A pilot randomised controlled trial of supported community exercise in people with Parkinson's disease

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Abstract

Exercise is a potentially important component within the management of Parkinson's disease (PD), but people within this population exhibit lower levels of physical activity and often report barriers to participation in exercise. This pilot study aimed to investigate the feasibility of delivering a supported community exercise programme for people with PD.

An exploratory randomised controlled trial was conducted within community leisure centres across Oxfordshire and Birmingham. Adults with idiopathic PD were randomised to receive either a three-month, individualised and supported exercise programme (intervention group), or to the control group. Participants were assessed at baseline, three and six months. The primary outcome measure was the Physical Activity Scale for the Elderly. Step count, mobility speed and endurance, strength, fatigue, cognition, quality-of-life and falls were also recorded.

Thirty-nine participants were recruited; 20 were assigned to the intervention group and 19 to the control group. Eighty-seven percent of participants completed the exercise programme and the gym was attended well (median of 12 visits). There were no significant changes in any of the outcome measures.

This study confirmed the feasibility of delivering the exercise programme for people with PD. To confirm the effectiveness of this intervention, a full scale trial is now required.

Introduction

Parkinson's disease (PD) is a common neurodegenerative condition, thought to affect around 120,000 people in the UK alone (1). The management of PD usually centres on the provision of pharmacological therapy (2), but even with optimal medical treatment in place, impairments, activity limitations and restriction of participation can develop (3). For this reason, additional management strategies are employed.

Exercise is often recommended for people with PD, with reports of beneficial effects on physical functioning and conditioning, quality of life, strength, posture, balance and gait (4, 5). Despite this, people within this population often lead a more sedentary lifestyle (6). A number of barriers to exercise have been reported by people with neurological conditions, including those with PD, such as inaccessible facilities, the costs of exercise and travel, a lack of relevant knowledge held by fitness professionals resulting in uneducated advice, and insufficient support (7). It has been hypothesised that by addressing these barriers via a community support system, people with neurological conditions may be encouraged to participate in physical activity (7).

This paper reports on a pilot study that aimed to assess the feasibility and acceptability of delivering an individualised exercise programme, supported by a Physical Activity Support System (PASS) with physiotherapeutic input, within community leisure centres for people with PD. This study was conducted as part of a larger exercise trial in people with long-term neurological conditions (8).

Methods

The study was conducted between November 2007 and July 2009 as an exploratory randomised controlled trial (RCT). The design of the study is illustrated in Figure 1.

Patients with PD were recruited from outpatient neurology clinics across Oxfordshire and the West Midlands, local Parkinson's UK support groups and the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN). Patients were deemed eligible to participate if they were aged eighteen years or over, had a confirmed diagnosis of idiopathic PD (9), were able to walk 10 metres using any aid or assistance as required, and had no cognitive, sensory or psychological impairments that could prevent participation in the study or put the participant at risk (as judged by the patient's physician).

Participants who consented to participate were then allocated to receive either the exercise programme (intervention group) or continue with their usual care (control group). The group allocation was revealed to the treating physiotherapist, but concealed to the assessor.

Participants randomised to the exercise programme began the intervention immediately following randomisation. This consisted of a gym induction followed by exercise sessions delivered at community leisure centres across Oxfordshire and Birmingham. The exercise programme was personalised to address each individual's own needs and driven by participant-led goals. During their gym inductions, participants were familiarised with the environment, equipment and staff. They were assessed by their fitness instructor and, through collaboration, a fitness programme was designed. Whilst the intervention was created to specifically address each individual's own requirements and goals, programmes typically included components of endurance, muscle strength, flexibility and cardiovascular fitness, and were designed to progress over the course of the intervention period. The intensity, duration and frequency of exercise were also decided at this point. Following the induction, participants attended the gym for a three month period, with the number and length of sessions being determined by the individual.

The PASS was delivered alongside the intervention to reduce any barriers to exercise. Full details can be found at http://www.brookes.ac.uk/lifesci/lifepass and have been published elsewhere (10). In summary, the PASS took into consideration the support required from fitness professionals, the importance of the exercise setting, and any financial assistance. The exercise intervention was delivered within local authority gymnasiums with Inclusive Fitness Initiative (IFI) or pending IFI status. These centres make exercise accessible by providing a suitably adapted environment, physically accessible equipment, and trained fitness staff with knowledge of a range of health conditions (http://www.inclusivefitness.org/). Physiotherapeutic support was available to participants and fitness professionals for the duration of the exercise programme, with therapists providing information, practical advice and physical support as required. Financial assistance was made available for gym and transport costs.

Participants allocated to the control group continued with their usual care for the three months following randomisation in order to provide a comparison for the intervention group. Following this, participants were offered the exercise intervention described above and all accepted it.

Participants were assessed at baseline (before randomisation), three months (immediately following the intervention) and six months (follow up). The primary outcome measure was the Physical Activity Scale for the Elderly (PASE); a seven day self-report questionnaire recalling community-based activity and mobility (11). Secondary outcome measures included average step count recorded via an ankle attached Step Activity Monitor (SAM) (12), mobility speed and endurance recorded through the ten metre and two minute walk tests respectively (13), lower limb muscle strength and hand grip strength, fatigue as measured by the Fatigue Severity Scale (FSS) (14), cognition as recorded through the Short Orientation Memory Concentration test (SOMC) (15), and quality of life measured through the Parkinson's Disease Questionnaire-39 (PDQ-39) (16). Number of falls was recorded as an adverse event, and other adverse events were also monitored (e.g. cardiovascular events). Baseline demographics for age, sex, body mass index, and the Barthel Activities of Daily Living Index score (17) were also collected, and following completion of the exercise programme, participants were asked to provide feedback via an optional questionnaire.

An exploratory intention to treat analysis was conducted for the demographic data and outcome measures. The two arms of the trial (intervention and control groups) were compared using the t-test at the each time point.

Ethical approval for this study was granted by Oxfordshire Research Ethics Committee (07/H0606/81).

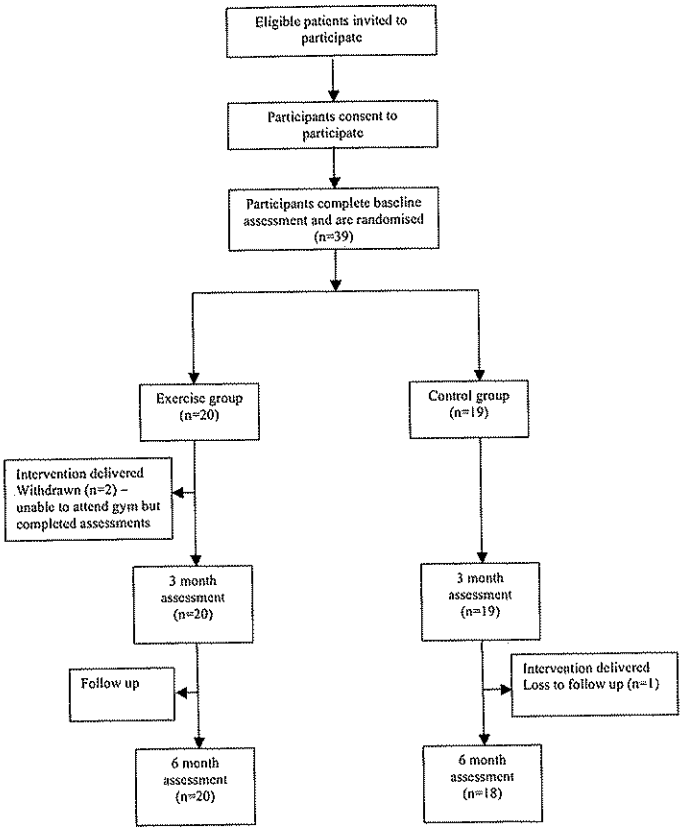
Results

Figure 1 shows the flow of participants through the study. Thirty-nine participants with PD were recruited, of which 20 were randomly assigned to the exercise group and 19 to the control group. There was one loss to follow up during the study in the control group. This occurred following the three month assessment and was due to medical reasons unrelated to the trial. Two patients from the exercise group completed the assessments but withdrew from the intervention, and one participant from the control group did not attend the gym during their allocated period (between three and six months) but still completed the assessments.

Assessments occurred on time and completion of the outcome measures was good. The primary outcome measure, the PASE, was reported for all participants at baseline, 38 out of 39 (97%) participants at three months, and 35 out of 38 (92%) active participants at six months. Data completion for all other outcome measures across the assessment time points ranged from 92% to 100% for the self-report questionnaires, and 76% to 100% for the objective measures recorded.

Uptake of the intervention was good, with 34 out of the 39 participants (87%) carrying out the exercise programme. Gym attendance data was available for 32 out of the 39 participants and the median gym attendance was 12 visits, with an interquartile range of 12 and a range of 2 to 31 visits.

Figure 1: Design of study and participant flow through



The demographic characteristics of the intervention and control groups were similar, with no significant differences between the two. In the intervention group the mean age was 63 years (5 female/ 15 male) and mean body mass index was 27.3 kg/m2. In the control group the mean age was 65 years (3 female/ 16 male) and mean body mass index was 28.2 kg/m2. The mean durations of disease were 5.1 years and 4.7 years in the intervention and control groups respectively, and the mean Barthel Index Score was 19/20 for both groups.

Data was collected for the outcome measures at baseline, three months and six months in each group, and the mean differences between the groups were calculated at each time point. Data collected at the baseline and three month assessments allowed for comparison between the group receiving the intervention immediately post randomisation, and the control group. Data collected at 6 months illustrated the carry over within the intervention group at follow up, and the immediate effect of the exercise programme on the control group. Statistical analysis revealed that there was no significant difference between the groups for any of the outcome measures or at any of the time points. Results for the PASE, two minute walk test, PDQ-39 and SAMs are illustrated in Figure 2.

Because both groups received the intervention, the data from outcome measures was pooled to allow statistical analysis of the whole study sample before and after treatment. Again, there was no significant difference

Figure 2: Results for outcome measurements

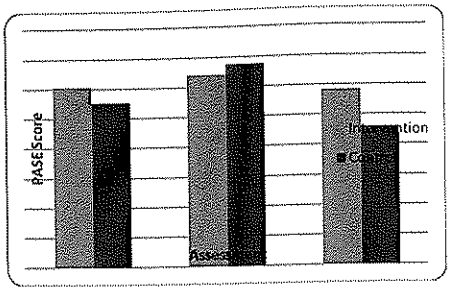


Figure 2a: Comparison of average PASE score at each time point
PASE (Patient Activity Scale for the Elderly): Range: 0 – 400+ (bad – good)

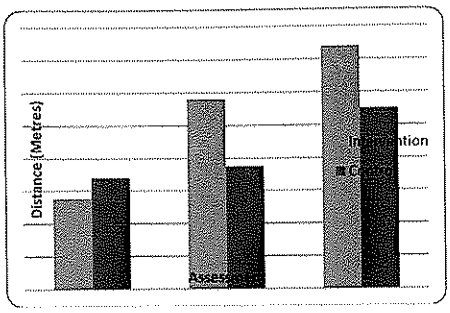


Figure 2b: Comparison of average Two minute walk test scores at each time point
Higher score= positive

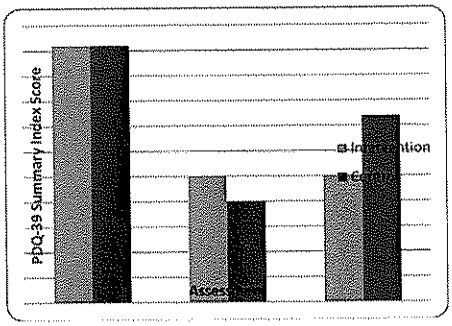


Figure 2c: Comparison of average PDQ-39 summary scores at each time point
PDQ-39 (Parkinson's Disease Questionnaire-39): Range: 0 – 100 (good – bad)

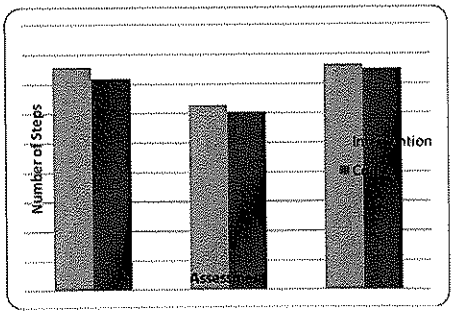


Figure 2d: Comparison of average step count at each time point
Higher score= positive

between the means for the pooled before and after data for any measure. Four participants reported falls at each time point in the intervention group, although the number of falls per patient decreased following the intervention. The number of fallers increased following delivery of the exercise programme to the control group after the three month assessment. No other adverse events were reported.

Participant feedback following completion of the exercise programme was largely positive. It identified that good gym access, the attitudes of staff, the type of equipment available, and support from the fitness professional and physiotherapist were all important factors in the success of the exercise programme. Most participants reported that they were confident to exercise following the intervention, with the majority ranking this as 8/10 or above. Encouragingly, most participants also stated that they would continue to exercise following completion of the trial, with one participant even stating that "exercise is, without doubt, the way forward to maintain a more flexible frame". When asked to identify any aspects of the exercise experience that could be improved, participants highlighted that a slightly more structured and varied programme may be useful, and that more input regarding progress throughout the programme would be beneficial. One participant also felt they would be encouraged to exercise harder if a competitive element was introduced, and a number of participants indicated that the exercise experience would be improved if the gym facilities were closer to their home.

Discussion

As a pilot study, this trial aimed to test the feasibility and acceptability of the exercise programme, and other elements such as the control intervention used and the outcome measures employed. Due to the small size of the study, there were an insufficient number of patients to test the actual effectiveness of the intervention, and so it is unsurprising that there were no significant differences between the groups for any of the outcome measure.

Delivery of the exercise intervention with the PASS, and within the community leisure centre setting, was proved to be feasible through completion of the trial, whilst its acceptability was confirmed by participants' uptake of the programme. Eighty-two percent of participants (32 out of 39) randomised to the trial were confirmed to have completed the intervention through the availability of gym attendance data. Whilst this data was lost for three participants during a database system switchover, analysis of the PASE questionnaires for these participants uncovered that two of the three did attend the gym during their allocated time period. Therefore, a total of 87% of participants undertook the exercise programme. This is higher than the 61 and 71% reported in a RCT of a physical activity intervention in 424 older adults (18), and much higher than the uptake of 35% recorded in a trial of primary care delivered physical activity for sedentary, healthy adults (19). Support for the exercise intervention within our trial was further evident through the positive feedback from participants at the end of the programme, and the reported confidence to exercise following completion of the intervention. However, the number of gym attendances by participants was variable, with the number of visits per participant ranging from 2 to 31. This may indicate that, whilst the PASS supported some participants in a very effective manner, for others additional barriers and personal circumstances could have impacted on their ability to regularly exercise. This was particularly apparent from the reasons given by participants for withdrawing from the intervention. One participant was still in full time employment and working shift pattern hours which led to difficulties fitting the gym programme into their daily schedule, whilst the other participant already exercised regularly and felt the programme was unable to enhance their current physical activity regime. This indicates that the exercise programme and its associated supportive system may have to be developed and modified if it were to be tested further, and finally implemented in practice.

Other elements of the trial also proved to be feasible and acceptable. The usual care comparator was accepted by participants, with only one participant dropping out (for unrelated medical reasons). The randomisation to no exercise may have been helped by the fact that participants could then receive the exercise programme following the three month assessment, as this crossover design has led to minimal loss to follow up in previous RCTs in PD (20). The outcome measures used within the trial were also confirmed to be feasible and acceptable through their high completion rates. However, some issues were noted, particularly with the PASE questionnaire. Whilst this measure has been previously tested for validity and reliability (11), the questionnaire does include elements such as "walking outside the home", "lawn work" and "outdoor gardening". These activities may be affected by season, particularly due to weather in the UK, and so their inclusion may counteract any increases seen due to participation in exercise. If the study was to be repeated in a larger group of PD patients, alternative physical activity questionnaires may be considered.

The trial had several limitations. The sample size was small and participants within the trial were all of a high functioning nature (indicated through the high Barthel index scores). Therefore, the sample was not representative of the highly variable PD population. The trial design did not allow for any comparison of carryover from the intervention with a control group receiving no care, and additional factors outside the intervention (such as physiotherapy and medication) were not controlled or monitored and so could have potentially impacted on the intervention. Despite these limitations, the study provided important information as, although the area of exercise and physiotherapy research in PD has grown substantially over the last decade (3), and previous trials have included physical activity levels as one of their outcome measurements (21, 22), no trial had focused on the delivery of an exercise intervention primarily for improving physical activity levels in this population. Since completion of this study, a large, multicentre RCT of 586 people with PD has commenced investigating a different, multifaceted behavioural intervention for improving physical activity

behavioural intervention for improving physical activity levels (23). Due to the large numbers of patients within this trial, the findings should give a clearer indication of the clinical effectiveness of an intervention for improving physical activity levels in people with PD.

Conclusion

This trial has confirmed the feasibility and acceptability of an individualised and supported exercise intervention, delivered within community leisure centres for people with PD, illustrated through the high uptake of the exercise programme. In order to confirm the effectiveness of this intervention, a full scale trial is now required.

Acknowledgements

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