study found in both groups a similar stabilisation on daily functioning and quality of life in patients and caregivers, while the Dutch trial detected significant differences between the intervention and the waiting-control group after three months. Thus our main hypothesis that intensive occupational therapy would result in the patients' better daily functioning than the routine care of one comprehensive consultation must be rejected.

In order to exclude potential measurement bias, we carried out revalidation studies of three measurement instruments translated for this study. The posthoc validation of instruments measuring daily functioning and quality of life revealed some weaknesses in the structures of subscales but no essential measurement bias.

Furthermore, we explored potential effect modifiers using an accompanying process evaluation. Effect modifications by study site effects, variations in treatment performance or systematic differences between experimental and control group in further medical resource utilisation during the treatment period could be excluded. However, compared to the Dutch original study our German patient sample with high daily functioning and low potential for improvement at baseline, the impact of the active control group and a partial poor performance of treatment components may have diminished group differences in the primary outcome.

Strengths and weaknesses

The project plan had to be carried out in a challenging two years time frame with a fixed starting point in spring 2008, both set by the funding agency. Consequently, we had to start planning before the results of the Dutch pilot and main implementation study had been analysed.[1] Thus we could not learn from the experience of how to transfer the mono-centre expert programme to the Dutch multi-centre routine care setting. Furthermore, it was not possible to involve clinical practitioners in the adaptation of the COTiD manual to the local context as suggested in implementation research.[2] Moreover, the practical training in treatment skills after the introductory seminar during the pilot phase could not be supervised face-to-face but only by e-mail and telephone. Also refreshment seminars after some months could not be offered because of this tight schedule. But the COTiD demonstrated such large effect sizes in the primary outcome with Cohen's d>2.0, that we reasonably hypothesised that at least moderate effects will be found despite variations in the treatment performance potentially arising from less elaborated and adapted implementation strategies. To control for such variations, we decided to perform a process evaluation as recommended in the guidance of the British Medical Research Council.[3]

An ideal situation regarding measurement instruments in cross-national transfer is given, when assessments applied in the source country are also available in the target country and have already been fully validated within similar samples. Our research framework differed from this ideal situation for three instruments. The Mayo/FDA Patient-Reported Outcomes Consensus Meeting Group recommended a reasonable pragmatism for such cases.[4] The authors differentiated four changes: (1) change in the content of an instrument, (2) in the mode of administration, (3) translation and (4) application to different patient population. Depending on the changes

made for the instrument, the Mayo group recommended revalidation strategies ranging from (a) a focus group or patient interview to confirm content validity, (b) a test of the basic psychometric properties posthoc or (c) a comprehensive revalidation a priori to the outcome study. Because we had in our research project only the translation but no changes in the content, administration modus or patient population, we decided for posthoc confirmation of the main psychometric properties of the IDDD, PRPP and DQoL.

The study's strengths were the exclusion of measurement bias and modifying effects, the conservative power calculation to assure the detection even of small effects and the elaborated design for a pragmatic multi-centre trial according to the recommendation of the CONSORT and PRACTIHCS groups.[5]

Comparison

In the international literature, we found two high quality studies sufficiently reporting methods and results relevant to our findings on cross-national transfer in dementia.

The only transfer trial on community occupational therapy was a replication and the extension of the pilot study in Philadelphia, USA.[6][7] Both trials were carried out by the same research team at the same study site with the same five interventionists plus one novice in the main study. The samples of the pilot and the main study differed slightly in MMSE at baseline (11.6 vs. 13.4). Challenging behaviour could be reduced for about one third after 4 months treatment in both studies. However, while the waiting-control group in the pilot study did not improve, the active control treatment in the main study had an effect comparable to the experimental treatment in both trials. These results support our finding that active control treatment can diminish group differences in a replica study, while a significant contrast occurred in the pilot with waiting-control group design. The therapists had the same study site context and the same expertise in both studies. Consistently to that also in both trials, they could improve the patients' engagement in activities and the caregivers' skills. This congruence between interventionists' expertise and improved outcome can in reverse support our finding that partial poor treatment performance may reduce outcome. Furthermore, it is notably that Gitlin and colleagues did not report a replication of the positive effect on time of informal care, although this was an essential outcome of the pilot study.[8] Differences in the socio-demographic sample characteristics might explain heterogeneous findings on this outcome. The pilot sample comprised 62 % of spouse carers, the replica sample only 38 %.

Mittelman and colleagues transferred their carer counselling programme in dementia from the USA and tried to replicate the positive effects on carer's depression and patient's institutionalisation in a three-country randomised trial in the USA, UK and Australia.[9-13] They found in both studies a slight reduction of depressive symptoms, although the intervention in the replica was shorter (3 instead of 4 months), less comprehensive (5 instead of 6 counselling sessions and no subsequent carer support groups) and not carried out by the same staff, whose expertise was not reported in detail. In both studies, the carers had minimal depressive symptoms at baseline with a score in the Beck Depression Inventory (BDI) of less than 11. A score of 14 indicates the cut off for mild depression. In both studies, a small difference could be found between experimental and control group after 2 years. The extend was about 1.5 points on the BDI score representing less than 3 % of scale range (0 to 63). The nearly one year delayed nursing home placement, which had been found in the origi-

nal study as effect of carer counselling (p=0.02), could not be shown in the replica study, although follow-up period was more than 8 years in both studies.[10-12] One reason might be that patients in the replica study were somewhat less severely affected by dementia as indicated by a score of 4.4 on the Global Deterioration Scale compared to a score around 5 in the original study.

Considering our findings and transfer studies as mentioned above, three areas can be determined as possibly modifying the replication of effects.

- o Differences of study samples in baseline characteristics, which represent a reasonable potential for improvement.
- o The impact of differences in control intervention design.
- o The expertise of the therapeutic study staff as well as the identification of active treatment components and the quality of its performance.

Implication for research

Cross-national transfer of complex psychosocial interventions based on evidence in a source country should be thoroughly prepared within the routine care context of the target country. The main challenges are the early adaptation of sampling criteria and the sound implementation of treatment modalities in the target context.
The transferability of the source intervention should be checked a priori and systematically by assessing (1) whether effects in the source country have been shown in a multi-centre context or replicated in a second mono-centre trial at another study site and (2) whether significant quantitative associations have been found between a sufficient performance of active treatment components and an improved outcome reasonably explaining the mechanism of the treatment impact. In our project, the assumed "mechanism" of positive effects was based on the Dutch case study revealing that a well structured physical environment with auditory or visual cues, a repetitive training of simplified and highly meaningful everyday tasks and an improved interaction between caregiver and patient are the active components to improve the patient's daily functioning.[14] However, there was no study providing evidence that e.g. the number of cues, the frequency of training or the degree of improvement in interaction within a sufficient number of treatment cases was clearly associated with daily functioning after the intervention. The established concept of dose-effect-relation in drug trials might be adapted to behaviour change intervention research. Therefore reliable quantitative measures for the implementation of treatment components proposed to be the active agents are to be developed and correlated to primary outcomes.[15 16]

Implication for practice

Our research results may have three main implications for dementia care. (1) Intensive community occupational therapy can be offered for patients with at least moderate need for assistance in daily functioning. (2) Based on global international guidelines for dementia care, occupational therapy guidelines should be provided for each country specifically adapted to the target context, before treatment is regularly applied within routine care. (3) The intensity of treatment is to be determined depending

on the dementia stage, the needs of the patient, the capabilities of the caregiver and the progress under treatment.

In summary: community occupational therapy in dementia as well as cross-national transfer research in complex psychosocial interventions are promising fields to improve health care in Europe. Other translational research efforts will tell us over time what the efficacy and effectiveness of occupational therapy outside the initial research setting may be.[17] Funding agencies, interdisciplinary and international research teams as well as providers of routine care should jointly prepare stepped research lines, at best based on the new guidance for developing and evaluating complex interventions[18] [19], which might also be extended by recommendations for cross-national transfer.

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8

Summary

Samenvatting

Acknowledgement

Curriculum Vitae

Summary

Dementia is syndrome primarily caused by chronic progressive diseases that result in deterioration of mental and physical capabilities, which in turn affects a person's ability to function independently. The number of people with dementia is predicted to be 16 million in the year 2050 in Europe.

The deterioration of dementia patients' daily functioning and their challenging behaviour is an increasing burden for their families and caregivers.

Literature on the efficacy of interventions on everyday functioning in dementia suggests that positive effects of currently available drugs (i.e. acethylcolinesterase inhibitors and memantine) on the activities of daily living are small and that high quality multi-centre randomised trials on the effects of psychosocial interventions are missing.

Purpose: The aim of the research described in this thesis was to determine whether an evidence-based Dutch home visit programme in dementia still has positive effects on patients' daily functioning when newly introduced therapists apply it within the German routine care context.

Method: We conducted a pragmatic randomised controlled trial at seven German study memory clinics. The study also focussed on exploring bias possibly introduced by study site effects or variations in the treatment performance caused by translation from a Dutch to a German context. This part of the research was carried out in extensive cross-national process evaluation. In the whole process of copying the intervention to Germany, we aimed to exclude measurement bias by trans-cultural validation efforts of the three main measurements (IDDD, PRPP and DQoL, see below), whose psychometric properties had not yet been investigated within German samples.

Participants: 141 patients with mild to moderate Alzheimer's disease or mixed type of Alzheimer's disease with vascular lesions, living in the community, with their primary carer available to take part in the study, and without severe depression or behavioural symptoms, were randomised to the experimental (N=71) and control group (N=70). Data for the 54 and 50 participants who were able to complete the study were analysed.

Intervention and control:
14 German occupational therapists (OTs) were trained in the occupational therapy intervention by using the translated treatment manual, watching videos and having role plays with feedback and group discussion. In the intervention, OTs spent about 20 hours per patient and caregiver for a full treatment series including 10 treatment sessions, travel, reports and a multidisciplinary briefing. Sessions of 1 hour's duration were held over five weeks at each patient's home. The occupational therapist explored the patient's preferences and performance of daily activities as well as the possibilities of modifying the patient's home and improving the interaction between carer and patient. After selecting the most meaningful activities, the occupational therapist defined, together with the patient and the carer, more effective compensatory and environmental strategies to adapt both the environment and the selected activities to the patient's habits and cognitive abilities. Patient and carer were taught how to use these suggested adaptations.

The control group received 1 h of occupation therapy instruction at the patient's home conducted by the same study interventionists. The semistructured control consultation was an explanation of 30 min of an OT leaflet and a talk of 30 min on individual problems that arose from the patient's and carer's needs.

Outcome measures: The primary outcome was the patients' daily functioning measured with the Interview of Deterioration in Daily activities in Dementia (IDDD) and the Perceive, Recall, Plan and Perform System of Task Analysis (PRPP). Secondary outcomes such as the Dementia Quality of Life instrument (DQoL) were also used. Assessments were at baseline, 6, 16, and 26 weeks, with a postal assessment at 52 weeks.

Results: The positive effects of the community occupational therapy programme found in The Netherlands could not be confirmed in the German target context. In the Dutch and German groups, a similar stabilisation on daily functioning and quality of life in patients and caregivers was found a half year after baseline.
The posthoc validation of instruments measuring daily functioning and quality of life revealed no essential measurement bias. Effect modifications by study site effects, variations in treatment performance, or group differences in medical resource utilisation could be excluded.
Compared to the Dutch study, the German patient sample showed a better daily functioning and therefore lower potential for improvement at baseline. The impact of this still rather active patient group and a partial poor performance of treatment components may have caused the lack of positive effects in the primary outcome.

Implications for practice: Intensive community occupational therapy might be offered when patients have at least moderate need for assistance in daily functioning. The treatment should be based on guidelines specifically adapted to the target context. The intensity of the treatment is to be determined depending on the dementia stage, the patient's needs, the caregiver's capabilities and the progress under treatment.

Implications for future research: In future research aiming at cross-national transfer of (psychosocial) interventions, the transferability of such, often complex, interventions should be checked a priori by assessing (1) whether effects in the source country has been shown in a multi-centre context or replicated in a second mono-centre trial at another study site and (2) whether significant quantitative associations have been found between intensity of performance of active treatment components and an improved outcome reasonably explaining the mechanism of the treatment impact.
Finally, it should be safeguarded that the intervention can be targeted at a patient population with similar characteristics as in the original intervention. Other translational research efforts will tell us over time what the efficacy and effectiveness of occupational therapy outside the initial research setting may be.

Samenvatting

Introductie: Dementie wordt met name verzoorzaakt door chronisch progressieve aandoeningen, die de psychische en lichamelijke functies aantasten en het zelfstandig functioneren beperken. In 2050 verwacht men dat in Europa 16 miljoen mensen lijden aan dementie.

De toenemende beperkingen in het dagelijks functioneren van dementie patiënten veroorzaken ook een steeds groter wordende belasting voor hun naasten en mantelzorgers.

De literatuur over de werkzaamheid van interventies ter verbetering van het dagelijks functioneren laat zien dat de positieve effecten van de thans beschikbare geneesmiddelen (de zogenaamde acethylcholinesterase remmers en memantine) op het algemeen dagelijks functioneren beperkt zijn en dat er eigenlijk vrijwel geen multi-centrum studies van goede kwaliteit zijn over psychosociale interventies.

Doel: het doel van het onderzoek beschreven in dit proefschrift was na te gaan of een bestaand en in Nederland effectief gebleken ergotherapie programma ter behandeling en instructie van dementia patiënten thuis, ook werkzaam is wanneer het wordt uitgevoerd in een vergelijkbare context in Duitsland, door ergotherapeuten die specifiek ten behoeve van de studie in de interventie zijn opgeleid.

Methode: We voerden een pragmatische gerandomiseerde en gecontrolleerde studie uit in zeven Duitse geheugenklinieken.

De studie was er met name ook op gericht om na te gaan of en waardoor verschil in setting of in uitvoering van de interventie verschillen in effect zou kunnen verzoorzken bij deze buitenlandse uitvoering van de ergotherapie interventie. Dit deel van de studie werd uitgevoerd met een uitgebreide procesanalyse.

Bij de vertaling van de interventie en de evaluatie ervan van Nederland naar Duitsland werd zorg gedragen voor validering van de drie belangrijkste meetinstrumenten die voor de studie waren vertaald in het Duits (IDDD, PRPP en DQoL, zie verder), en werden de psychometrische eigenschappen hiervan onderzocht. Dit was voor deze instrumenten nog niet eerder gedocumenteerd in een Duitstalige context.

Deelnemers: Er namen 141 patiënten met lichte tot matige ernst van dementie deel aan de studie. De patiënten konden zowel lijden aande ziekte van Alzheimer, als aan een combinatie van Alzheimer type pathologie en vaatschade. Alle patienten woonden nog thuis en hadden een mantelzorger die wilde deelnemen aan de studie. Ze hadden geen ernstig depressieve kenmerken, noch gedragsproblemen. De 141 patiënten werder gerandomiseerd over een interventie (N=71) en een controlegroep (N=70). We konden uiteindelijk de gegevens analyseren van respectievelijk de 54 en 50 patiënten die de gehele studie voltooiden.

Interventie: 14 Duitse ergotherapeuten werden getraind in de interventie door het leren gebruiken van de vertaalde handleiding voor de interventie, het bekijken van instructievideo's en het uitvoeren van rollenspelen met feedback en groepsdiscussies. In de interventiegroep werd gemiddeld 20 uur per patient en mantelzorger besteed aan een volledige serie van 10 behandelingen, inclusief reistijd, rapportage en een multidisciplnair overleg.

De controlegroep kreeg 1 uur ergotherapie thuis, door dezelfde ergotherapeuten. Dit uur bestond voor de helft uit instructie aan de hand van een ergotherapie folder en voor de helft uit een inventarisatie van de problemen van de patient en mantelzorger.

Uitkomstmaten: De primaire uitkomstmaten van de studie waren een instrument genaamd "Interview van het Dagelijks leven met Dementia" (IDDD in het Engels) en de zorgenaamde "Perceive, Recall, Plan and Perform System of Task Analysis" (PRPP). Secundaire uitkomstmaten zoals de kwaliteit van leven (DQoL: Dementia Quality of Life Instrumen) werder ook gemeten. De metingen warden afgenomen bij de start van de studie en na 6, 16 en 26 weken, met een laatste schriftelijke afname na 52 weken.

Resultaten: De positieve effecten van de ergotherapie interventie thuis zoals behaald in de Nederlandse context konden niet worden bevestigd in de Duitse interventie. In Nederlandse en Duitse groepen werd echter wel een gelijkaardige stabilisatie van het dagelijks functioneren en de kwaliteit van leven gezien van de patiënten en mantelzorgers een half jaar na start van de studie.
De posthoc validering van de vertaalde meetinstrumenten in Duitsland maakte een vertekening door deze vertaling onwaarschijnlijk.
De vermindering van dit resultaat van de interventie door een eventueel verschil tussen de verschillende deelnemende instellingen in Duitsland, of door variatie in het geven van de ergotherapie interventie, of het gebruik van andere hulpmiddelen kon onwaarschijnlijk worden gemaakt in aanvullende analyses.
Vergeleken met de Nederlandse populatie toonde de Duitse groep patiënten bij wie de studie was uitgevoerd echter wel een wat beter niveau van algemeen functioneren bij start van de interventie, waardoor zij mogelijk minder goed konden verbeteren. Dit verschil in functioneren en een mogelijk minder goed uitvoeren van onderdelen van de interventie, met een actieve controle groep waarin ook een uur ergotherapie werd gegeven, zou samen het verschil in werkzaamheid tussen de Nederlandse en Duitse uitvoering van de ergotherapie thuis bij dementie patiënten kunnen verklaren.

Betekenis voor de praktijk: Intensieve ergotherapie thuis zou het beste aangeboden kunnen worden aan dementiepatiënten met tenminste een matig ernstige noodzaak van ondersteuning in het dagelijks functioneren. De behandeling zou moeten worden gebaseerd op richtlijnen die specifiek zijn geschreven voor de (land-specifieke) context waarin de interventie wordt uitgevoerd. De intensiteit van de bahandeling moet daarbij worden aangepast aan de ernst van de dementie, de vragen en problemen van de patient, de mogelijkheden van de mantelzorger en de mate waarin men vooruitgang ziet tijdens de behandeling.

Betekenis voor verder onderzoek: In toekomstig onderzoek waarin men een (psychosociale) interventie wil toepassen in een ander land zou met een aantal lessen uit dit onderzoek rekening moeten houden:
1. Zijn de effecten van de interventie die men wil toepassen ook al aangetoond in multi-centre onderzoek of is er tenminste replicatie in het land van herkomst van de interventie uitgevoerd?
2. Zijn er al gegevens die een dosis-effect relatie van de intensiteit van de uitgevoerde interventie met de grootte van het effect aannemelijk maken?

3. Kan de interventie bij een voldoende gelijkaardige populatie worden uitgevoerd bij translatie naar het andere land?

Andere translaties zullen mettertijd leren in hoeverre ergotherapie thuis effectief is buiten de initiële research setting.

Acknowledgement

Many persons accompanied my academic way until this milestone of the PhD degree. Within the thesis, I conclude that a cooperative stepped research line could be beneficial. Similarly, I would like to describe the process to my PhD thesis and through the PhD student period as a step-by-step journey full of great support by co-walkers, experienced guides and "elators".

The first elator was the former head of our Geriatric Centre, Prof. Dr. Wolfgang Heiß, who was the first recognising my curiosity. He "lifted" me to scientific research just by giving me the task of assessment development, providing a network of experienced scientists to help me and enabling my successful participation in a European Master programme.

Here I met a long lasting Dutch co-walker, Fenna van Nes, who helped me to build up a European Cooperation in Occupational Therapy Research and Occupational Science, an increasing informal network of young researches. She was a PhD student at the same time and we established a very helpful "concept" of regular fellow inter-vision.

Visibility in Europe and connection to the Netherlands prepared the field for the contact with Dr. Maud Graff, the first guide in this walking tour. I am very thankful to her that she was willing to share and transmit the evidence-based programme she masterminded. She ventured to start a Dutch-German joint venture with a very tight schedule and with a new partner, being for her initially an unknown entity. She was the first, who crossed the Dutch-German border by visiting our Geriatric Centre in Freiburg, greatly contributing to the study protocol and giving seminars to the interventionists – in German language!

Having support from excellent Dutch partners with a more than promising intervention programme was the first half of the cake preventing from inanition during the cross-national research expedition. The second half was "funding", one of the most magic words in the scientific world. A treasure hunt needs a very experienced guide. I was lucky. I am very grateful to Prof. Dr. Michael Hüll, the head of our Geriatric Centre. He did not hesitate to use his expertise and connections, in order to make funding available. Furthermore, he greatly supported my "activities of daily travelling" to reach the PhD target line and provided me with great opportunities to publish - beside the PhD papers - in established journals relevant for dementia care in Germany.

Once the first treasure chest had been found, the next experienced guides were needed to blow a breach through the jungle of being an external PhD student and going for international publications. Prof. Dr. Myrra Vernooij-Dassen and Prof. Dr. Marcel Olde Rikkert welcomed me not only as PhD student, but right from the beginning gave me the feeling that I am seen as fellow researcher. This meant a lot of responsibility for me but actually even more encouragement than the words, they also used very wisely to inspire and guide me. They did both, challenging me with critical comments and encouraging me with the provision of opportunities to take part in the international research community. Marcel's supervision feedbacks were guidance at its best in concreteness, encouragement and expanding the view to an overview.

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Although I am not sure, if they really intended to do so, my children elated me with their jokes on "the old father climbing the social ladder". These jokes made by jolly adult children imply the unspoken confirmation that it was right to care first for the young family and later on for the "social ladder". One of the most touching compliments during my life journey.

The "elator" with the highest impact factor in this travel over sunny hills and dark dales was and hopefully ever will be my wife Barbara. There is a lot in my mind but nothing more to tell about this highly elating and deeply touching precious top secret.

There were many more people during this journey who – to speak in metaphors – carried my rucksack for a while, offered fresh water or brightened me up with a common song, e.g. Prof. Dr. Chris Mayers helped me very much to sing in the right language. To all of them I say simple words but based on complex psychosocial gratefulness: Thank you!

Curriculum Vitae

Sebastian Voigt-Radloff was born on the 5th of June in 1962 as forth of five children in Schwelm, near Wuppertal, Germany. He has three adult children with his wife Barbara. After 12 years school, an apprenticeship as baker and working for several years at his father's factory he got baker asthma and changed to occupational therapy.

Working as therapist, quality manager and study coordinator at the University Hospital Freiburg for more than 15 years, he has been concerned with the development and scientific evaluation of (1) new occupational therapy treatment for geriatric outpatients, (2) group programmes for dementia care, (3) assessment instruments for occupational, physical and speech therapy and (4) community occupational therapy in dementia.

His degree in European Master of Science in Occupational Therapy helped to underpin his experiences theoretically in various fields of practice and management, such as improvement of therapeutic care and quality management, supervision of occupational therapy students at several universities across Germany, membership in the working group of the German Federal Ministry of Education and Research on research development in the field of allied health professions and project management of ECOTROS, the European Cooperation in Occupational Therapy Research and Occupational Science.