

Occupational therapy to optimise independence in Parkinson's disease: the designing and recording of a randomised controlled trial intervention

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PDOT (Parkinson's Disease Occupational Therapy) was a pilot randomised controlled trial investigating occupational therapy for people with Parkinson's disease (PD) exhibiting difficulties with activities of daily living (ADL). This article describes the process undertaken to design and record the intervention.

Intervention development was informed by the current evidence base and practice consensus. An expert steering group synthesised this information to develop an intervention framework. A recording tool was identified from a previous occupational therapy trial and adopted for PDOT. This was completed for all participants receiving the intervention, capturing the dose and content of therapy delivered.

Nineteen participants received occupational therapy. A mean number of 5.7 visits was delivered over 60.3 days, with the initial visit lasting 60 minutes (median) and subsequent visits lasting 50 minutes (median). The intervention log demonstrated that a large proportion of therapist visits involved equipment provision/environmental adaptation, mobility/transfers/ADL training, review/discussion, and the teaching of techniques/provision of education.

The intervention developed was found to be feasible and acceptable, and the findings of PDOT have been used to inform a phase III rehabilitation trial (PD REHAB). The intervention log has been revised in light of the findings and will be used within this trial.

Introduction

The clinical management of Parkinson's disease (PD) consists predominantly of pharmacological therapy. However, even with optimal medical treatment in place, disability can still persist and progress (Deane et al 2001). In particular, PD has a profound impact on a person's ability to carry out self-care and activities of daily living (ADL) (Birleson 1998), resulting in increased dependence. For this reason, non-pharmacological treatments, such as occupational therapy, are often employed as an adjunct to traditional medical management (Deane and Playford 2003).

The inclusion of occupational therapy in the management of PD is supported by anecdotal evidence from patients and health care professionals (Deane et al 2002) and national guidelines (National Collaborating Centre for Chronic Conditions 2006). Despite this, supportive trial evidence is fairly limited, with a systematic review by Deane et al (2001) uncovering only two small randomised controlled trials (RCTs) and concluding that there was insufficient evidence to support or refute the efficacy of occupational therapy in PD. These authors recommended that large, methodologically sound, RCTs should be carried out. Consequently, in 2005 a phase II pragmatic RCT began

to evaluate the acceptability of occupational therapy as practised in the United Kingdom (UK) and to provide data to underpin a sample size calculation for the large phase III RCT required in this area. This was the Parkinson's Disease Occupational Therapy trial (PDOT) (Clarke et al 2009).

To ensure reproducibility, the reporting of an RCT should include 'precise details of the interventions intended for each group, and how and when they were actually administered' (CONSORT statement, Item 4, Moher et al 2001, p1192). Therefore, in an attempt to fulfil this requirement, the PDOT team developed the intervention using a clear stepped approach and then adopted an intervention log to be used throughout the trial in order to capture the actual treatment delivered.

Following the recommendations of Deane (2006), this paper aims to detail the PDOT intervention through a designated intervention paper. More specifically, it aims to:

1. Provide a brief overview of the PDOT trial (Clarke et al 2009)
2. Describe the process undertaken to design the therapeutic intervention (including providing an outline of the evidence base available at the time of the trial)
3. Present the intervention log used within the PDOT trial
4. Report and discuss the information captured by the intervention log
5. Discuss the limitations of the log and the measures taken to improve the tool for the follow-on trial to PDOT, the phase III RCT PD REHAB.

Overview of the PDOT trial

PDOT was a phase II pragmatic RCT investigating an occupational therapy intervention designed to optimise functional independence in people with PD. The trial aimed to assess accrual and withdrawal rates, to ascertain the feasibility and acceptability of the intervention and outcome measures, and to inform a sample size calculation for a phase III RCT. As a pilot study, it was not powered to assess the effectiveness of the intervention delivered.

Briefly, patients with idiopathic PD (Hoehn and Yahr stages II to IV) exhibiting difficulties with ADL, who had *not* received occupational therapy within the previous 12 months, were recruited from neurology and older people's clinics within the West Midlands. Patients were randomised at the level of the individual and stratified by level of ADL impairment, as recorded by the Barthel ADL Index (Mahoney and Barthel 1965). Participants were randomised to receive either an individualised, community-delivered occupational therapy intervention or standard care with no intervention (this group received occupational therapy immediately following their final assessment at the end of the trial). For the purposes of this paper, only the intervention group is discussed.

Outcome measures included the Nottingham Extended Activities of Daily Living Scale (Nouri and Lincoln 1987), Rivermead Mobility Index (Collen et al 1991), Unified

Parkinson's Disease Rating Scale (ADL) (Fahn et al 1987), Parkinson's Disease Questionnaire – 39 (Peto et al 1995) and the EuroQol-5D (EuroQol Group 1990) and were recorded at baseline, 2 months and 8 months. Full details of the PDOT trial are published in Clarke et al (2009).

Development of the intervention

The development of the PDOT intervention followed a three-step approach:

1. Published trial evidence was gathered (until recruitment commenced in July 2005) to ensure that the PDOT intervention was evidence based where possible; the evidence considered included occupational therapy specific PD studies, multidisciplinary PD interventions which incorporated occupational therapy, studies from the wider PD rehabilitation literature and clinical guidelines
2. Current UK practice was examined through two published surveys
3. The expert steering group met to evaluate and synthesise the findings of the first two steps with expert opinion consensus, formalising the PDOT intervention.

The aim was to provide treatment that was informed by best practice, but could be delivered within the structure and format of the National Health Service (NHS): an 'enhanced' current practice intervention.

Overview of the evidence base

Occupational therapy specific PD evidence

Evidence supporting the effectiveness of occupational therapy within PD is limited. Systematic reviews (Deane et al 2001, 2002, Gage and Storey 2004) have uncovered only three RCTs and one observational study that claim specifically to be investigating occupational therapy for PD, either as a single intervention or in conjunction with physiotherapy.

These studies have individually produced predominantly positive outcomes. Gauthier et al (1987) (n = 64) reported significantly improved psychological wellbeing, bradykinesia, akathisia and maintained functional ability within the intervention group of their RCT following 10 sessions of group-based occupational therapy. Similarly, Fiorani et al (1997) (n = 20) reported improvements in walking velocity, ADL and quality of life following an RCT of group-delivered occupational therapy and physiotherapy. An observational study by Beattie and Caird (1980) also supported the inclusion of occupational therapy in PD management, noting an unmet need for ADL aids within this population (although the efficacy of this intervention was not considered). Not all studies have produced results in favour of occupational therapy for PD though: Gibberd et al (1981) (n = 24) reported no significant changes in any outcome measures during a controlled crossover trial comparing 'active' physiotherapy and occupational therapy with an 'inactive' control intervention.

Although this evidence base appears largely to support the inclusion of occupational therapy in the management of PD, it provided little with which to inform the PDOT intervention. The interventions described were heterogeneous in nature, providing little consensus as to what occupational therapy for PD should entail and what dose should be delivered. The papers also failed to report the content of the interventions in a detailed manner, decreasing reproducibility. Finally, the studies were methodologically weak with small sample sizes, poorly defined populations, unclear randomisation methods, allocation concealment and masking (where relevant), a lack of follow-up and a lack of intention-to-treat analysis.

Multidisciplinary PD interventions including occupational therapy

Occupational therapy has featured as part of a wider multidisciplinary programme in a number of observational studies (Trend et al 2002, Ellis et al 2005) and RCTs (Wade et al 2003). These studies have produced both positive (Trend et al 2002, Ellis et al 2005) and inconclusive (Wade et al 2003) findings, but it is difficult to know the extent to which occupational therapy contributed to the overall outcome because of limited reporting and a lack of outcome measures targeted specifically at measuring the occupational therapy contribution. Therefore, this literature could not be used to inform the PDOT intervention.

Wider PD rehabilitation literature

In order to manage patients effectively, occupational therapists often synthesise knowledge from a wide range of sources and disciplines (Creek 2003). For this reason, the wider PD rehabilitation literature was looked to in order to inform the PDOT intervention. In particular, because a key role of the PD occupational therapist is to provide practical techniques and strategies to improve or maintain functional ability (Robertson et al 2001), there was a focus on experimental trials investigating external cueing techniques and cognitive movement strategies. Positive findings for the use of audio/visual external cueing techniques during a number of functional tasks have been reported, including sit to stand (Mak and Hui-Chan 2004), reaching (Majsak et al 1998, Ma et al 2004), writing (Oliveira et al 1997) and most notably walking (Thaut et al 1996, Rochester et al 2005, Willems et al 2006). There is supportive evidence for the reduction of dual task interference to improve walking (O'Shea et al 2002, Rochester et al 2004) and cognitive movement strategies, such as use of mental rehearsal, internal cues and the breaking down of complex movement sequences, have been found to improve functional tasks in people with PD (Kamsma et al 1995). However, although this literature was useful in informing the PDOT intervention, its low methodological quality was noted, with external cueing and practical strategies studies being largely limited to pre-experimental and quasi-experimental design at the time of the PDOT trial.

Clinical guidelines

At the time of commencement of this trial, there was a

lack of clinical guidelines to inform the management of patients with PD. The only guidance documents available were the Parkinson's Disease Consensus Working Group's *Guidelines* (and *Updated Guidelines*) for the *Management of Parkinson's Disease* (Bhatia et al 1998, 2001) and the Parkinson's Disease Society guidance document *Parkinson's Aware in Primary Care* (Parkinson's Disease Society 2003). Although these advocated the inclusion of occupational therapy in PD management, they did not detail what should be delivered and so could not be used to inform the PDOT intervention.

Current practice

In 2003, two surveys were published detailing current and perceived best practice for occupational therapy for PD in the UK (Deane et al 2003a, 2003b). Owing to the limited trial evidence available, and the need to deliver an intervention that would fit within the current therapy services delivered within the NHS, these surveys were used extensively to provide a framework for the PDOT intervention.

The survey of current practice (Deane et al 2003a) (n = 242) provided information on the assessment process utilised, the dose of therapy delivered, the goals of occupational therapy in PD patients and the content of treatment in UK practice. It revealed that a high proportion of therapists carried out disability (75%) and needs (90%) assessments, but less than half reviewed a PD patient's response to the intervention delivered and only 46% reported using standardised assessment scales. An average dose of 6 sessions lasting 45 minutes was said to be delivered over a period of 2 months. The most commonly cited goals of therapy were recognised to centre on the improvement or maintenance of transfers and mobility, ADL and home safety. The content of treatment was reported to be individualised to the patient, rather than based on a particular named theoretical approach.

The Delphi survey of perceived best practice (Deane et al 2003b) provided an insight into potentially effective therapeutic interventions. Cueing, cognitive movement strategies, involvement of the carer through teaching handling techniques, education and the provision of equipment/environmental adaptation were some of the main interventions reported as effective when addressing mobility, transfers and various ADL. The teaching of techniques was advocated for the management of medication on/off fluctuations, fatigue and anxiety. Education about PD was recognised as important to allow patients to adjust and to reduce the sense of loss of control.

Method: formalising the PDOT intervention through expert consensus

An expert steering group was established by the PDOT study team, comprising clinical occupational therapists, researchers

with experience in the design and running of occupational therapy trials, clinical managers, educators and members of the study team. This group evaluated and synthesised findings from the evidence base and clinical practice surveys, and combined this with expert consensus to formalise the PDOT intervention. The points outlined below were considered.

Treating clinician

The steering group agreed that the intervention would be delivered by a registered NHS occupational therapist with experience in treating patients with PD. The therapist would be made aware of the current evidence base (as presented above) and clinical and research support would be provided to the therapist by occupational therapists within the NHS trust and members of the steering committee as and when required.

Structure of the process

It was decided that treatment should be delivered within the standard occupational therapy process, as defined by the College of Occupational Therapists in the UK and illustrated by Creek (2003).

Focus of the PDOT intervention

It was recognised that targeted interventions often deliver better outcomes within neurological rehabilitation (Walker et al 2004). For this reason, the focus of the PDOT intervention was to address mobility and transfers, ADL and home safety, reflecting the findings of Deane et al (2003a). However, to ensure that client-centredness and practitioner autonomy were maintained, the group agreed that additional problems and patient goals would be addressed as the treating therapist felt appropriate for individual patients. To uncover the needs and goals of each participant, it was agreed that both an initial assessment and a separate assessment of the patient's environment using the Westmead Home Safety Assessment (Clemson et al 1992) would be conducted.

Content of the PDOT intervention

It was agreed that the content of the intervention should reflect the treatments deemed effective within the best practice survey (Deane et al 2003b) and from the evidence base, for example, equipment provision/environmental adaptation, task-specific training using external cueing and cognitive movement strategies, but would again be based on the judgement and professional remit of the treating practitioner and the goals identified by patients. Therefore, treatment may also include interventions such as referral to other health professionals, fatigue management, leisure therapy, continence management, communication strategies and relaxation techniques (as required). Group work, specialised cognitive interventions and large home adaptations were excluded because of timing and cost issues.

Dose of the PDOT intervention

The group agreed that the dose of occupational therapy delivered should loosely reflect the current practice

average reported by Deane et al (2003a) of 6 x 45-minute sessions, but should ultimately be left to the discretion of the treating therapist and the individual needs of the participant.

Documenting the therapeutic process

The importance of documenting the therapeutic process through comprehensive, structured records is advocated by the Department of Health (2006) and the College of Occupational Therapists (2006). Despite this, few studies detail how they have documented the intervention delivered. Within complex interventions such as occupational therapy, using a standardised method of recording the intervention can provide a breakdown of the content of treatment provided and the time spent providing these varying aspects of the intervention. Sackley et al (2004) designed and used an intervention log within an RCT investigating occupational therapy for stroke in nursing and residential care settings. Owing to the absence of a PD-specific coding system, the PDOT steering committee supported the adoption of this system to record the primary aim of each intervention (see Fig. 1), capturing the dose and content of the therapy delivered. It was acknowledged that the trial would provide an opportunity to test the feasibility and effectiveness of the log for recording PD interventions. In addition, the steering group agreed that the treating therapist should keep full clinical records as in standard NHS practice.

Results

The results for the PDOT intervention group only are presented below.

Intervention group characteristics

Thirty-nine patients with PD were recruited over 16 months from four hospitals in the West Midlands. Nineteen were randomised to receive the intervention (results presented here). Of these, 11 were male and 8 female, and with a mean age of 74.8 years. Three were living alone and 16 were living with someone or in a care home. The median Barthel score at entry was 18 out of 20. Twelve patients within the intervention group had a Hoehn and Yahr score of 2-2.5, six had a score of 3.0, and one patient had a score of 4.0.

All 19 participants completed both their initial assessments and the treatment sessions required to address the goals identified.

Frequency, duration and dose of the intervention

Treatment was delivered by one occupational therapist. The mean number of visits was 5.7 (range 3-9, standard deviation 1.2). A total of 108 therapist visits were carried out. The distribution of the number of contacts can be seen in Fig. 2. The interval between visits varied from 3 days to 63 days.

Fig. 1. The PDOT intervention log.*

	Date						
Contexts	Initial interview						
	Goal setting						
	Review/discussion						
	Information						
	Environmental adaptations						
	Liaison						
	Referral						
Performance areas	Caregiver training						
	Transfers/mobility training						
	Daily living activities training						
	Adaptive equipment						
	Wheelchairs/seating						
Performance components	Techniques/education						
	Other						

*The treating clinician categorised the treatment delivered as time (minutes) spent within the relevant categories for each therapy session.

The initial assessment took a median of 60 minutes (range 45-90 minutes). Subsequent visits lasted a median of 50 minutes (range 5-180 minutes). On average, the occupational therapist spent a mean of 5.4 hours in total with each patient. The mean duration of the complete intervention (from first to last visit inclusive) was 60.3 days.

Content of the intervention

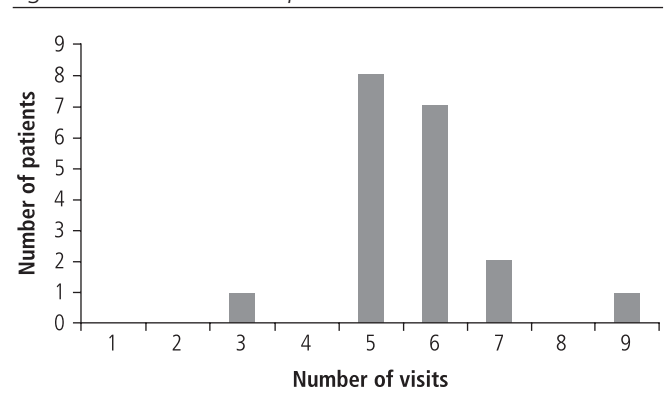
The content of the intervention for each patient was categorised and recorded as time (minutes) spent under the appropriate headings by the treating therapist. It must be noted that more than one category of intervention would have often been delivered during a single therapy session. Two hundred and seventy-four interventions were delivered in total. The category and frequency of the interventions delivered can be seen in Table 1.

Table 1. Category and frequency of interventions

Intervention category	Number of interventions delivered (n = 274)*
Goal setting.....	15.....
Adaptive equipment.....	56.....
Environmental adaptations.....	38.....
Transfers/mobility training.....	46.....
Daily living activities training.....	35.....
Techniques/education.....	25.....
Wheelchairs/seating.....	0.....
Information.....	8.....
Caregiver training.....	4.....
Liaison.....	1.....
Referral.....	14.....
Other.....	0.....
Review/discussion.....	32.....

*These interventions were delivered over a total of 108 therapist visits; more than one treatment could be delivered in any one visit.

Fig. 2. Distribution of therapist visits.



Following completion of the trial, the treating therapist provided feedback on the intervention log. The log was reported as easy to use and was viewed to contain categories that were relevant to the treatment being delivered. Difficulties in using the tool were also noted, with overlap between categories and issues identifying the primary aim of an intervention both leading to problems with accurate categorisation.

Discussion

PDOT confirmed the feasibility and acceptability of an individualised, community-based occupational therapy intervention for people with PD experiencing difficulties with ADL, with all participants receiving the intervention completing both their assessments and the treatment sessions required to address the goals identified.

Dose of the PDOT Intervention

The PDOT intervention was not restricted to a specific dose, but was instead governed by what the treating occupational therapist deemed sufficient to address individual patient's goals adequately (as illustrated by the distribution of patient visits in Fig. 2). However, the intervention was developed to fit within current NHS services: the findings of the current practice survey by Deane et al (2003a) were consulted while designing the intervention and the therapist was aware of this evidence prior to commencing the trial. Therefore, it is unsurprising that the dose of the intervention delivered is comparable to the standard NHS therapy dose as reported by Deane et al (2003a).

Content of the PDOT intervention

The intervention log captured the broad focus of treatment delivered. The majority of interventions fell into the categories discussed below.

The largest number of therapist interventions (94 out of 274) involved some form of adaptive equipment provision or environmental adaptation. With the exception of Beattie and Caird's (1980) observational study, the importance of equipment provision and environmental adaptation has not been highlighted within occupational therapy specific

PD trials. Its inclusion has, however, been reported in occupational therapy RCTs in stroke (Logan et al 1997, Sackley et al 2003), with these studies noting significant improvements in ADL following the interventions. The use of equipment and environmental interventions has also been investigated in the frail older population, through an RCT of 104 participants (Mann et al 1999). Although functional decline was noted in both the intervention and control participants through the Functional Independence Measure, Mann et al (1999) reported a significantly slower rate of decline in the intervention group.

Many of the visits centred on transfers and mobility training, and ADL training (46 and 35 interventions delivered respectively). This is not surprising because the focus of the PDOT intervention was to address mobility, transfers and ADL, mirroring the commonly cited goals of NHS occupational therapists reported by Deane et al (2003a).

A high proportion of therapist interventions also involved an element of review and discussion (32 out of 274). Previous studies of occupational therapy within PD and the surveys of current NHS and perceived best practice (Deane et al 2003a, 2003b) have not detailed specifically the aspect of therapist-client communication. However, this may be because communication is central to the therapeutic relationship within occupational therapy (Tickle-Degnen 2002) and so is viewed as integral to all treatment delivered rather than as a separate entity. Furthermore, the importance of communication has been noted for other neurological conditions, particularly within occupational therapy for stroke (Sackley et al 2004).

Finally, the therapist reported delivering 25 interventions involving the teaching of techniques and the provision of education. The teaching of techniques to improve or maintain functional ability is recognised as a core role of the occupational therapist in PD management (Robertson et al 2001, Parkinson's Disease Society 2007). This category may have had increased relevance to the participants within the intervention arm of this trial because, owing to their high functioning nature (illustrated by the Barthel score of 18/20 and 67% of participants presenting with a Hoehn and Yahr score of 2.5 or below), they may have benefited from the discussion of techniques that could be retained for future use when the disease progressed, as opposed to the immediate acting hands-on physical interventions that are perhaps more relevant to those in the complex stages of the condition.

Appraisal of the intervention log

In line with CONSORT Item 4, the intervention log had been employed to provide information on the content of the intervention and how and when it was administered (Moher et al 2001). The information captured by the log and presented within this paper provides an overview of the focus of therapy and the dose at which it was delivered. For this reason, these criteria were partially met.

The CONSORT statement requests, however, that 'precise details' of the intervention are recorded so that the treatment delivered within a trial can be reproduced accurately.

This is possible in trials of simple interventions (such as medication) in which all components are standardised. It may not be so for complex interventions like that delivered within PDOT, in which treatment is individualised to fit the participant's needs and dependent on who is delivering and receiving the intervention (for example, if the treatment was to be delivered by another therapist to another group of patients with PD, it may be different). If the PDOT intervention was to be truly reproducible, the exact details of all treatments delivered would have to be presented for every participant. Publication of this quantity of information is not feasible and, in the light of the flexibility required for delivering complex interventions, the use of such rigid information is questionable.

That is not to say that the intervention log is without limitation. Hawe et al (2004) suggested that, in complex interventions, the function and process should be standardised, but not the components themselves, allowing for tailoring to 'local conditions' to optimise effectiveness. However, in order for components of therapy to be tailored to individual needs, there must be sufficient information on what these components actually are. Within the context of occupational therapy for people with PD, this means identifying the areas of limitation targeted during therapy and the treatment methods used to address them. The current intervention log did not capture this level of information. Therefore, further development is required if it is to be used within other trials.

The next step ...

PDOT confirmed the feasibility and acceptability of an occupational therapy intervention for people with PD. A phase III trial with an adequately powered, representative sample and multiple therapists is now required to provide evidence on clinical and cost effectiveness. Utilising the findings of PDOT, this trial has been designed and funded: PD REHAB (ISRCTN17452402). The study is currently taking place nationwide, delivering community-based physiotherapy and occupational therapy to patients with PD experiencing difficulties with ADL.

As in PDOT, details of the therapy delivered need to be captured. Therefore, the expert group have made the aforementioned changes to the log, revising its structure to capture more specific information, while still retaining the flexibility needed to accommodate individual variation in therapist approach and participant needs. The intervention log now takes on a grid format to allow cross-referencing of the potential areas of impairment uncovered when goal setting with the type of intervention that could be used. For example, interventions delivered to address a participant's difficulties with transfers can now be categorised under a number of headings, such as assessment, provision of education, referral (to other professionals), equipment prescription and the provision of specific techniques. The intervention will still be recorded as number of minutes spent on the task. This revised log is currently being piloted within PD REHAB, with a view to reassessment following feedback from participating therapists.

In addition to the intervention log alterations, advances in the evidence base also mean that the treatment delivered in PD REHAB will differ slightly from that provided in PDOT (although the focus of the intervention will remain the same). No new occupational therapy specific PD intervention trials have been published since completion of the PDOT trial (Dixon et al 2007), but other relevant PD rehabilitation studies (of higher methodological quality) have been produced, such as the external cueing RESCUE RCT (Nieuwboer et al 2007). Furthermore, guidelines have been published both for the management of PD across disciplines in the form of the *National Clinical Guideline for Diagnosis and Management in Primary and Secondary Care* (National Collaborating Centre for Chronic Conditions 2006) and for occupational therapy practice alone (*Dutch Guidelines for Occupational Therapy in Parkinson's Disease*; Stuerkenboom et al 2008). These documents provide evidence-based guidance, attempting to standardise care by outlining the areas that should be addressed and treatments that may be used by occupational therapists when treating people with PD, and supporting the inclusion of occupational therapy in PD management across the disease spectrum. These advances in the evidence base will move the therapy delivered in PD REHAB forward.

Conclusion

The PDOT trial provided evidence for the feasibility and acceptability of a community-delivered occupational therapy intervention designed to optimise functional independence in people with PD. By combining evidence with practice consensus and expert opinion, an occupational therapy intervention was developed and, in an attempt to record the treatment delivered, a log was piloted. Although the intervention log was successful in capturing some broad aspects of treatment, the PDOT trial also highlighted that more detailed information on the areas addressed and techniques used during therapy may be useful. The findings of the PDOT trial have now been utilised to develop a phase III RCT (PD REHAB) and the intervention log has been revised in order to capture successfully the treatment delivered within this trial.

Key findings

- It was possible to develop, document and deliver an occupational therapy intervention within a randomised trial of the treatment of Parkinson's disease.
- PDOT delivered an intervention at a similar dose to current UK practice: 5.7 visits over 60.3 days, with an initial visit of 60 minutes and subsequent visits lasting 50 minutes.

What the paper has added

Through an intervention log, it was possible to capture broad information regarding the content and dose of the PDOT intervention, providing an initial step in supporting reproducibility of an intervention.

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