Occupational Therapy to Optimise Independence in Parkinson’s Disease: the Designing and Recording of a Randomised Controlled Trial Intervention

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Background
Occupational therapy and Parkinson’s disease

- Clinical management of Parkinson’s disease (PD) predominantly consists of pharmacological therapy, but even with optimal medical treatment in place disability can persist and progress.

- In particular, PD has a profound impact on activities of daily living (ADL), resulting in increased dependence.

- For this reason, occupational therapy (OT) is often employed as an adjunct to medical management.

- However, supportive evidence of occupational therapy in PD is limited with a systematic review noting insufficient evidence to support or refute the efficacy of OT for PD (Deane et al, 2001).

- In 2005 a pilot randomised controlled trial (RCT) began to add to the evidence base – the PDOT trial (Clarke et al, 2009).
Overview of the PDOT trial

- **Objective:** To perform a pilot trial of OT for the optimisation of functional independence in PD to assess feasibility, acceptability, accrual/withdrawal rates, outcome measures, and to inform a sample-size calculation for a phase III RCT

- **Design:** A phase II pragmatic RCT with blinded assessment

- **Participants:** people with idiopathic PD, exhibiting difficulties with ADL, who had not received OT in the past 12 months

- **Setting:** Participants recruited from clinics in the West Midlands and treated in their home environment

- **Intervention:** Participants randomised to receive either individualised OT or no intervention

- **Outcome measurement:** Nottingham Extended Activities of Daily Living Scale, Rivermead Mobility Index, Unified Parkinson’s Disease Rating Scale, Parkinson’s Disease Questionnaire-39 and EuroQol-5D recorded at baseline, 2 months and 8 months

Clark et al (2009)
Reporting of an intervention

- 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).

- This requirement can be fulfilled through publication of a designated intervention paper (Deane et al, 2006).

- Therefore, a paper was published to outline the PDOT intervention (Meek et al, 2010):
  - Describing the process undertaken to design the therapeutic intervention
  - Presenting the intervention log used in the trial
  - Reporting the information captured by the intervention log
  - Discussing the limitations of the log and the measures taken to improve the tool for the next trial.
Methods
Development of the intervention

- A three stepped approach was utilised:
  1. Published trial evidence was gathered (until recruitment commenced in July 2005) to support evidence-based practice including; OT specific PD studies, multidisciplinary trials incorporating OT, wider PD rehabilitation literature and clinical guidelines
  2. Current UK practice was examined through two published surveys
  3. An expert steering group evaluated and synthesised the findings of the first two steps with expert consensus, formalising the PDOT intervention.

- **Aim:** To provide an intervention that was informed by best practice, but could be delivered within the structure and format of the NHS; an “enhanced” current practice intervention.
Step 1: OT specific PD evidence

- Systematic reviews uncovered:
  - One observational study - Beattie and Caird (1980)

- Some studies have produced positive outcomes, reporting improvements in psychological well-being, bradykinesia, akathesia, (Gautheir et al, 1987), walking velocity, ADL and quality of life (Fiorani et al, 1997) following OT.

- In comparison, Gibberd et al (1981) reported no significant changes in any outcomes following their intervention.

- The interventions within these trials were heterogeneous in nature and limited in their reporting, providing little with which to inform the PDOT intervention.

- The trials were also all of a low methodological quality.
Step 1: Other PD evidence

Multidisciplinary trials including OT
- These observational studies (Trend et al, 2002; Ellis et al, 2005) and RCTs (Wade et al, 2003) have produced both positive and inconclusive findings.
- It is difficult to pinpoint the effect of the OT within these interventions, and the reporting of treatment is limited.

Wider PD literature
- There is positive evidence for the use of external cueing techniques during functional tasks, such as sit to stand (Mak et al, 2004), reaching (Ma et al, 2004), writing (Oliveira et al, 1997) and walking (Thaut et al, 1996; Rochester et al, 2005).
- Supportive evidence also exists for the use of cognitive movement strategies (Kamsma et al, 1995).
- This evidence was useful for informing the PDOT intervention but, at the time of the trial, was still low in methodological quality.

Clinical guidelines
- Lack of clinical guidelines at the time of commencement of the trial.
- Guidelines supported the inclusion of OT in PD management, but did not detail how or what should be delivered.
Step 2: Current OT practice

- Two surveys have been published, detailing current (Deane et al, 2003a) and perceived best practice (Deane et al, 2003b) for OT for PD in the UK.

- The surveys were used extensively to provide a framework for the PDOT intervention, due to the limited trial evidence available.

- The current practice survey provided an insight into:
  - **Dose of an average course of OT**: six sessions lasting 45 minutes delivered over two months
  - **Focus of OT treatment**: improvement and maintenance of transfers and mobility, ADL and home safety
  - **Content of OT treatment**: individualised to suit the patient’s needs

- The best practice survey provided an insight into:
  - **Potentially effective treatment techniques**: cueing, cognitive movement strategies, education, provision of equipment/environmental adaptation, techniques for management of medication on/off fluctuations, fatigue and anxiety, and involvement of the carer (teaching handling techniques)
Step 3: Formalising the intervention through expert group consensus

- The expert group consisted of: clinical occupational therapists, researchers, clinical managers, educators and members of the PDOT study team.

- The group considered the following when formalising the intervention:
  - Who the treating clinician should be
  - The structure of the intervention process
  - The focus, content and dose of the intervention
  - How the intervention should be documented.

- **Treating clinician**: a registered OT with experience in treating people with PD

- **Structure of the intervention process**: treatment delivered within the standard OT process as defined by the College of Occupational Therapists in the UK (Creek, 2003)
Step 3: Formalising the intervention through expert group consensus

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<thead>
<tr>
<th>Structure of the process (continued):</th>
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<tbody>
<tr>
<td>Referral</td>
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<tr>
<td>Information gathering</td>
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<td>Initial assessment</td>
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<td>Reason for intervention/ needs</td>
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<td>identification/ problem information</td>
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<td>Identification of aims/ goal setting</td>
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<td>Action planning</td>
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<td>Action (treatment implementation)</td>
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<td>Ongoing assessment/ revision of action</td>
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<td>Outcome and outcome measurement</td>
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<td>End of intervention/ discharge</td>
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<td>Review</td>
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Adapted from Creek (2003)
Step 3: Formalising the intervention through expert group consensus

- **Focus of the PDOT intervention**
  - To address mobility and transfers, ADL and home safety to reflect the findings of the current practice survey
  - In addition, client centredness and practitioner autonomy would be maintained by addressing additional problems and patient goals as appropriate for the individual patient

- **Content of the PDOT intervention**
  - To reflect the treatments deemed effective in the best practice survey and from the evidence base e.g. equipment provision/ environmental adaptation, task specific training utilising external cueing and cognitive movement strategies, education
  - Individualised, based on the therapist’s judgement and patient’s needs

- **Dose of the PDOT intervention**
  - To loosely reflect the dose of OT uncovered in the current practice survey: six sessions lasting 45 minutes delivered over two months, but still individualised to meet patient’s needs
Step 3: Formalising the intervention through expert group consensus

- Documenting the therapeutic process: the intervention log
  - No specific PD coding system was available, so an intervention log was adopted from a previous trial (Sackley et al, 2004).

<table>
<thead>
<tr>
<th>Category</th>
<th>Date</th>
<th>Initial Interview</th>
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<tbody>
<tr>
<td></td>
<td>Goal Setting</td>
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<td>Review/Discussion</td>
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<td></td>
<td>Information</td>
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<td>Environmental</td>
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<td></td>
<td>Adaptations</td>
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<td>Liaison</td>
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<td>Referral</td>
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<td>Performance Areas</td>
<td>Caregiver Training</td>
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<td>Transfers/Mobility</td>
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<td>Training</td>
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<td>Daily Living</td>
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<td></td>
<td>Activities Training</td>
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<td>Adaptive Equipment</td>
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<td>Wheelchairs/Seating</td>
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<td>Performance Cptnt</td>
<td>Techniques</td>
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<td>Education</td>
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<td>Other</td>
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</tbody>
</table>

The treating clinician categorises the treatment delivered as time (mins) spent within the relevant categories for each therapy session.
Results
Results

- **Intervention group characteristics:**
  - 39 people with PD recruited: 19 randomised to receive the intervention
  - 11 male and eight female
  - Mean age of 74.8 years
  - Mean Barthel score of 18 out of 20
  - 12 patients with a Hoehn and Yahr score of 2.0-2.5, six with a score of 3.0 and one patient with a score of 4.0
  - All 19 patients completed both their initial assessments and the treatment sessions required to address the goals set

- **Frequency, duration and dose of the intervention:**
  - Treatment was delivered by one OT
  - Mean number of visits was 5.7 (range 3-9, SD 1.2)
  - 108 visits were carried out in total
  - The interval between visits varied from three days to 63 days
  - Initial assessment took a median of 60 minutes (range 45-90 minutes)
  - Follow up sessions lasted a median of 50 minutes (range 5-180 minutes)
  - Mean of 5.4 hours spent with each patient in total
Results: Distribution of therapist visits
Results: Content of the intervention

- The content of the intervention for each patient was categorised and recorded as time (mins) spent under the appropriate headings by the therapist.

- 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.

<table>
<thead>
<tr>
<th>Intervention Category</th>
<th>Number of interventions delivered (n=274)</th>
</tr>
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<tbody>
<tr>
<td>Goal setting</td>
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<tr>
<td>Adaptive equipment</td>
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<tr>
<td>Environmental adaptations</td>
<td>38</td>
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<tr>
<td>Transfers/ mobility training</td>
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<tr>
<td>ADL training</td>
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<tr>
<td>Techniques/ education</td>
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<tr>
<td>Wheelchairs/ seating</td>
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<td>Provision of information</td>
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<tr>
<td>Caregiver training</td>
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<tr>
<td>Liaison</td>
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<tr>
<td>Referral</td>
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</tr>
<tr>
<td>Other</td>
<td>0</td>
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<tr>
<td>Review/ discussion</td>
<td>32</td>
</tr>
</tbody>
</table>
Results: Intervention log

The occupational therapist gave the following feedback for the intervention log on completion of the trial:

**Positive**
- Easy to use
- Contains categories relevant to the treatment being delivered

**Negative**
- Overlap between categories
- Difficulties identifying the primary aim of an intervention for accurate categorisation
Discussion
Discussion: Dose and content of the PDOT intervention

- **Dose:**
  - Treatment delivered had a comparable dose to the findings of the current practice survey by Deane et al (2003a).

- **Content:**
  - The largest number of therapy interventions involved some form of adaptive equipment provision or environmental adaptation. This has been found to lead to significant improvements in ADL in the stroke population (Logan et al, 1997).
  - Many therapist visits involved transfers, mobility and ADL training, mirroring the OT goals set out in the current practice survey by Deane et al (2003a).
  - Review and discussion featured highly, highlighting the importance of communication in OT.
  - The provision of education and teaching of techniques was particularly important to the sample population due to their high functioning nature.
Discussion: Appraisal of the intervention log

- The intervention log captured the broad focus of treatment and the dose delivered, but did not provide precise details on every individual treatment session for each participant.

- Whilst it would be difficult, and potentially of limited use, to record this information, it is suggested that the function and process of a complex intervention should be standardised to then allow it to be adapted to “local conditions” (Hawe et al, 2004).

- Within the context of occupational therapy for people with PD, this means identifying the areas of limitation targeted during therapy, and the types of treatment used to address them.

- Therefore, the intervention log required further development if it was to be used within future trials.
The next step... PD REHAB

- A phase III, multi-centre RCT to assess the clinical and cost effectiveness of physiotherapy and OT is currently being conducted - PD REHAB.

- The intervention log:
  - As in PDOT, details of the therapy delivered need to be captured.
  - The intervention log has been revised to record more specific information, whilst still retaining the flexibility needed to accommodate individual variation.
  - The intervention log now takes on a grid format to allow cross referencing of the potential areas of impairment uncovered when goal setting, and the type of intervention that could be utilised.
  - This revised log is currently being piloted within the PD REHAB trial.

- The intervention:
  - No further OT specific trials have been published within the PD lit.
  - However, higher methodological quality trials have been published in the wider PD rehabilitation literature (e.g. Nieuwboer et al, 2007), and national/international guidelines for the management of PD (NICE, 2006; Stuerkenboom et al, 2008).
  - As the evidence base has moved forward, the intervention delivered in PD REHAB may differ slightly from that in PDOT, but the focus is the same.
References

Thank you