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Why did an effective Dutch complex psycho-social intervention for people with dementia not work in the German healthcare context? Lessons learnt from a process evaluation alongside a multicentre RCT

Sebastian Voigt-Radloff, 1 Maud Graff, 2 Rainer Leonhart, 3 Michael Hüll, 4 Marcel Olde Rikkert, 5 Myrra Vernooij-Dassen 6

ABSTRACT
Background: The positive effects of the Dutch Community Occupational Therapy in Dementia programme on patients’ daily functioning were not found in a multicentre randomised controlled trial (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 was analysed in exploratory ANCOVA and regression analyses. (2) Therapists 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 in the Dutch and German study design were identified, and the 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 healthcare 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 a 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 transfer studies should be prepared by small-scaled pilot studies assessing the applicability of the intervention, the appropriateness of inclusion criteria and the specific patient needs in 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 be sufficiently 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 healthcare 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 that has already been developed, piloted and evaluated on effectiveness in one country can be directly 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 healthcare 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 being highly valuable in RCTs to provide an 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
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 IDDD 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 described 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 The percentage variance explained in mean changes from baseline in the IDDD and PRPP was assessed using multiple regression.

COTiD performance in the German experimental group
Therapists completed semistructured 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 in 20 subprocesses for each experimental case. The subprocesses were defined according to the study protocol (table 1 and 4). After the treatment period, therapists 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 questionnaires.12–16 A focus-group discussion served as a member check, in order to achieve consensus among the therapists about the main performance problems.17–21

Furthermore, the therapists dichotomously scored the 20 treatment subprocesses 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 subprocesses were performed without any problems.

The therapists 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; as well as regarding the patient’s daily changing mental capacity, their collaboration with the carer and regarding the acceptance of innovations. Therapists 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.

### Table 1 Statements by therapists stating main performance problems within the therapeutic subprocesses

| Setting therapy goals | *‘Priorisation by the patient was difficult, because he was very uncritical.’*  
| Directing patient in new skills | *‘The carer needs much guidance. Concentration and endurance are very limited. Assistance for simple tasks is needed.’*  
| Adapting physical or social environment | *‘The carer is the house owner and refuses any adaptation.’*  
| Training of carer’s competence | *‘The carer is many a time overstrained and tries to give away the responsibility to the therapist.’*  

### Utilisation of healthcare resources in the German study

The Resource Utilisation in Dementia 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, comorbidity indicating a possible need for further healthcare services was rated using the Cumulative Illness

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Rating Scale.24 These data were tested for the significance of group differences between the experimental and the control arm (non-parametric two-tailed Mann–Whitney U test owing to the negative skewness of the data distribution).

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 sample within the identical measurement period of 5 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 therapists in terms of pre-experience with the experimental intervention and intensity of treatment delivery (patients per therapist) and the study designs regarding the control-group intervention.2 3

RESULTS
Specific participant characteristics of the German sample
The mean changes to baseline in the IDDD and the PRPP were associated neither 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 Dementia25; r=0.21; p=0.044). 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 in the patient’s daily functioning. An adjusted ANCOVA using the 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.

COTiD performance in the German experimental group
Eleven therapists from seven study sites delivered the COTiD to 54 patients. The therapists’ 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.

The quality of the subprocess performance (table 4) 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 al15 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

<table>
<thead>
<tr>
<th>Patient</th>
<th>N</th>
<th>Perceive, Recall, Plan and Perform System of Task Analysis change to baseline (German completers of the Community Occupational Therapy in Dementia Programme and control group)</th>
<th>Interview for Deterioration in Daily Living Activities in Dementia change to baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>104</td>
<td>−0.02</td>
<td>0.11</td>
</tr>
<tr>
<td>Gender</td>
<td>104</td>
<td>−0.16</td>
<td>−0.11</td>
</tr>
<tr>
<td>Education</td>
<td>104</td>
<td>−0.13</td>
<td>−0.02</td>
</tr>
<tr>
<td>Financial limitation</td>
<td>93</td>
<td>0.07</td>
<td>0.14</td>
</tr>
<tr>
<td>Mood, Cornell Scale for Depression in Dementia25</td>
<td>95</td>
<td>0.16</td>
<td>0.21*</td>
</tr>
<tr>
<td>Cognition, Mini-Mental State</td>
<td>104</td>
<td>0.02</td>
<td>0.10</td>
</tr>
<tr>
<td>Carer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>104</td>
<td>0.08</td>
<td>−0.11</td>
</tr>
<tr>
<td>Education</td>
<td>104</td>
<td>−0.12</td>
<td>0.11</td>
</tr>
<tr>
<td>Relationship to patient</td>
<td>104</td>
<td>0.15</td>
<td>0.09</td>
</tr>
<tr>
<td>Sense of competence, Sense of Competence Questionnaire26</td>
<td>103</td>
<td>−0.06</td>
<td>−0.02</td>
</tr>
<tr>
<td>Mood, Center for Epidemiologic Depression Scale27</td>
<td>103</td>
<td>0.09</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*p<0.05; **p<0.0001 (two-tailed).
training of carer’s competence in instruction and problem-solving. In the questionnaires, the therapists commented on the main performance problems in these subprocesses (table 4).

**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 in 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.

**Utilisation of healthcare resources in the German study**

The COTiD group had a somewhat higher comorbidity index, slightly more visits to general practitioners and fewer 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 or comorbidity. 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%).

**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 improve notably 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 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 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 subsample matched to the Dutch sample with a 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 the possible benefits of COTiD in addition to standard care. Compared with 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

<table>
<thead>
<tr>
<th>Subprocesses</th>
<th>Performance*</th>
<th>Main problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Receiving medical information</td>
<td>52 (96) 2</td>
<td>Received wrong phone number or no detailed medical information</td>
</tr>
<tr>
<td>02 Making appointments with participants</td>
<td>49 (91) 5</td>
<td>Participants had other appointments</td>
</tr>
<tr>
<td>03 Travelling to participants</td>
<td>46 (85) 8</td>
<td>Long travel to patient’s home (some &gt;40 km)</td>
</tr>
<tr>
<td>04 Meeting the participants</td>
<td>50 (93) 4</td>
<td>Participants forgot to cancel the date and were late or not at home</td>
</tr>
<tr>
<td>05 Contacting and providing confidence</td>
<td>50 (93) 4</td>
<td>Patient was sceptic or abrasive</td>
</tr>
<tr>
<td>06 Informing about the procedure</td>
<td>50 (93) 4</td>
<td>Patient could not understand procedure, misunderstood procedure as test for nursing home placement</td>
</tr>
<tr>
<td>07 Observing the time frame</td>
<td>42 (78) 12</td>
<td>Participants (mainly carer) had a great need to tell and talk</td>
</tr>
<tr>
<td>08 Explaining clearly, responding to questions</td>
<td>50 (93) 4</td>
<td>Patient could not understand the explanations, owing to communication deficits or mood swings</td>
</tr>
<tr>
<td>09 Mastering conflicts and problematic situations</td>
<td>39 (72) 15</td>
<td>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</td>
</tr>
<tr>
<td>10 Interviewing patient with OPHI</td>
<td>38 (70) 16</td>
<td>Patient was unable or hardly able to tell, had anoxia or severe deficits in biographic memory or was disorientated</td>
</tr>
<tr>
<td>11 Observing patient activity with Volitional Questionnaire, if OPHI not done</td>
<td>5 (71*) 2</td>
<td>Patient not motivated to demonstrate activities; *Volitional Questionnaire not necessary in 47 cases, because OPHI was done</td>
</tr>
<tr>
<td>12 Interviewing carer with Ethnographic Interview</td>
<td>47 (87) 7</td>
<td>Carer had only little understanding of dementia or felt very burdened</td>
</tr>
<tr>
<td>13 Observing activities of patient and carer</td>
<td>43 (80) 11</td>
<td>Patient did activity incompletely, was very passive or was fraught when being observed; carer was demanding or impatient</td>
</tr>
<tr>
<td>14 Setting therapy goals with patient and carer</td>
<td>41 (76) 13</td>
<td>Participants negated need for change or could not specify goals</td>
</tr>
<tr>
<td>15 Defining occupational therapy problems</td>
<td>43 (80) 11</td>
<td>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 related not to dementia but to depression or physical limitations</td>
</tr>
<tr>
<td>16 Educating patient in new skills and compensation capability</td>
<td>25 (46) 29</td>
<td>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</td>
</tr>
<tr>
<td>17 Adapting physical environment</td>
<td>24 (44) 30</td>
<td>Participants refused or hesitantly accepted necessary adaptations</td>
</tr>
<tr>
<td>18 Adapting social environment</td>
<td>25 (46) 29</td>
<td>Participants were reluctant to change social environment; informal social support or care services were lacking</td>
</tr>
<tr>
<td>19 Training of carer’s competence in instruction and interaction</td>
<td>32 (59) 22</td>
<td>Carer could not change behaviour as being very burdened or impatient or bound in firm habits; was not willing to take responsibility or was missing sessions</td>
</tr>
<tr>
<td>20 Training of carer’s competence in problem solving</td>
<td>29 (54) 25</td>
<td>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</td>
</tr>
</tbody>
</table>

*Number of cases, in which the performance of this subprocess was rated as unproblematic (=good) or problematic (=poor).

OPHI, Occupational Performance History Interview.
the Dutch therapists, the therapists 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 h vs 40 h) and fewer COTiD patients per therapist during the treatment period (34 vs 5).

**DISCUSSION**

The process evaluation of our multicentre 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 subprocesses, which were 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 healthcare resources was equal in the experimental 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 misinterpretation,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 evaluating adherence in dementia research,28 in order to deal with limited resources.29 However, therapists tend to overestimate their own performance.30 Although the therapists 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 overestimation or overcriticism 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 variance—especially in multicentre RCTs.

Data on the association of treatment performance and primary patient outcomes, although encouraged, are scarce in RCTs studying complex interventions. Teri et al.8 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 did not operationalise the impact of this rating and any outcome variable. Similar studies adhered to protocol but found no associations between the adherence to protocol and any outcome variable. Similar studies in the field did not operationalise the impact of this rating and any outcome variable.

**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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Acknowledgements
We thank all participants and therapists for their contribution. We acknowledge C. Meyers, Research Fellow, Faculty of Health & Life Sciences, York St John University, UK, for critical reading and English correction.

Funding
German Federal Ministry of Health, Reference Number: IIA5-2508FS111/44-004.

Competing interests
MOR: consultancy for Jansen-Cilag and Numico. MH: grants from Wyeth, Pfzer and Merz.

Ethics approval
Ethics approval was provided by the Medical Ethics Committee of the University Hospital Freiburg (no 110/08).

Contributors
SVR, MG, RL, MH and MVD contributed to the study conception and design. SVR conducted the data and study management, and prepared the statistical analysis. RL performed the statistical analysis. SVR drafted the manuscript. MG, RL, MH, MOR and MVD revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Provenance and peer review
Not commissioned; externally peer reviewed.

Data sharing statement
Data sets can be provided on request for fellow researchers in the context of collaborative projects and publications.

REFERENCES
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BMJ Open 2011 1: originally published online August 9, 2011
doi: 10.1136/bmjopen-2011-000094

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