

## **PRIORITY BRIEFING**

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation projects.

## **QUESTION DETAILS**

**Question ID:** 7

**Question type:** Intervention

**Question:** Does physiotherapy, when introduced in the early stages of Parkinson's disease (PD), delay the onset of postural instability and falls?

**Population:** People diagnosed with idiopathic Parkinson's disease in the early stages of the disease who have not yet had a fall.

**Intervention:** An individualised community physiotherapy programme including strength, balance and gait training, advice on posture and movement strategies.

**Control:** An advice leaflet on physical activity and falls prevention.

**Outcome:** Onset of postural instability and falls among people with Parkinson/s disease; health and social care costs. Quality of life of people with PD and their carer.

### **Note on Parkinson's disease:**

Idiopathic Parkinson's disease differs from other forms of Parkinson's disease only in its cause – idiopathic means the cause is unknown. Idiopathic Parkinson's is the most common form, other causes might include drugs, and conditions that are less common, such as multiple cerebral infarction and degenerative conditions such as progressive supra-nuclear palsy (PSP) and multiple system atrophy (MSA).

## **Part 1: Research Background**

**Guidelines:** The NICE Guidelines Parkinson's Disease: Diagnosis and management in primary and secondary care (2006) recommend that physiotherapy should be available for people with PD. Particular consideration should be given to: gait re-education, improvement of balance and flexibility; enhancement of aerobic capacity; improvement of movement initiation; improvement of functional independence, including mobility and activities of daily living; and provision of advice regarding safety in the home environment.

### **Research Summary:**

The focus of this question is on primary prevention of falls in people with newly diagnosed PD. Some studies investigate the use of physiotherapy as a primary prevention measure (before the first fall) but few record the number of falls as an outcome. A number of systematic reviews were identified during the brief search of the literature: two in 2001 looking at a comparison of physiotherapy techniques in Parkinson's disease.<sup>1,2</sup> Both studies reported that evidence was insufficient to support or refute the efficacy of any given form of physiotherapy in PD. Both studies suggest the need for larger scale randomized control trials (RCTs) to demonstrate the effectiveness of various forms of physiotherapy in PD.

More recently (2007 and 2008) two further systematic reviews have been conducted on the impact of physical therapy<sup>3</sup> and exercise interventions<sup>4</sup> for people with Parkinson's disease (one also included a meta-analysis of the literature). Between the two, there were mixed reports on the quality of methods used in the studies reviewed, with some obvious limitations in the studies. However, both reviews suggested that the quality of evidence had improved in recent years. Both reviews found a limited number of relevant RCTs for inclusion.

Results from the two reviews were also mixed. One found that the benefits of physical therapy were restricted to the specific tasks being trained within the therapy and were not transferable to other related activities; whilst the other found broader benefits with regard to physical functioning, health related quality of life, strength, balance and gait speed. The reviews highlighted that the evidence does imply a need for longer term therapy for people with PD, as the beneficial effects appear to wear off if therapy is stopped; and also that the studies reviewed did not support or refute the value of physical therapy in reducing falls.

Only one related trial could be identified since 2008 (all studies previous to this were assumed to be covered by the findings of the above review). This trial on changes in walking activity and endurance following rehabilitation for people with Parkinson's disease was published in 2009.<sup>5</sup> Looking at people with mild-to-moderate Parkinson's disease, the study found that time spent walking around the home and walking endurance did not significantly increase with increasing

dosage of rehabilitation. However, higher doses of rehabilitation were associated with better improvements in endurance, in those with lower baseline walking endurance and better improvements in walking around the home in those with higher baseline walking around the home activity. This trial does not consider falls as an outcome measure and in general it is apparent that few studies consider falls as an outcome to monitor in relation to the benefits of physiotherapy.

**Ongoing Research:**

A study (the GETuP study) currently ongoing as an evaluation of a group strength and balance training programme on reducing falls and improving physical function and quality of life for people with Parkinson's disease. The study has been funded by the NIHR/NCCRC and is included in DeNDRoN and PCRN portfolios. The study is being run in Devon by the submitter of this question but does not involve looking at the impact of provision of physiotherapy during the earlier stages of PD. This study began in May 2007 and recruitment was completed in November 2008, but the results are yet to be published.

A randomized control trial is planned by Canning, C. G., C. Sherrington, and others to investigate exercise therapy for the prevention of falls in people with Parkinson's disease. The main objective of this randomised controlled trial is to determine whether fall rates can be reduced in people with Parkinson's disease using exercise targeting three potentially remediable risk factors for falls (reduced balance, reduced leg muscle strength and freezing of gait) in a community setting. The study will also be assessing the cost effectiveness of the exercise program from the health provider's perspective. It appears that this study may be using a similar physiotherapy treatment to the treatment mentioned in the current question but it is not investigating the impact of treatment at an earlier stage of PD onset. No further progress appears to have been made on this project as of 25<sup>th</sup> September 2009.

## **Part 2: Prioritisation Information**

### **1. The health problem**

#### **Epidemiology:**

Parkinson's disease (PD) is a progressive neurodegenerative condition resulting from the gradual death of the specific brain cells that produce the neurotransmitter dopamine. There is no consistently reliable test that can distinguish PD from other conditions that have similar clinical presentations. The diagnosis is primarily clinical, based on a history and examination. Although PD is predominantly a movement disorder, other impairments frequently develop including psychiatric problems such as depression and dementia. The condition progresses to cause significant disability and handicap with impaired quality of life for the affected person. Family and carers are also affected indirectly.

The average age of onset is between 55 and 60 years. PD is estimated to affect 100–180 people per 100,000 of the population (between 6 and 11 people per 6000 of the general population in the UK) and has an annual incidence of 4–20 per 100,000. There is a rising prevalence with age and a higher prevalence and incidence of PD in males.

Unable to find information of the prevalence of PD in the southwest peninsula but as the population of the over 65's continues to grow the likelihood of PD related problems are likely to increase.

### **2. Identification of the topic as a priority:**

NICE guidelines on Parkinson's disease (2006) recommend research into the cost effectiveness of the use of physiotherapy in PD. They also recognise the need for research to examine which components of physiotherapy are effective and whether it is effective in the earlier stages of the disease.

The Government Inquiry into access to health and social care services for people with Parkinson's disease and their carers (Please Mind the Gap, 2009) support better commissioning and planning of services for people with Parkinson's disease through the provision of evidence and guidance.

The Department of Health National Service Framework for Long term Conditions (2005) states two quality requirements in progressing services for those with long term neurological conditions:

- Early and specialist rehabilitation: People with long term neurological conditions who would benefit from rehabilitation are to receive timely, ongoing, high quality rehabilitation services in hospital or other specialist settings to meet their continuing and changing needs. When ready, they

- are to receive the help they need to return home for ongoing community rehabilitation and support.
- Community rehabilitation and support: People with long term neurological conditions living at home are to have ongoing access to a comprehensive range of rehabilitation, advice and support to meet their continuing and changing needs, increase their independence and autonomy and help them to live as they wish.

### **SW SHA Priorities framework 2008-11**

- Fully implement the National Service Framework for long term conditions.
- Reduce emergency admission as a result of a fall by 30% through effective falls prevention.

### **3. Local perspective**

#### **Tractability:**

- Devon has a good recruitment track record in neurology.
- Local interest and expertise.

#### **An overview of the local context**

No other information available.

## References

(1) Deane, K., E. Jones Diana, et al. (2001). "Physiotherapy for Parkinson's disease: a comparison of techniques." Cochrane Database of Systematic Reviews(1).

**BACKGROUND:** Despite optimal medical and surgical therapies for Parkinson's disease, patients develop progressive disability. The role of the physiotherapist is to maximise functional ability and minimise secondary complications through movement rehabilitation within a context of education and support for the whole person. What form of physiotherapy is most effective in the treatment of Parkinson's disease remains unclear. **OBJECTIVES:** 1. To compare the efficacy and effectiveness of novel physiotherapy techniques versus 'standard' physiotherapy in patients with Parkinson's disease. Standard physiotherapy is defined as the type of therapy that the physiotherapist would usually use to treat Parkinson's disease. 2. To compare the efficacy and effectiveness of one physiotherapy technique versus a second form of physiotherapy. **SEARCH STRATEGY:** Relevant trials were identified by electronic searches of MEDLINE, EMBASE, CINAHL, ISI-SCI, AMED, MANTIS, REHABDATA, REHADAT, GEROLIT, Pascal, LILACS, MedCarib, JICST-EPlus, AIM, IMEMR, SIGLE, ISI-ISTP, DISSABS, Conference Papers Index, Aslib Index to Theses, the Cochrane Controlled Trials Register, the CentreWatch Clinical Trials listing service, the metaRegister of Controlled Trials, ClinicalTrials.gov, CRISP, PEDro, NIDRR and NRR; and examination of the reference lists of identified studies and other reviews. **SELECTION CRITERIA:** Only randomised controlled trials (RCT) were included. **DATA COLLECTION AND ANALYSIS:** Data was abstracted independently by KD and CEH and differences settled by discussion. **MAIN RESULTS:** Seven trials were identified with 142 patients. All used small numbers of patients and the method of randomisation and concealment of allocation was poor or not stated in all of the trials. These methodological problems could potentially lead to bias from a number of sources. The methods of physiotherapy varied so widely that the data could not be combined. **AUTHORS' CONCLUSIONS:** Considering the small number of patients examined, the methodological flaws in many of the studies and the possibility of publication bias, there is insufficient evidence to support or refute the efficacy of any given form of physiotherapy over another in Parkinson's disease. Another Cochrane review, Physiotherapy for patients with Parkinson's Disease, found that there was insufficient evidence to support or refute the efficacy of physiotherapy compared to no physiotherapy in Parkinson's disease. A wide range of physiotherapy approaches were used in these studies and a survey of UK physiotherapists confirmed that they also use an eclectic combination of techniques in the treatment of Parkinson's disease (Plant 1999). Therefore a consensus must be found as to 'best practice' physiotherapy for Parkinson's disease. The efficacy of 'standard' physiotherapy should be proved first before examining variations in physiotherapy methods. Therefore large well designed randomised controlled trials are needed to judge the effect of physiotherapy in Parkinson's disease. After this large RCTs are needed to demonstrate the most effective form of

physiotherapy in Parkinson's disease. Outcome measures with particular relevance to patients, carers, physiotherapists and physicians should be chosen and the patients monitored for at least 6 months to determine the duration of any effect. The trials should be reported according to CONSORT guidelines (CONSORT 1996). IN SPITE OF THE BEST MEDICAL AND SURGICAL TREATMENTS FOR PARKINSON'S DISEASE, PATIENTS DEVELOP SIGNIFICANT PHYSICAL PROBLEMS. PHYSIOTHERAPISTS AIM TO ENABLE PEOPLE WITH PARKINSON'S DISEASE TO MAINTAIN THEIR MAXIMUM LEVEL OF MOBILITY, ACTIVITY AND INDEPENDENCE THROUGH THE MONITORING OF THEIR CONDITION AND THE TARGETING OF THE APPROPRIATE PHYSICAL TREATMENT. A RANGE OF APPROACHES TO MOVEMENT REHABILITATION, WHICH WITH EDUCATION AND SUPPORT ARE EMPLOYED TO MAXIMISE FUNCTIONAL ABILITY, MINIMISE SECONDARY COMPLICATIONS AND ENHANCE QUALITY OF LIFE OVER THE WHOLE COURSE OF THE DISEASE.: This review will compare the benefits of one form of physiotherapy versus another for people with Parkinson's disease. Relevant trials were identified by electronic searches of 21 medical literature databases, various registers of clinical trials and an examination of the reference lists of the identified studies and other reviews. Only randomised controlled trials were included in this review. These were studies where two groups of patients were compared, each group of patients receiving a different form of physiotherapy. The patients were assigned to each of the two groups in a random fashion to reduce the potential for bias. Data from the selected trials were extracted independently by two reviewers and differences settled by discussion. Seven trials were found comparing two forms of physiotherapy in a total of 142 patients. The quality of the trials' methods was variable with all the studies failing in at least one critical area. The methods and outcome measures varied so much that the results of the individual trials could not be combined. Considering the small number of patients and the methodological flaws in many of the studies, there is insufficient evidence to support the use of one form of physiotherapy over another for the treatment of Parkinson's disease. Another Cochrane review that examined the efficacy of physiotherapy versus placebo (sham) therapy (Physiotherapy for patients with Parkinson's Disease) concluded that there was insufficient evidence to support or refute the efficacy of physiotherapy in Parkinson's disease. The benefits of 'standard' physiotherapy should be proved first before examining variations in physiotherapy methods. Therefore large well designed randomised controlled trials (RCTs) are needed to judge the effect of physiotherapy in Parkinson's disease. After this, large RCTs are needed to demonstrate the most effective form of physiotherapy in Parkinson's disease. The design of the trials should minimise bias and be reported fully using CONSORT guidelines. Outcome measures with particular relevance to patients, their carers, physiotherapists and physicians should be chosen and the patients followed for at least 6 months to determine the duration of any improvement.

(2) Deane, K., E. Jones Diana, et al. (2001). "Physiotherapy versus placebo or no intervention in Parkinson's disease." Cochrane Database of Systematic Reviews(3).

**BACKGROUND:** Despite optimal medical and surgical therapies for Parkinson's disease, patients develop progressive disability. The role of the physiotherapist is to maximise functional ability and minimise secondary complications through movement rehabilitation within a context of education and support for the whole person. **OBJECTIVES:** To compare the efficacy and effectiveness of physiotherapy with placebo or no interventions in patients with Parkinson's disease. **SEARCH STRATEGY:** Relevant trials were identified by electronic searches of MEDLINE, EMBASE, CINAHL, ISI-SCI, AMED, MANTIS, REHABDATA, REHADAT, GEROLIT, Pascal, LILACS, MedCarib, JICST-EPlus, AIM, IMEMR, SIGLE, ISI-ISTP, DISSABS, Conference Papers Index, Aslib Index to Theses, the Cochrane Controlled Trials Register, the CentreWatch Clinical Trials listing service, the metaRegister of Controlled Trials, ClinicalTrials.gov, CRISP, PEDro, NIDRR and NRR; and examination of the reference lists of identified studies and other reviews. **SELECTION CRITERIA:** Only randomised controlled trials (RCT) were included, however those trials that allowed quasi-random methods of allocation were allowed. **DATA COLLECTION AND ANALYSIS:** Data was abstracted independently by KD and DJ and differences settled by discussion. **MAIN RESULTS:** Eleven trials were identified with 280 patients. Eight trials did not have adequate placebo treatments, all used small numbers of patients and the method of randomisation and concealment of allocation was good in only four trials. These methodological problems could potentially lead to bias from a number of sources. Although ten of the trials claimed a positive effect from physiotherapy, few outcomes measured were statistically significant. Walking velocity was measured in four trials and increased significantly in two of them. Stride length was the only other outcome measured in more than one trial, it was significantly improved in two trials. Five other outcomes improved significantly in individual studies, but eight other outcomes did not improve significantly. **AUTHORS' CONCLUSIONS:** Considering the methodological flaws in many of the studies, the small number of patients examined, and the possibility of publication bias, there is insufficient evidence to support or refute the efficacy of physiotherapy in Parkinson's disease. The studies illustrate that a wide range of approaches are being employed by physiotherapists to treat Parkinson's disease. This was confirmed by the UK survey of physiotherapists (Plant 1999). There is a need to develop a consensus as to 'best-practice'. Large well designed placebo-controlled RCTs are then needed to demonstrate the efficacy and effectiveness of 'best practice' physiotherapy in Parkinson's disease. The stage of the disease at which the physiotherapy is given should be specified at the outset. Outcome measures with particular relevance to patients, carers, physiotherapists and physicians should be chosen and the patients monitored for at least six months to determine the duration of any beneficial effects. The trials should be reported according to CONSORT guidelines (CONSORT 1996). In spite of the best medical and surgical treatments for Parkinson's disease, patients gradually develop significant

physical problems. Physiotherapists aim to enable people with Parkinson's disease to maintain their maximum level of mobility, activity and independence through the monitoring of their condition and the targeting of the appropriate treatment. A range of approaches to movement rehabilitation are used to maximise physical ability, minimise secondary complications and enhance quality of life over the whole course of the disease. This review will compare the benefits of physiotherapy versus placebo (sham treatment) or no treatment for people with Parkinson's disease. Relevant trials were found by electronic searches of 21 medical literature databases, various registers of clinical trials and an examination of the reference lists of the identified studies and other reviews. Only randomised controlled trials were included in this review. These were studies where two groups of patients were compared, one group of patients had physiotherapy, the other was given no or sham treatment. The patients were assigned to each of the two groups in a random fashion to reduce the potential for bias. Data from the selected trials was extracted independently by two reviewers and differences settled by discussion. Eleven trials were found comparing physiotherapy with placebo or no therapy in a total of 280 patients. The quality of the trials' methods was variable, with all the studies failing in at least one critical area. All but one of the trials reported a positive effect of physiotherapy in patients with Parkinson's disease. Considering the flaws in many of the studies' methods, the small number of patients, and the possibility that studies with negative results were not published (publication bias), there is insufficient evidence to prove or disprove the benefit of physiotherapy for people with Parkinson's disease. However it should be stressed that this lack of evidence does not mean that physiotherapy does not have a positive effect. The studies illustrate that a wide range of approaches are being employed by physiotherapists to treat Parkinson's disease. The results of the Parkinson's disease physiotherapy evaluation project in the UK also suggest that an eclectic approach is currently used by physiotherapists, drawing on a range of techniques and approaches. A consensus needs to be reached as to an appropriate 'standard' form of physiotherapy to be used in a trial. Large well designed randomised placebo-controlled trials are needed to judge the effect of physiotherapy in Parkinson's disease. The design of the trials should minimise bias and be reported fully according to CONSORT guidelines. The stage of the disease at which the physiotherapy is given should be specified at the outset. Outcome measures with particular relevance to patients, their carers, physiotherapists and physicians should be chosen and the patients followed for at least six months to determine the duration of any improvement.

(3) Kwakkel, G., C. J. de Goede, et al. (2007). "Impact of physical therapy for Parkinson's disease: a critical review of the literature (Provisional abstract)." *SO: Parkinsonism and Related Disorders*(Supplement 3): S478-s487. A systematic review of the literature found 23 randomized clinical trials reflecting specific core areas of physical therapy (PT), that is, transfer, posture, balance, reaching and grasping, gait, and physical condition. All studies were of moderate methodological quality. Important limitations of the studies were: (1) insufficient

statistical power (type II error); (2) poor methodological quality due to inadequate randomization and blinding procedures; (3) insufficient contrast in dosage and treatment between experimental and control groups; and (4) lack of appropriate measurement instruments able to identify clinically meaningful changes according to the International Classification of Functioning (ICF). In the last 5 years, the methodological quality of RCTs has shown substantial improvement. Most high-quality studies investigated the effects of exercise therapy, including the use of external rhythms to improve gait and gait-related activities. The results of these trials suggest that the effects of PT are task- and context-specific. This indicates that the tasks that are trained tend not to generalize to related activities that are not directly trained in the rehabilitation programme itself, and suggests that future programmes should train meaningful tasks preferably in patients' home environment. In addition, the decline in treatment effects after an intervention has ended suggests the need for permanent treatment of patients with PD, i.e. chronic treatment for this chronic disease. Future studies should aim to develop responsive measurement instruments able to monitor meaningful changes in activities, as well as better understanding of insufficiently understood symptoms such as freezing, rigidity and bradykinesia and greater insight into neurophysiological mechanisms underlying training-induced changes in activities such as improved gait performance by rhythmic cueing.

(4) Goodwin, V. A., S. H. Richards, et al. (2008). "The effectiveness of exercise interventions for people with Parkinson's disease: a systematic review and meta-analysis (Provisional abstract)." *SO: Movement Disorders*(5): 631-640.

Parkinson's disease (PD) is a neurodegenerative disorder affecting the physical, psychological, social, and functional status of individuals. Exercise programs may be an effective strategy to delay or reverse functional decline for people with PD and a large body of empirical evidence has emerged in recent years. The objective is to systematically review randomized controlled trials (RCTs) reporting on the effectiveness of exercise interventions on outcomes (physical, psychological or social functioning, or quality of life) for people with PD. RCTs meeting the inclusion criteria were identified by systematic searching of electronic databases. Key data were extracted by two independent researchers. A mixed methods approach was undertaken using narrative, vote counting, and random effects meta-analysis methods. Fourteen RCTs were included and the methodological quality of most studies was moderate. Evidence supported exercise as being beneficial with regards to physical functioning, health-related quality of life, strength, balance and gait speed for people with PD. There was insufficient evidence support or refute the value of exercise in reducing falls or depression. This review found evidence of the potential benefits of exercise for people with PD, although further good quality research is needed. Questions remain around the optimal content of exercise interventions (dosing, component exercises) at different stages of the disease.

(5) White, D. K., R. C. Wagenaar, et al. (2009). "Changes in walking activity and endurance following rehabilitation for people with Parkinson disease." *SO: Archives of physical medicine and rehabilitation*(1): 43-50.

**OBJECTIVE:** To investigate changes in walking activity and endurance after interdisciplinary rehabilitation in people with Parkinson disease (PD). **DESIGN:** Randomized controlled trial. **SETTING:** Clinic, home, and community. **PARTICIPANTS:** Mild to moderate PD (Hoehn and Yahr stage 2-3). **INTERVENTIONS:** Three experimental conditions lasting 6 weeks in duration: (1) no active rehabilitation; (2) 3.0 hours of interdisciplinary rehabilitation a week; or (3) 4.5 hours of interdisciplinary rehabilitation a week. Participants had stable medication regimes during the study. **MAIN OUTCOME MEASURES:** Walking activity was estimated with an activity monitor (AM) (time spent walking and number of 10-second walking periods) in the home and community settings over a 24-hour period. Walking endurance was measured in the clinic with the two-minute walk test (2MWT). Linear contrast analyses were applied to examine changes in walking activity and endurance after higher doses of rehabilitation, and 2-way analysis of variance models with interaction were applied to examine the effect of high and low baseline walking levels on changes. **RESULTS:** The 2MWT was completed by 108 people with PD (mean age, 66.53y; with PD, 6.59y), and AM data were used from 74 of these people (mean age, 66.7y; with PD, 5.8y). Improvement in AM measures and the 2MWT did not significantly change across increasing dosages of interdisciplinary rehabilitation. Higher doses of rehabilitation resulted in significant improvements in the 2MWT for subjects with low baseline walking endurance ( $P=.001$ ), and in AM measures for subjects with high baseline walking activity ( $P<.02$ ). **CONCLUSIONS:** Interdisciplinary rehabilitation can improve walking activity and endurance depending on baseline walking levels.