Individualized, Challenging Balance Training in Groups for People with Mild to Moderate Disabling Parkinson's Disease: A Feasibility Study

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ABSTRACT

Background

Parkinson's disease causes various impairments of balance performance resulting in a greater risk of falling, lower level of physical activity and impaired quality of life. The 'European Physiotherapy Guideline for Parkinson's Disease' strongly recommends challenging and functional mobility exer- cises to improve balance. However, translation of the recommendations into clinical practice has been sparsely assessed.

Objective

To evaluate the feasibility of an individualised, group-based, challenging balance intervention ba- sed on the European Physiotherapy Guideline for Parkinson's Disease.

Material and methods

Eleven people with Parkinson's disease (55-76 years old with Hoehn and Yahr stage 2-3) from three outpatient clinics took part in an eight-week balance intervention comprising two weekly one-hour training sessions and one weekly home training session. Feasibility was measured by process out- comes, acceptability of the intervention and efficacy outcomes (Mini-BESTest, Six-Spot Step Test, 10-meter walk test, stabilometry and fear of falling (FES-I)).

Results

The median rate of attendance was 81.5 % and three of 11 subjects used the training diary. One drop-out was registered. Results showed a high degree of acceptance among subjects and a mode- rate degree among therapists. Results from the Mini-BESTest found a significant improvement of one (0;2) (median (10;90) percentile), but no other efficacy outcomes presented significant results.

Conclusions

The intervention was feasible measured on attendance rate, dropouts, subjects' acceptance and efficacy. Use of training diary and home exercises might not be feasible. Further studies could look at other recommendations in the 'European Physiotherapy Guideline for Parkinson's Disease' to investigate the feasibility thereof.

Keywords

Feasibility study, functional balance training, challenging balance training, Parkinson's disease, physiotherapy.

Introduction

Parkinson's disease is a progressive disease. Cardinal symptoms include bradykinesia with freezing of gait, muscle rigidity and rest tremor all of which contribute to impaired balance and fear of fal- ling (1). Prospective assessments report fall rates from 38-54 % within a three-month period for people with Parkinson's disease (2), and bone fractures and impaired quality of life may be serious consequences of these (3). Most people with Parkinson's disease suffer from various cognitive impairments leading to poorer capacity to learn motor tasks and plan automatic movements (2). 'The European Physiotherapy Guideline for Parkinson's Disease' strongly recommends functional mobility exercises to improve balance and walking; i.e. conventional physiotherapy which inclu- des training of gait, transfers, physical capacity and balance with a recommended dose of three weekly sessions of 45 minutes for a minimum period of eight weeks. In addition, the guideline emphasizes that balance training needs to be challenging and individualised to achieve the correct intensity (2). Multiple studies have shown that challenging balance training interventions result in improved functional balance in people with Parkinson's disease (4-7). Nonetheless, the feasi- bility of recommendations regarding functional mobility exercises is sparsely assessed in clinical research and practice, and the exact intensity and duration of balance training to optimally induce motor learning in people with Parkinson's disease remains unclear. Task specific and challenging exercises optimise motor learning (8), whereas tasks that are too challenging lead to a decline in motor learning (9).

Differences between controlled trials, clinical guidelines and clinical practice entail an adaptation when translating evidence into practice (10). Feasibility studies bring insight into the possibilities and limitations when implementing results gained from controlled trials in a clinical setting (11). Although there is no well-established consensus on the design of such studies, practitioners are advised to investigate several areas of focus to determine feasibility (12,13).

The aim of this study was to assess the feasibility of an intervention with individualised, functional and challenging balance training in groups for people with Parkinson's disease based on the 'Euro- pean Physiotherapy Guideline for Parkinson's Disease' in an outpatient setting.

Material and methods

Design

This feasibility study followed the first two stages recommended by the Medical Research Council to develop and evaluate complex interventions (14):

1. Developing an intervention

2. Piloting and feasibility.

The intervention protocol with conceptual framework of balance training for people with Parkin- son's disease was developed after a thorough literature search that included 'the European Physio- therapy Guideline for Parkinson's Disease', observation of clinical practice and dialogue with the- rapists. Consequently, the balance training was tailored to fit local outpatient clinics. Further, the intervention was tested in a prospective one-arm study design to examine to what extent the recommendations from 'European Physiotherapy Guideline for Parkinson's Disease' are feasible in a Danish setting. To ensure progression and safety, a physiotherapist with experience of working with people with Parkinson's disease supervised all training sessions.

All subjects gave signed informed consent and the study conformed with the Declaration of Hel- sinki. The Danish Data Protection Agency (j.nr. 2013-41-2130) and The Danish Ethical Committee of Region Midtjylland (request: 72/2017) approved the study.

Subjects

Subjects were recruited from three outpatient clinics. Inclusion criteria were: 1) diagnosed idio- pathic Parkinson's disease; 2) age >18 years; 3) experiencing instability regarding balance; 4) Hoehn and Yahr stage 2-4

(verified by a medical specialist in movement disorders) and 5) referred to state funded physiotherapy. An exclusion criterion was dementia. During intervention the following cri- teria would lead to exclusion: 1) pregnancy; 2) substantial adjustment in medication or 3) worsening of the disease.

Intervention

The intervention period was eight weeks with two one-hour training sessions per week executed in groups. The intervention protocol required the therapists to prescribe an individualised home exercise programme for each subject to comply with the European Physiotherapy Guideline for Parkinson's Disease's recommended three training sessions per week. This was the only acceptable way to conduct three training sessions per week in the outpatient clinics. This way of combining group training with home exercise programmes is shown to be feasible (10). The intervention was based on a protocol developed with four basic mobility activities (8) to target symptom-specific ba- lance impairments associated with instability and falls in people with Parkinson's disease; walking, standing, transfers and stepping. These four basic exercises were trained for ten minutes each fol- lowed by 20 minutes of supplementary activities, all recommended in the European Physiotherapy Guideline for Parkinson's Disease.

WALKING EXERCISES		10 MINUTES
Exercise	**Dual-task**	**Sensory**
Change of speed ***Different types of walking:*** - Lateral stepping (potentially crossing legs) - Tandem walk - Backwards walking - Walking in figure of eight - Walking with change of direction - Walking with flexed knees ***Change in surroundings:*** - Slalom walking/obstacle course - Exercises with a partner ***Change in base of support:*** - Walking with narrow base of support - Walking with wide base of support - Walking on toes - Walking on heels	**Cognitive** ***Mathematical*** - X-tables, e.g. "start with the number 93 and subtract 7 while doing the exercise" ***Linguistic*** - E.g. spelling difficult words or spelling words backwards - Mention words in a category e.g. flowers, countries, girl's names starting with a certain letter - Reading a text out loud or in your head ***Memory*** - Remembering a number of objects - Remembering a series of numbers ***Motor*** - Arm swinging or moving arms up and down - Button a shirt - Dribbling a ball/throwing ball with your partner - Kicking a ball - Carrying a tray with a glass of water/juggling a balloon on a fly-swatter - Lee Silvermann Voice Treat- ment (LSVT) – BIG concept	**Cueing** - *Visual cueing:* Walking on a marked line, Walking in each other's footsteps - *Verbal cueing:* Therapist counts or directs "left, right" in the desired pace - Metronome/music with distinct beat **Sensory** - *Visual:* Walking with eyes closed - *Proprioception:* Walking on a foam mat or on toes/heels - *Vestibular:* Walking while moving their head up and down or from side to side, either with or without eyes fixated

FIGURE 1: The intervention protocol with conceptual framework of balance training showing walking exercises as an example.

The error rate scale was introduced in the protocol to regulate and standardise the intensity of the individualised balance exercises (15).

ERRORS DURING THE EXERCISE IN TERMS OF REPETITIONS OR TIME (%)					
0-10	11-20	21-40	41-60	61-100	
Very Easy		**Moderate**	**Challenging**	**Difficult**	**Impossible**

FIGURE 2: The error rate scale for balance training intensity showing the intervals of the scale.

The purpose was to enhance motor learning by adjusting the intensity of exercises within a chosen interval, and to ensure that the programmes remained feasible in outpatient clinics, where one therapist often is responsible for the treatment and safety of several patients at the same time (typically more than six subjects). The therapist regulated the exercises aiming at an error rate of 21-40 %. This means that an exercise executed at "moderate" intensity is performed with approxi- mately 60-79 % faultless repetitions or time depending on the exercise. Strategies for complex motor sequence, cueing, sensory integration and dual-tasking were used to adjust the difficulty of the exercises (see Figure 1) (2). The final 20 minutes of the intervention protocol could be used for patient education, comprising movement strategies, empowerment, motivation and self- management, as well as introducing the subjects to exercise diary, home exercise programmes and goal setting.

Data collection

Feasibility was assessed through three focus areas; process, acceptance and efficacy. The thera- pists recorded attendance rates and dropout rates during the intervention. After the intervention, the therapists were asked if they had instructed subjects in individualised home exercises and subjects were asked to what extent they had completed their home exercises including training diary. To examine the subjects' and the therapists' acceptance, they were given a questionnaire to measure their degree of satisfaction and appropriateness of the intervention protocol as well as their intent to continue to use it (Appendix 1 and 2) (12). The research team devised its own ques- tionnaire and face validity was assessed by a small population of elderly people (n=3), one physio- therapist and one expert in questionnaire development.

Subjects were tested at baseline and after the eight-week intervention. The procedure for testing followed a strict protocol where tests were completed in a varying order. All subjects were tested by the same member of the research team at the same time of day in an ON-medication period.

Balance

The Six-Spot Step Test (SSST) measures complex walking agility requiring continued adaptation of speed, orientation and extremity control to maintain stability. Recently, our research group has found the test valid and reliable for people with Parkinson's disease, and the test is extensively described in these articles (16,17).

The Mini-BESTest consists of 14 items that examine multiple aspects of balance performance with a maximum score of 28 points indicating good balance. The test is reliable and valid to evaluate balance impairments in people with Parkinson's disease, as well as to predict the risk of falling (18).

Walking speed was tested with the 10-metre walk test (10MWT), which is a short distance walking test proven valid and reliable as a clinically useful measure for people with Parkinson's disease (19).

Static balance was measured with a test on the Nintendo Wii Balance Board (NWBB). In the NWBB test, subjects are asked to stand with feet close together and remain standing as still as possible for 30 seconds.

The NWBB records displacement of centre of mass in mm2 (area) and speed of postural sway in mm/s (velocity). The NWBB has proven reliable (20) and valid as a measurement tool for the assessment of postural stability in people with Parkinson's disease (18). The 'European Physiotherapy Guideline for Parkinson's Disease' recommends the Fall Efficacy Scale - Internatio-nal (FES-I) (21), which measures subjects' fear of falling when performing 16 different everyday activities (e.g. getting dressed, climbing stairs or going to the shops), rated on a five-point Likert scale. The total score ranges from 16 to 64 points. A high score indicates a greater fear of falling.

Statistical analysis

Descriptive analysis was performed to determine group characteristics of the subjects. Distribution of data from efficacy tests is described by median and 10th and 90th percentile. Intention-to-treat was used in the event of dropout during intervention, in which case baseline score was given as post-test score. Wilcoxon's signed ranks test was used to analyse the differences within the group from baseline to post-test. The level of significance was set at $p \leq 0.05$.

Results

Subjects

Thirtyone people with Parkinson´s disease were invited and 16 agreed to participate. Of these, four subjects were sick on the day of baseline testing and one subject scored one on the Hoehn and Yahr scale resulting in 11 subjects; two females and nine males. Furthermore, one subject was not tested in the 10MWT and the SSST due to logistics issues.

Subjects had a median (minimum-maximum) age of 72 years (55-76), a Hoehn and Yahr score of three (2-3), and the time since being diagnosed with Parkinson's disease was six years (2-10). Two out of 11 subjects had fall incidents in the two-month period leading up to the intervention, and one subject used a walking stick. One subject worked part time, one was on sick leave and the remainder had either retired or retired early. None of the subjects took part in any new therapies during the intervention but continued other activities as usual. Furthermore, none of the subjects reported having any considerable diseases aside from Parkinson´s disease.

Process outcome

The median rate of attendance (%, range) was 13 of 16 sessions (81.5 %, 11-15) for the group. The most frequent reason for not participating was either that subjects or therapists were on holiday (38 % of all cancellations). Three subjects agreed or strongly agreed to having performed their weekly home exercise programme and used the training diary (Appendix 1). None of the therapists reported spending time instructing in home exercises or training diary (Appendix 2).

Acceptance

Nine of the subjects either agreed or strongly agreed to the training being adequately challenging (Appendix 1). All subjects would recommend the balance training to other people with Parkinson's disease and were motivated to continue training. All three therapists agreed that the intervention protocol was ideal to use at clinics in which people with Parkinson's disease exercise (Appendix 2). One therapist would continue to use the protocol as it is, and two out of three therapists would recommend the protocol to other therapists.

Efficacy

A significant improvement was found in the Mini-BESTest (median difference (10;90 percentile); (1 (0;2), P=0.047), but no significant improvements were seen in other outcome measures; 10MWT (-0.20 (-0.73;0.26), P=0.14), SSST (0.04 (-0.30;0.48), P=0.41), FES-I (0 (-2;5), P=1.0), NWBB Velocity (1.9 (-0.6;14.1), P=0.056), NWBB Area (2 (-12.1;123.2), P=0.4). Furthermore, results indicated that a subgroup of subjects with a higher functioning level at baseline improved more in standing and walking performance (Mini-BESTest and SSST) during the intervention period (see figures 3 and 4).

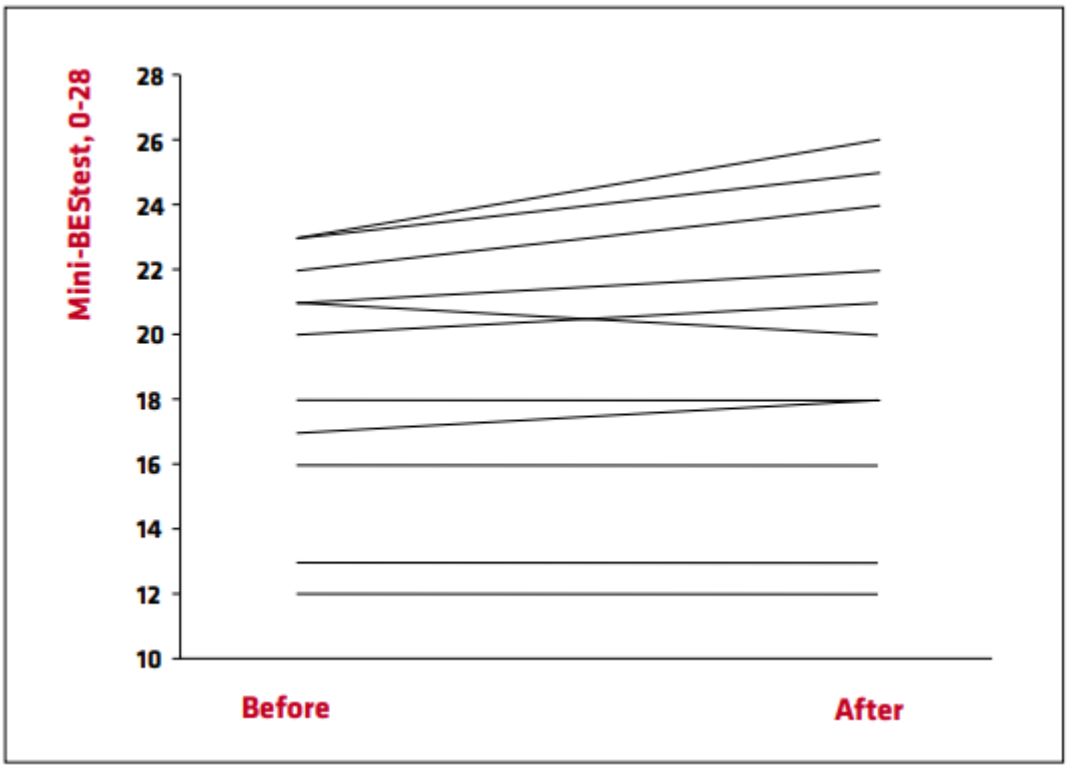

FIGURE 3: Scores on the Mini-BESTest before and after eight weeks of balance training.

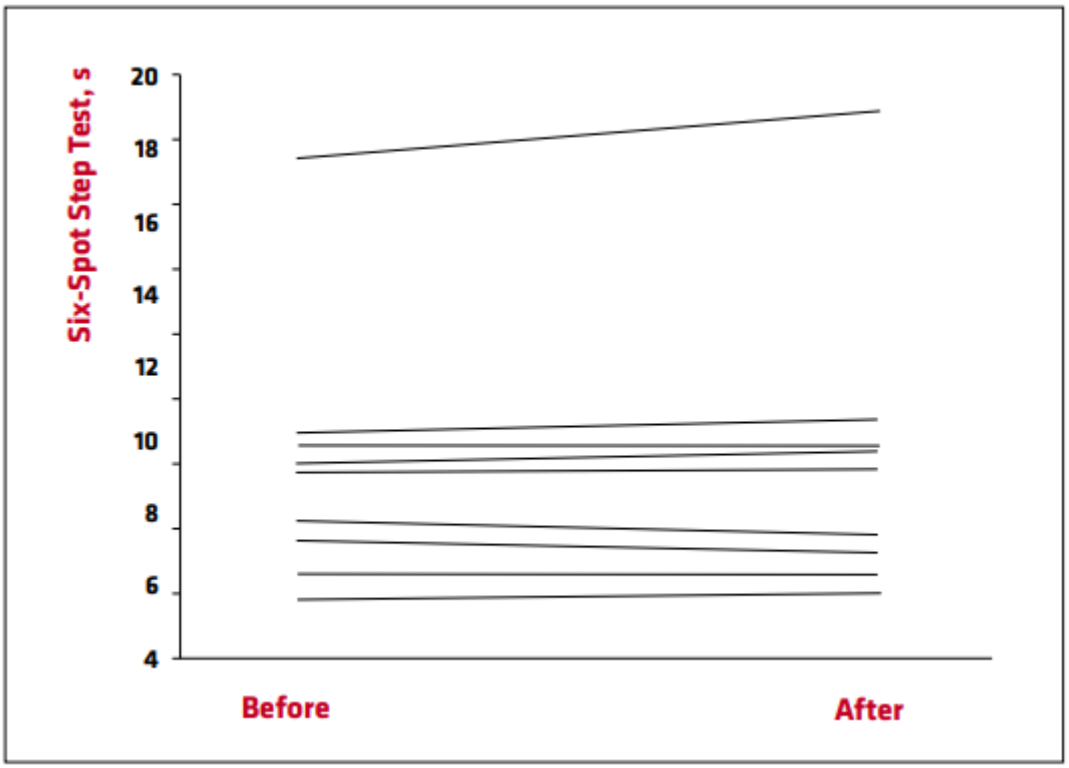

FIGURE 4: Scores on the Six-Spot Step Test before and after eight weeks of balance training.

Discussion

Individualised, challenging balance training executed in groups was feasible for people with Parkin- son´s disease. Subjects attended approximately four out of five training sessions (81.5 %), which is consistent with studies implementing two hours of weekly training in groups of people with Parkin- son's disease

(attendance rate between 80-90 %) (22,23). The principal reason for cancellations (38 %) in this study was holiday (both therapists and subjects) due to a one-week public holiday in the in- tervention period, which might explain the slightly lower attendance rate compared to a similar study with 93 % (24). The dropout rate of 9 % was identical with a previous randomised controlled study (5).

All subjects were motivated to continue the balance training, which indicated a high level of accep- tance of the balance training. Furthermore, they all found the training meaningful and would recom- mend it to other people with Parkinson's disease. These positive findings are in line with a feasibility study with similar training setup for people with Parkinson´s disease (24). Compared to the subjects, the therapists expressed a slightly lower level of acceptance of the intervention protocol. All thera- pists reported positively regarding use of the protocol. However, their responses varied more when evaluating whether the protocol was adequate and if they had the resources necessary to plan the functional balance training. With regard to using the protocol, one could hypothesise that a degree of experience of working with people with Parkinson's disease may be important. Two of the the- rapists had supplementary education within this field and both found the protocol inadequate to plan the individualised balance training. This may explain why they reported having deviated from the protocol. However, both therapists would recommend the protocol to others. On the other hand, the therapist who had less experience found the protocol adequate to plan the balance training but would not recommend the protocol. This therapist was also the only one reporting the error rate scale difficult to use for regression and progression of exercises. This may indicate that the error rate scale is more relevant and feasible for therapists with additional expertise of working with people with Parkinson's disease. As there is no tool with the same purpose in general use, it is possible that the error rate scale is a plausible way to secure adequate intensity during balance training.

This study found no significant differences between baseline and post-tests results except in the Mini-BESTest. The median difference of the Mini-BESTest was one with a range from 1-3 which is less than the minimal clinically important change of four (25). The European Physiotherapy Guide- line for Parkinson's Disease states that the aim of the recommendations is to preserve or improve the capability of people with Parkinson's disease, which, combined with the fact that Parkinson's disease is a progressive disorder, might explain the lack of improvement. Another explanation could be that balance training intensity of 21-40 % on the error rate scale might be less effective to achieve motor learning compared to a highly challenging balance training called HiBalance (5,10).

The HiBalance study was conducted with two therapists for each group consisting of four to seven subjects to ensure safety while training with high risk of falling. The results showed an improve- ment of three points on the Mini-BESTest. By way of comparison, in the present study, one the- rapist trained five to eight subjects as this number of subjects is a realistic outpatient setting in Denmark. Moreover, HiBalance provides a higher frequency of supervised training sessions (three sessions per week) and higher intensity of the balance training. The better effect of the HiBalance intervention may also be explained by the generally higher functional level of balance of the par- ticipating subjects at baseline measured on Mini-BESTest. While 2 % scored 18 points or less at baseline in the HiBalance RCT-study (5), our study included five out of 11 subjects (45.5 %) scoring 18 or less at baseline, i.e. their balance was poorer from the start. The sources establish that a sco- re of less than 19 points in the Mini-BESTest for people with Parkinson's disease correlates with a significantly higher risk of falling within the next six months (26).

The failure of subjects to perform their home exercise programmes was surprising, as Joseph et al. found that a balance intervention consisting of two sessions of supervised training and one session at home per week was feasible (10). Their home exercises consisted of a clearly predefined programme designed by the researchers. By way of contrast, the home exercise programme in our study was inten- ded to be individualised to each subject, but no therapists introduced the home exercises nor the trai- ning diary to the subjects. One therapist implied that some subjects had enough activities aside from the training at the clinic. It could be argued that more precise instructions to the framework concept in form of a workshop might have underlined the importance of home exercises and use of a training
diary. Whether or not this might be feasible in a Danish healthcare setting needs to be investigated.

Despite the lack of significant results in efficacy outcomes, a tendency was shown in the SSST and Mini-BESTest. Subjects with the best scores at baseline improved most, while subjects with the lowest score improved only a little or not at all. This interesting finding might be due to the subje- cts with the lowest score needing more attention from the therapist to be adequately challenged, which cannot be adequately achieved due to the size of the training groups. In addition, this study included five subjects with scores in the Mini-BESTest correlating with a significantly higher risk of falling, which may make these subjects more reluctant to challenge themselves in the balance exercises. Nonetheless, it is worth noting that nine out of ten subjects reported finding the training sufficiently challenging in the post-test questionnaire.

This study has limitations. First, the findings cannot be generalized with certainty to Danish clinical practice due to local confounders, small sample size and the lack of a control group. Secondly, the sub- jects were recruited by a method which can lead to a sample population of individuals more intrigued by training and improving balance performance. Finally, it is debatable whether a self-constructed questi- onnaire is a suitable method to examine acceptance including satisfaction and appropriateness of the balance training. An article on the subject suggests a qualitative method to approach such matters.
This might have brought to the fore other aspects of the subjects' experience of balance training (12).

Conclusion

Individualised challenging balance training in groups based on the 'European Physiotherapy Guide- line for Parkinson's Disease' was feasible for people with Parkinson's disease in outpatient clinics in Denmark with regard to attendance rate, dropout and subjects' acceptance. Positive tendencies were found regarding efficacy of the balance training, especially among less disabled people with Parkinson´s disease. The therapists' acceptance of the intervention protocol including the error rate scale for adjusting the intensity of the balance training was fair, and findings indicate that experience and knowledge of Parkinson´s disease are important in handling the protocol. Individu- alised home exercises and training diary were not feasible in this group of people with Parkinson´s disease at different disability levels.

Perspective

As described in the methods, the study design is based on the recommendations of the Medical Research Council (14) for developing and evaluating complex interventions. This study comprises stage 1) developing an intervention and stage 2) piloting and feasibility. To continue to stage 3) evaluating and 4) implementation, further studies are needed to answer more questions. Another feasibility study or a qualitative paper could illuminate the limiting factors of this study regar- ding the evaluation of the feasibility of the protocol and help determine whether further adju- stment to the protocol is required. Other studies based on the 'European Physiotherapy Guide- line for Parkinson's Disease' could investigate aspects other than balance training to further the knowledge of rehabilitation in people with Parkinson's disease in a wider perspective.

The findings of the study show a tendency for the subjects with the highest baseline scores to benefit most from the training. This could be used in clinical practice as it indicates that training is an im- portant early post-diagnosis treatment for people with Parkinson's disease. Further research on this topic is needed to determine whether the tendency is accurate and to examine the reasons behind it.

Declaration of Interest

The authors declare no conflicts of interests regarding the research and publishing of this study.

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Appendix

Appendix 1

Post intervention subject questionnaire with results

Question	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
1. I am motivated to continue training of balance.	0	0	0	2	8
2. The balance training has been adequately challenging – neither too hard nor too easy.	0	0	1	6	3
3. Due to my disease, training my balance makes sense.	0	0	0	2	8
4. I will recommend the balance training to other people with Parkinson's disease.	0	0	0	2	8
5. I have experienced an improvement of my balance during the last 8 weeks.	0	0	7	3	0
6. The training has been too monotonous.	5	4	1	0	0
7. I would like to spend more time on strength training during the sessions.	3	0	2	4	1
8. I would like to spend more time on training conditioning during the sessions.	2	1	3	2	1
9. I have been afraid of falling during the training sessions.	2	1	2	2	3
10. During the last 8 weeks I have been looking forward to the training sessions.	0	0	2	5	3
11. I feel that the training has taken too much of my energy during the week.	6	3	1	0	0
12. I have completed my weekly training session at home, in which my physiotherapist has instructed me.	1	1	5	2	1
13. I will continue doing the home exercises prescribed by the physiotherapist.	0	1	2	4	3
14. I have used the training diary every time I have trained excluding the sessions at the clinic.	3	1	3	0	3

Note: question 8 was left unanswered once giving a total of 9 answers instead of 10.

Appendix 2

Post intervention therapist questionnaire with results

Question	Strongly disagree	Disagree	Neither nor	Agree	Strongly agree
1. The training protocol is ideal to use at clinics where people with Parkinson's disease come to exercise.	0	0	0	2	1
2. The training protocol has been inadequate in the planning of the functional balance training.	0	1	1	1	0
3. I have had the necessary resources to implement the protocol (time, training tools, space etc.).	0	1	2	0	0
4. I have deviated from the training protocol.	0	1	1	1	0
5. The functional balance training is associated with an excessive risk of falling.	1	1	1	0	0
6. I found the error rate scale difficult to use concerning regression and progression during exercises.	0	1	1	1	0
7. I would recommend the training protocol to other therapists who instruct people with Parkinson disease.	0	0	1	1	1
8. I will continue to use the training protocol.	0	0	2	1	0

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