The impact of occupational therapy in Parkinson’s disease: a randomized controlled feasibility study
Ingrid H Sturkenboom, Maud J Graff, George F Borm, Yvonne Veenhuizen, Bastiaan R Bloem, Marten Munneke and Maria W Nijhuis-van der Sanden
Clin Rehabil published online 18 July 2012
DOI: 10.1177/0269215512448382

The online version of this article can be found at:
http://cre.sagepub.com/content/early/2012/07/16/0269215512448382

Published by:
SAGE
http://www.sagepublications.com

Additional services and information for Clinical Rehabilitation can be found at:
Email Alerts: http://cre.sagepub.com/cgi/alerts
Subscriptions: http://cre.sagepub.com/subscriptions
Reprints: http://www.sagepub.com/journalsReprints.nav
Permissions: http://www.sagepub.com/journalsPermissions.nav

>> OnlineFirst Version of Record - Jul 18, 2012

What is This?
The impact of occupational therapy in Parkinson’s disease: a randomized controlled feasibility study

Ingrid H Sturkenboom1, Maud J Graff2, George F Borm3, Yvonne Veenhuizen4, Bastiaan R Bloem5, Marten Munneke6 and Maria W Nijhuis-van der Sanden2

Abstract
Aim: To evaluate the feasibility of a randomized controlled trial including process and potential impact of occupational therapy in Parkinson’s disease.

Design: Process and outcome were quantitatively and qualitatively evaluated in an exploratory multicentre, two-armed randomized controlled trial at three months.

Participants: Forty-three community-dwelling patients with Parkinson’s disease and difficulties in daily activities, their primary caregivers and seven occupational therapists.

Intervention: Ten weeks of home-based occupational therapy according to the Dutch guidelines of occupational therapy in Parkinson’s disease versus no occupational therapy in the control group.

Main measures: Process evaluation measured accrual, drop-out, intervention delivery and protocol adherence. Primary outcome measures of patients assessed daily functioning: Canadian Occupational Performance Measure (COPM) and Assessment of Motor and Process Skills. Primary outcome for caregivers was caregiver burden: Zarit Burden Inventory. Participants’ perspectives of the intervention were explored using questionnaires and in-depth interviews.

Results: Inclusion was 23% (43/189), drop-out 7% (3/43) and unblinding of assessors 33% (13/40). Full intervention protocol adherence was 74% (20/27), but only 60% (71/119) of baseline Canadian Occupational Performance Measure (COPM) was completed.

1Department of Rehabilitation, Nijmegen Centre of Evidence Based Practice, Radboud University Nijmegen Medical Centre, The Netherlands
2Department of Rehabilitation and Scientific Institute for Quality of Healthcare, Nijmegen Centre of Evidence Based Practice, Radboud University Nijmegen Medical Centre, The Netherlands
3Department of Biostatistics, Nijmegen Centre of Evidence Based Practice, Radboud University Nijmegen Medical Centre, The Netherlands
4Department of Rehabilitation, Radboud University Nijmegen Medical Centre, The Netherlands
5Department of Neurology, Donders Institute for Brain, Cognition and Behaviour, Radboud University Nijmegen Medical Centre, The Netherlands
6Department of Neurology, Nijmegen Centre of Evidence Based Practice, Radboud University Nijmegen Medical Centre, The Netherlands

Corresponding author:
Ingrid Sturkenboom, Department of Rehabilitation-Occupational Therapy (898), Radboud University Nijmegen Medical Centre, PO Box 9101, 6500HB Nijmegen, The Netherlands
Email: i.sturkenboom@reval.umcn.nl
Performance Measure priorities were addressed in the intervention. The outcome measures revealed negligible to small effects in favour of the intervention group. Almost all patients and caregivers of the intervention group were satisfied with the results. They perceived: ‘more grip on the situation’ and used ‘practical advices that make life easier’. Therapists were satisfied, but wished for a longer intervention period.

**Conclusions:** The positive perceived impact of occupational therapy warrants a large-scale trial. Adaptations in instructions and training are needed to use the Canadian Occupational Performance Measure as primary outcome measure.

**Keywords**
Parkinson disease, occupational therapy, patient-centred care, Canadian Occupational Performance Measure, randomized controlled trial

Received: 17 February 2012; accepted: 19 April 2012

**Introduction**

Parkinson’s disease is a neurodegenerative disease affecting both motor and non-motor brain systems, which can result in multiple deficits like impairments in gait, balance, hand coordination, memory or executive functioning. This inevitably leads to various limitations in daily functioning and increasing need for support.1–4 Consequently, Parkinson’s disease has a great impact on quality of life of patients and their caregivers.5–7 A client-centred and multidisciplinary approach in Parkinson’s care is required to address the great variety of difficulties and needs of patients.8,9

Occupational therapy aims to optimize a person’s functional performance and engagement in everyday activities and life roles and uses a client-centred approach.10 Although the merits of occupational therapy for people with Parkinson’s disease are widely recognized by clinicians and a few small-scale studies appear promising, rigorous studies testing the specific effects of client-centred occupational therapy for people with Parkinson’s disease do not exist.11–14

An important obstacle in setting up clinical trials was a lack of best practice guidelines for occupational therapy in Parkinson’s disease.15–16 In 2008, we developed national Dutch guidelines for occupational therapy in Parkinson’s disease to improve uniformity and quality of care. The guidelines are based on (1) extensive literature review in the fields of occupational therapy and rehabilitation for people with Parkinson’s disease and other neurodegenerative conditions, (2) expert opinion and (3) field-testing rounds.8,17 This resulted in 31 recommendations for referral, assessment and treatment of patients with Parkinson’s disease and their caregivers. Implementation is facilitated by using the guidelines as a basis in the training of occupational therapists who join the Dutch multidisciplinary networks of professionals specialized in Parkinson’s disease (ParkinsonNet).18,19 We do not know, however, what the effectiveness is of occupational therapy according to these guidelines within the context of multidisciplinary care.

Following the recommendations of the Medical Research Council for evaluation of complex interventions, we conducted a phase II exploratory study using a combination of quantitative and qualitative methods, as a precursor for a definite trial.20,21 The aim of this study, called the OTiP pilot, was to evaluate the feasibility of a randomized controlled trial including process of the study procedures (accrual, drop-out, burden, protocol adherence), process of the intervention (actual intervention delivery, protocol adherence and experiences) and the potential impact of occupational therapy in Parkinson’s disease.
Methods

An exploratory randomized controlled trial was performed with random allocation of intervention 2:1 control, and an assessor-blinded post-intervention measurement at three months followed by a qualitative evaluation of the intervention procedures and outcome. The qualitative evaluation had a phenomenological design exploring perceptions of the intervention procedures and outcome using individual interactive interviews with participants (patients, caregivers, therapists), and focus group discussion with therapists.

Full ethical approval was granted by the medical ethical committee of Arnhem-Nijmegen and the trial was registered at clinicaltrials.gov (identifier NCT01010529).

From October 2009 to February 2010 we recruited patients from four neurology outpatient departments in different regions in the Netherlands. Eligible patients had idiopathic Parkinson’s disease, lived at home, reported difficulties in daily activities relevant for the patient (covering self-care, domestic activities, work or leisure), and had a non-professional caregiver who could provide assistance at least twice a week. Exclusion criteria were: use of occupational therapy in the last 12 months, disabling comorbidity, inability to complete questionnaires (i.e. due to severe cognitive problems), and participation in another intervention trial. Considering the complexity of the intervention and potentially large heterogeneity in participants, we expected to require approximately 40 patient–caregiver dyads in the exploratory randomized controlled trial to gain insight in all relevant feasibility factors. This is not based on a power calculation.

The neurologist sent invitation letters to patients with Parkinson’s disease who had visited the outpatient department in the previous year. The researcher (IS) or research assistant (both assessors) informed interested patients and their caregivers by phone and verified eligibility. Accordingly, the assessors visited eligible patient–caregiver dyads to obtain written consent and perform baseline measurements. After baseline, an independent secretary executed a balanced randomization per region using a computerized randomization protocol.

To provide the intervention we recruited one to two occupational therapists in each participating region. They had to be part of ParkinsonNet, because these therapists already completed three days training in Parkinson’s disease and the occupational therapy guidelines. To further improve intervention skills and to inform about trial procedures, study participants received an additional three days training.

In the qualitative evaluation we included all participating therapists and their first willing patient–caregiver dyad.

The intervention group received occupational therapy following the Dutch guidelines of occupational therapy in Parkinson’s disease. The intervention was standardized in the OTiP protocol and described diagnostics, goal setting and a guide for choosing appropriate individualized interventions for patients and caregivers. Priorities in problems in daily functioning were evaluated at baseline by the assessor using the Canadian Occupational Performance Measure (COPM), and the named activities and scores were communicated to the therapist by an independent secretary. The therapist formulated the treatment plan based on this information and additional information from the therapist’s own diagnostic phase. The intervention was delivered at home for 10 weeks within three months while the number of sessions could vary depending on complexity of goals, with a maximum of 16 sessions (45–60 minutes). The characteristics of the OTiP intervention are summarized in Figure 1. The control group did not receive any occupational therapy intervention until after the three months measurement (wait-listed).

In both groups, patients and caregivers could have other medical or allied healthcare interventions except occupational therapy during the study period. Patients and caregivers registered these other interventions in a care utilization questionnaire at baseline and three months, both focusing on the preceding three months (not reported).

A variety of assessment procedures and measures were used. To enable evaluation of baseline characteristics, assessors collected data on the patients’ and caregivers’ age, gender, caregiver’s relationship to the patient, severity of Parkinson’s
disease motor symptoms (Unified Parkinson Disease Rating Scale part III\textsuperscript{21} and Hoehn &Yahr), duration of Parkinson’s disease, comorbidity (Cumulative Illness Rating Scale–Geriatrics\textsuperscript{24,25}) and baseline scores on the outcome measures. From the therapists we collected years of work experience and years of involvement in ParkinsonNet.

Trial recruitment was evaluated based on inclusion and drop-out rates. Assessment procedures were evaluated based on patients’ and caregivers’ feedback on clarity and perceived burden of the assessments using custom-made questionnaires at baseline and post intervention. Assessors used an assessment log to register duration of the visit,

Figure 1. Characteristics of the OTiP Intervention. COPM, Canadian Occupational Performance Measure.
adherence to the assessment protocol and any irregularities encountered.

To evaluate the feasibility of the intervention we used a number of measurements. First, therapists completed standardized OTiP patient records allowing insight in adherence to the protocol and actual treatment delivery (process, content and time). We compared priorities identified by patients in the baseline Canadian Occupational Performance Measure, with goals addressed in the intervention. Second, within one month after the intervention we evaluated perceived barriers and facilitators for a successful intervention by individually interviewing the participants of the qualitative evaluation. The interviews were conducted by a trained research assistant (YV) not involved in the randomized controlled trial. Topics were: expectations beforehand, experiences of the intervention procedures and outcome, personal context and factors of the therapist. In addition, all patients and caregivers of the intervention group received a custom-made questionnaire based on the Consumer Quality index26,27 evaluating the experiences of the intervention (OTiP experiences questionnaire). Third, after completion of all interventions the researcher (IS) and interviewer (YV) evaluated the therapists’ opinions on adherence to and practicability of the intervention protocol and the standardized patient records in a focus group discussion.

For outcome measurement, assessors conducted assessments at baseline (before randomization) and at three months (post intervention) at the patients’ homes. To allow for possible response fluctuations in Parkinson’s disease, live performance measures were administered within 1–2 hours after medication intake (the on phase).

The primary outcome for patients was daily functioning, encompassing both objective evaluation of skills with the Assessment of Motor and Process Skills28 and patient-rated perceived performance in activities measured with the Canadian Occupational Performance Measure.22 These are both well-established generic occupational therapy measures with good clinometric properties.28,29–33 Both measures produce two scores and in our protocol we selected one score from each measure as primary outcome. In the Canadian Occupational Performance Measure we used the perceived performance score as primary outcome. Although the second score of satisfaction with performance is important, we primarily wanted to know whether occupational therapy contributes to improved performance in daily activities as perceived by the patient. In the Assessment of Motor and Process Skills we used the score of process skills as primary outcome and not motor skills. This was because process skills incorporate skills of adaptation to problems encountered in the performance of activities and this is the specific focus of occupational therapy in the multidisciplinary context. The primary outcome for caregivers – perceived burden – was measured using the Zarit Burden Inventory.34 For detailed characteristics of the primary outcome measures see Table 1.

The impact of the intervention was also evaluated in the OTiP experiences questionnaire26,27 with specific questions on perceived benefit of the intervention, and in the in-depth interviews.

Descriptive statistics were used to present baseline characteristics and results of quantitative process measurements. Primary outcome measures were analysed by covariance analysis with post-intervention scores at three months as dependent variable and baseline scores as covariates. Two-sided 95% confidence intervals were calculated, as well as effect size (Cohen’s d).

For the analysis of qualitative evaluation data, we used the constant comparative method resulting in identification of main themes.35 Triangulation was performed with data from interviews, questionnaires and patient records.

**Results**

Forty-three patient–caregiver dyads were included (n = 29 patient–caregiver dyads in the intervention group; n = 14 in the control group) in the randomized controlled trial (Figure 2). Of the 43 patient–caregiver dyads, three dyads and one extra caregiver dropped out because of worsening comorbidity or...
hospitalization of patient or caregiver. Seven female occupational therapists with a mean experience of 16.6 years (range 6–26 years) participated in the trial. In the qualitative evaluation all seven therapists and their first willing patient–caregiver dyads participated (21 individuals).

The intervention group and control group were well matched at baseline (Table 2) and did not differ in primary outcome scores (Table 4; first columns). Analysis of type and frequency of priorities in daily functioning identified in the baseline Canadian Occupational Performance Measure (total 178) reveals that patients’ priorities covered domains of self-care/housekeeping (55%; 98), leisure/day structure (40%; 71) and work (5%; 9). Priorities involved improving activity performance and performance skills (ease, speed, safety) (77%; 137), taking up (new) activities (8%; 14), dealing with fatigue (8%; 14), and improving feeling of self-efficacy in daily functioning (7%; 13).

**Table 1. Primary outcome measures: properties**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domain</th>
<th>Type</th>
<th>Outcome range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>Perceived performance capacity in 3–5 self-prioritized problems in daily activities</td>
<td>Semi-structured interview</td>
<td>Mean score range: 1–10 (higher scores indicate better skills). Clinical important difference 2</td>
</tr>
<tr>
<td>Canadian Occupational Performance Measure (COPM) performance</td>
<td>Quality of process performance skills in daily activities</td>
<td>Rater observation</td>
<td>Linear score range: −3 to 4 (higher scores indicate better skills). For the process skills there is a cut-off point of 1, below which assistance in daily activities is to be expected. Clinical important difference 0.5</td>
</tr>
<tr>
<td>Assessment of Motor and Process Scale (AMPS) process skills</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Caregiver</strong></td>
<td>Perceived burden of care. Covering competence, feelings of anger, embarrassment and the impact of care giving on social relations, other responsibilities, health, privacy, time for self and finances</td>
<td>Self-report questionnaire</td>
<td>Item 0–4. Sum score range: 0–88 0–20 indicates no to mild burden; 21–40 mild to moderate burden and above 40 high burden. Clinical important difference: not available</td>
</tr>
<tr>
<td>Zarit Burden Inventory (ZBI)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Process evaluation**

To include 43 dyads, 189 patients were approached, giving an inclusion percentage of 23%. Drop-out was 7% (n = 3). Participants notified no adverse events, clear procedures and no burden. Although we instructed participants not to reveal group allocation to the assessor, blinding was broken unintentionally in 13 of 40 analysed dyads (33%).

Analysis of the OTiP patient records show that therapists performed all subprocesses of the OTiP protocol in 74% (n = 20) of patient–caregiver dyads. Adherence was lowest in the subprocesses of formulating treatment goals together with the patient and caregiver (adherence 81%; n = 22) and conducting a separate caregiver interview (adherence 81%; n = 22). The therapists addressed 60% (71/114) of patients’ priorities formulated in the baseline Canadian Occupational Performance Measure. In six patients (22%) all baseline Canadian
Occupational Performance Measure priorities were addressed and in 13 patients (48%) problems not identified in the baseline Canadian Occupational Performance Measure were (also) addressed. None of the therapists used the maximum intervention dose: average number of sessions was 7.9 (SD =

Figure 2. Recruitment and participant flow randomized controlled trial. OT, occupational therapy.
2.40), mean patients’ face-to-face contact was 6.6 hours (SD = 2.07) and 2.4 hours for caregivers (SD = 2.16). For 5 out of 27 patient–caregiver dyads the occupational therapy intervention was not terminated at 10 weeks.

Results from the interviews on perceived facilitators and barriers of the intervention are presented in Table 3. Although expectations at the beginning differed, patients and caregivers valued various aspects of the intervention positively, namely: the thorough diagnostic phase, the client-centred approach, involvement of the caregiver, and the home setting. Expertise of the therapist and personal click were deemed important, as well as unity and sharing between patient and caregiver. Therapists mentioned a lack of willingness or ability to change behaviour (skills or routines) in some patients as a barrier. The duration of 10 weeks was mentioned by therapists and some patients and caregivers as too short to achieve optimal results.

In the OTiP experiences questionnaires all patients and caregivers of the intervention group indicated the expertise of their occupational therapist as adequate and stated that they had been involved in joint goal setting. Most patients (76%; 19/25) and caregivers (71%; 17/24) judged 10 weeks intervention as adequate, although five patients and caregivers mentioned this had been too short, and the remaining one patient and two caregivers found it too long. Two patients and caregivers in the intervention group had not completed this question.

In the focus group discussion, therapists expressed appreciation for the structure of the protocol, although they found the diagnostic phase too lengthy for some patients. Initially they feared they were not being client-centred when not immediately starting therapy. They indicated that it took a while to get used to taking the time for a structured diagnostic phase in which client-centred problems and goals could be explored. Therefore they stressed the importance of

Table 2. Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention n = 27</th>
<th>Control n = 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years): mean (SD)</td>
<td>66.7 (11.8)</td>
<td>68.5 (9.6)</td>
</tr>
<tr>
<td>Men/women: n</td>
<td>19/8</td>
<td>10/3</td>
</tr>
<tr>
<td>Living status with caregiver/alone: n</td>
<td>26/1</td>
<td>11/2</td>
</tr>
<tr>
<td>Paid work: n</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Time since diagnosis (years): mean (SD)</td>
<td>7.5 (7.1)</td>
<td>6.9 (4.3)</td>
</tr>
<tr>
<td>Hoehn &amp; Yahr stage: n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5a</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>UPDRS III, motor function, range 0–108a: mean (SD)</td>
<td>28.2 (12.7)</td>
<td>28.5 (10.3)</td>
</tr>
<tr>
<td>CIRS-G, comorbidity range 0–56a: mean (SD)</td>
<td>9.3 (2.8)</td>
<td>10.2 (4.4)</td>
</tr>
<tr>
<td>MMSE, cognition, range 0–30b: mean (SD)</td>
<td>28.2 (1.9)</td>
<td>27.3 (1.4)</td>
</tr>
<tr>
<td>Use of physiotherapy, yes/no: n</td>
<td>16/11</td>
<td>8/5</td>
</tr>
<tr>
<td>Age caregiver (years): mean (SD)</td>
<td>61.5 (16.8)</td>
<td>62.5 (6.4)</td>
</tr>
<tr>
<td>Caregiver, men/women: n</td>
<td>7/19</td>
<td>3/10</td>
</tr>
</tbody>
</table>

*a Minimum score indicates best functioning.

*b Maximum score indicates best functioning.

UPDRS III, Unified Parkinson Disease Rating Scale part III; CIRS-G, Cumulative Illness Rating Scale-Geriatrics; MMSE, Mini-Mental State Examination.
### Table 3. Qualitative evaluation of the intervention (n =21)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subthemes</th>
<th>Example quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘More grip on the situation’</td>
<td>Improved understanding: ‘What balance is all about’ ‘That this is a consequence of Parkinson’s’ ‘That he can actually do it himself’ ‘Possibilities in the healthcare resources’</td>
<td>‘. . . the insight. Of what makes up the strain and how I can better influence that, how I can better balance it. That helped me a lot.’ (patient) ‘Mentally that had a very positive effect. Because you [herself] get grip of the situation and the feeling of yes he [patient] can do it, although just in another way.’ (caregiver) ‘That he accepts that there are days that performance is more difficult.’ (therapist)</td>
</tr>
<tr>
<td>‘Practical advice that makes life easier’</td>
<td>‘Carrying things out in a different way’</td>
<td>‘. . . occupational therapy has contributed to adaptations that make life more pleasant and easier.’ (patient) ‘For me it has had the result that now he [patient] does those little things himself.’ (caregiver) ‘She can help him out of bed in a less straining way and negotiate with him what he can and can’t do himself.’ (therapist)</td>
</tr>
<tr>
<td><strong>Possible barriers and facilitators</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expectations</td>
<td>‘A question mark’ and ‘openness towards the intervention’</td>
<td>‘. . . but with a question mark. Am I in a phase that that [occupational therapy] can contribute?’ (patient) ‘So let it go, we’ll see what comes. That in itself I found quite pleasant.’ (caregiver) ‘. . . I don’t know whether I have something to offer to this man.’ (therapist)</td>
</tr>
<tr>
<td>Diagnostic phase</td>
<td>‘Long and difficult and setting out a good line’</td>
<td>‘It gives a basis of trust and contact. You are being heard. So because of that I think I become opener, because she listens.’ (patient) ‘I was quickly tempted to address the practical issues and had to sit on my hands: no, just continue on this part and let the conversation flow.’ (therapist)</td>
</tr>
<tr>
<td>Duration</td>
<td>‘Just enough’ versus ‘too short’</td>
<td>‘The duration was appropriate, so that was good. At one point, yeah, she [the occupational therapist] no longer needed to come.’ (patient) ‘For us it was too short. Considering the situation it could have been longer. The results for us are only in the long term.’ (caregiver) ‘[if it was not for the intervention protocol] Then I would have given him more time and now it was my time I had to force upon him.’ (therapist)</td>
</tr>
<tr>
<td>Involvement caregiver</td>
<td>‘We’re going through it together’</td>
<td>‘Also for her [caregiver] process, I think. She has to start realize as well what it [Parkinson’s disease] all involves. We both don’t know this.’ (patient) That [involvement in intervention] I found not more than normal. You are husband and wife. And especially these sort of things you have to do together.’ (caregiver) ‘And when I told him [patient] what was important for her [caregiver], in a neat way...now then he was more conscious of ‘oh it is not only for me important but also for her’.’ (therapist)</td>
</tr>
<tr>
<td>Home setting</td>
<td>‘My home is where I do the things’</td>
<td>‘In the hospital you are in a theoretical situation, while my problems are here [at home]. So then she can better see what it looks like here and how we can adapt things than there [in hospital].’ (patient) I found that [treatment at home] real good . . . I believe that there you can pick up certain things best.’ (caregiver) ‘Yes I find that [treatment at home] very good. Because people will tell you more about how things are and they can show how they can do other things.’ (therapist)</td>
</tr>
</tbody>
</table>
adequate training and practice. Again, all therapists mentioned that the period of 10 weeks was too short for interventions on behavioural changes and for delivery of particular aids and adaptations.

**Outcome evaluation**

Analysis of the primary outcome measures at three months demonstrated a small positive trend in favour of the intervention group. Results are presented in Table 4. As to be expected in an underpowered pilot study, differences were not significant \( P > 0.05 \) and within-group variability was high. Following Cohen’s rule for interpreting effect sizes, only the Canadian Occupational Performance Measure reached a small effect size.\(^{36}\) Almost all patients (96%; 23/24; three missing responses) and caregivers (96%; 24/25; one missing response) indicated in the OTIP experiences questionnaire that they were mostly or absolutely satisfied with the results of the intervention. The mean grade for satisfaction with the intervention was 8.5 on a (scale of 1–10). Also in the interviews, participants reported benefits. Even patients with mild

---

**Table 3.** (Continued)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subthemes</th>
<th>Example quotes</th>
</tr>
</thead>
</table>
| Factors of the therapist | ‘There has to be a click’ ‘Address what I want’ ‘The expertise of the therapist’ | ‘Attention for me as a person, looking at the situation, adjusting interventions to the situation, practical, thinking creatively to find what fits best in that situation.’ (patient)  
‘Yes, there was a click, so then it becomes a lot easier.’ (caregiver)  
‘I think I was able in the right way to make him think [about issues]. That is the feeling he gave me.’ (therapist) |
| Factors of the patient/context | Openness for changes Possibility to change Level of sharing between patient and caregiver | ‘In the process of acceptation you can ask yourself a hundred thousand times why me or why not, and how . . . I gain more from looking at what are we going to do now.’ (patient)  
‘And we are like ‘if they want to help you, you have to go for it.’ (caregiver)  
‘I think the fact that a lot has happened in his life and was still going on, I think that has had a lot of influence. So I think that the results are affected by that. He cannot do everything at once.’ (therapist) |

---

**Table 4.** Results primary outcome measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline intervention (SD)</th>
<th>Baseline control (SD)</th>
<th>Three months intervention (SD)</th>
<th>Three months control (SD)</th>
<th>Mean difference intervention versus control corrected for baseline (95% CI)</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPM, performance</td>
<td>4.31 (1.50)</td>
<td>4.64 (0.92)</td>
<td>5.36 (1.57)</td>
<td>5.20 (1.01)</td>
<td>0.36 (–0.48–1.91)</td>
<td>0.23</td>
</tr>
<tr>
<td>AMPS, process skills</td>
<td>0.82 (0.44)</td>
<td>1.00 (0.59)</td>
<td>0.99 (0.55)</td>
<td>1.08 (0.46)</td>
<td>0.05 (–0.18–0.28)</td>
<td>0.11</td>
</tr>
<tr>
<td>ZBI</td>
<td>15.95 (11.30)</td>
<td>17.69 (14.64)</td>
<td>17.25 (11.32)</td>
<td>19.84 (15.24)</td>
<td>–0.84 (–4.31–2.64)</td>
<td>0.07</td>
</tr>
</tbody>
</table>

COPM, Canadian Occupational Performance Measure; AMPS, Assessment of Motor and Process Skills; ZBI, Zarit Burden Inventory; SD, standard deviation; CI, confidence interval; d, Cohen’s d for effect size.
problems were pleasantly surprised about what the occupational therapy intervention had offered them. The perceived results were diverse, but two main themes were identified: ‘more grip on the situation’ and ‘practical advices that make life easier’ (Table 3).

Discussion

This study confirms the value of a phase II exploratory study as recommended by the Medical Research Council. What we learned is that although recruitment and assessment procedures were feasible, only 23% of patients met the inclusion criteria of the study. This means that we need a large Parkinson’s disease population to recruit an appropriate number of patients (estimated $n = 168; \alpha = 0.05$, power 80%) for the final randomized controlled trial. Therapists mentioned they needed time and coaching to get confidence and competence in conducting the intervention according to the protocol. And although only a small effect size on the Canadian Occupational Performance Measure and negligibly small effect sizes on the Assessment of Motor and Process Skills and Zarit Burden Inventory were found, the interviews and OTiP experiences questionnaires clearly revealed a positive impact of the occupational therapy intervention. We will next discuss some of the findings in detail and their implications for modifications of a future trial.

A relevant finding was that not all priorities in daily functioning identified at baseline in the Canadian Occupational Performance Measure were addressed in the intervention. The reason for this could be that patients’ opinions on priorities might change during the intervention. This was also found in test–retest studies of the Canadian Occupational Performance Measure.30,32 Therapists could base treatment planning on both the Canadian Occupational Performance Measure conducted by the assessor and findings from the therapist’s own diagnostic phase which also included evaluation of priorities. Evidence suggests that the therapist’s personal attitude, skills and expertise can also greatly influence the priorities and choice of goals or the focus in the intervention.32,37,38 To optimize a client-centred and focused treatment planning process, more attention should be paid in the training and coaching of therapists to the translation of Canadian Occupational Performance Measure priorities to specific, measurable, attainable, relevant and time-based goals and treatment plans together with the patient. Moreover, in the administration protocol of the baseline Canadian Occupational Performance Measure an extra verification of priorities can be included. Following a client-centred approach, we do not expect nor demand that all priorities of the baseline Canadian Occupational Performance Measure are addressed in each patient, but with suggested adaptations, congruence between baseline Canadian Occupational Performance Measure priorities, goals and interventions is likely to improve. During coaching divergence from the baseline priorities can be monitored and should be justified by the therapist.

Although participants appreciated the intervention process and content, opinions varied on the duration. Interestingly, the therapists in particular perceived 10 weeks as too short to fully address some goals and felt a time pressure. In contrast, they did not use all the hours allowed. Therapists felt they could not increase the intensity as patients needed time for information to settle and for trying out advice. Nonetheless, there is evidence in Parkinson’s disease rehabilitation that high-intensity training during a short period is more effective for skill acquisition.8,14 It seems logical that this might also be the case for occupational therapy interventions that involve skill training. However, most occupational therapists working in the community are not used to providing intensive interventions over a short period of time, and it seems that the issue of intensity needs to be addressed in the training of therapists. Enhancing and consolidating behaviour change in the longer term requires an early focus on patient–caregiver dyad empowerment using own resources (self-management). Only in incidental cases of lengthy application procedures for aids and adaptations, a follow up visit after
delivery will be necessary to ensure safe and proper use of the equipment.

Although we did not intend to provide definite data on effectiveness, we expected larger changes in the outcome measures. A likely explanation for the small effect size on the Canadian Occupational Performance Measure is the already mentioned incongruence between baseline Canadian Occupational Performance Measure and focus of the intervention. Despite this drawback, we still judge this client-centred measure to be suitable as a primary outcome measure for evaluating the occupational therapy intervention following the Dutch guidelines. Standardized measures of limitations in activities do not cover the diversity and specificity of types of priorities worked on in occupational therapy. In other studies the Canadian Occupational Performance Measure was successfully used as a patients’ primary outcome measure for client-centred occupational therapy interventions. We expect that the earlier suggested adaptations in the administration protocol and coaching for therapists will increase the responsiveness of the Canadian Occupational Performance Measure.

Lack of responsiveness of the Assessment of Motor and Process Skills might be explained by the high mean process skills score at baseline, suggesting a ceiling effect for participants who scored little inefficiency. Moreover, for some patients problems with daily functioning were exclusive to the off-phase, and the Assessment of Motor and Process Skills observation took place in the on-phase. Finally, the Assessment of Motor and Process Skills is an observational performance measure which only evaluates motor and process skills and does not capture effects on interventions addressing feeling of self-efficacy, taking up activities or overall problems such as fatigue. In a definite trial, we would therefore suggest the use of an observational measure of activity performance and additional measures of participation and fatigue as secondary outcomes.

For caregivers, the small effect size in the Zarit Burden Inventory might be explained by low mean caregiver burden at baseline. Caregivers’ own needs were therefore less important than we had expected beforehand. As participants valued the caregivers’ involvement in the occupational therapy intervention positively, we recommend keeping the intervention protocol the same, but evaluating caregiver burden as secondary outcome with subgroup analysis for caregivers’ perceived burden.

Another feasibility issue the study revealed was the high unblinding rate. It is difficult to prevent unblinding as patients are visited at home and asked to talk about their daily lives. In a future trial unblinding rates might be improved by instructing patients to only give answers to the questions and not elaborate on the context of their answers. A researcher who is not the assessor should be readily available by phone to answer any questions from participants.

A weakness of the study was that all therapists treated a relatively small number of patients each. A large number of therapists was chosen in order to be able to cover a large geographical region and to make it easier to generalize the results to clinical practice. However, this limits a rapid increase in expertise and gives rise to more variation in treatment delivery and outcome. In a future large-scale study we still suggest using a high number of therapists, but from the current findings we recommend providing regular coaching and monitoring of therapists during the study period to improve adherence to the protocol. The allowance of variation in amount and content of treatment sessions can be seen as a limitation in the study protocol but is a consequence of following a client-centred approach. As providing adequate intensity seemed to be an issue in this exploratory trial, the dose might need to be a factor to control for in a definite trial.

In summary, this feasibility study pointed out that it is warranted to test the effectiveness of occupational therapy following the Dutch guidelines in a future trial, but outcome measures need to be refined, treatment intensity should be increased, and aligning priorities with goals and interventions together with the patients and caregivers is an important issue in training and coaching of therapists. Moreover, a planned process evaluation alongside the effect study is appropriate to enable conclusions to be drawn.
Clinical messages

- Patients with Parkinson’s disease and caregivers report positive benefits from the home-based occupational therapy intervention, but its effectiveness is not yet ascertained.
- During the intervention process, incongruence can arise between initial priorities and intervention goals. This may affect the responsiveness of a client-centred outcome measure such as the Canadian Occupational Performance Measure.

Author contributions

Study concept and design: IS, MM, BB, GB, MG, MN. Acquisition of subjects/data: IS, YV. Analysis and interpretation of data: IS, YV, GB. Writing manuscript: IS. Critical revision of manuscript: MN, MM, MG, BB, YV, GB.

Acknowledgements

We like to thank Anita de Vries-Uiterweerd, research assistant, for her contribution in the data collection; Jolanda Gons (Verpleeghuis Birkhoven), Irma Jansen (Ziekenhuis Rijnstate), Rianne Merks and Selma Sari (Ergotherapie Thuis), Astrid Rothuis (Ergotherapie Dieren), Martine Valk (Ziekenhuis Rivierenland) and Silvia van Rijswijk (Stichting Zorgcentra de Betuwe) for delivering the OTiP intervention; the local coordinators of the participating hospitals: Tanja Hoogendoorn (Ziekenhuis Rivierenland), Edo Hoogerwaard (Ziekenhuis Rijnstate), Ad Hovestadt (Meander Medisch Centrum), Erik van Wensen (Gelre Ziekenhuizen), for the collaboration in this study; and all participating patients with Parkinson’s disease and their caregivers. Clinical Trial Registration: NCT01010529.

Conflict of interest

None.

Funding

Supported by the Radboud University Nijmegen Medical Centre; Fonds Nuts Ohra (grant number 0804-066) and Prinses Beatrix Fonds/Parkinson Vereniging (grant number WR0-029).

References

38. Richard LF and Knis-Matthews L. Are we really client-centered? Using the Canadian Occupational Performance Measure to see how the client’s goals connect with the goals of the occupational therapist. Occup Ther Mental Health 2010; 26: 51–66.