Large-Amplitude Group Exercise Training Programme For Individuals With Mild To Moderate Parkinson's Disease: A Pilot Intervention Study

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LARGE-AMPLITUDE GROUP EXERCISE TRAINING PROGRAMME FOR INDIVIDUALS WITH MILD TO MODERATE PARKINSON’S DISEASE: A PILOT INTERVENTION STUDY

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September 2016

Supervisor: Dr. Helen French
DECLARATION

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree MSc Physiotherapy in Neurology and Gerontology is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work.

Furthermore, I took reasonable care to ensure that the work is original and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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SUMMARY

Parkinson’s disease (PD) is a complex neurodegenerative disorder which affects the physical, psychological and functional status of individuals. It is the second most common neurodegenerative disease in the world today affecting approximately 8,000 people in Ireland. The most common motor disturbances related to PD are reduced balance and mobility which can lead to a reduction in physical functional performance and health-related quality of life.

Pharmacology is the cornerstone of treatment in PD. However, even with optimal medical management people with PD (PwPD) still experience a deterioration in functional performance. Research relating to the efficacy of physiotherapy and exercise interventions in the management of PD has tripled in the last decade. However, uncertainty remains as to which type, intensity and frequency of exercise are most beneficial.

Aims

The aim of this study is to assess the feasibility of a six week large-amplitude group exercise class on physical functional performance in individuals with mild-moderate PD.

Objectives

To determine if a one hour weekly large-amplitude group exercise class incorporating a daily home exercise programme:

1) Is feasible and safe to carry out both in a hospital setting and a home environment as measured with a safety adverse events form.
2) Improves physical functional performance measures of balance, gait, functional mobility and exercise tolerance with mild to moderate PD as measured with the Six Minute Walk Test (6MWT), Dynamic Gait Index (DGI) and Timed Up and Go (TUAG).
3) Improves health-related quality of life (HRQOL) using the Parkinson’s Disease Questionnaire-39 (PDQ-39).
4) Yields participant satisfaction as measured with a satisfaction questionnaire.
5) Facilitates exercise motivation and adherence as measured with a daily home exercise logbook.
Methods
A pretest-posttest single study pilot design was utilised to address the research question. Eligibility criteria included a diagnosis of idiopathic PD, a Hoehn and Yahr score of 1-3, independently mobile with or without a gait aid and the ability to give informed consent.

Feasibility outcome measures included safety, exercise compliance, adherence rates, retention rates and participant satisfaction.

The primary clinical outcome measure was the 6MWT.

Secondary clinical outcome measures of interest included the Movement Disorder Society-Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part II and Part III, TUAG, DGI and the PDQ-39.

Results
Large-amplitude group exercise training is both feasible and safe to carry out in an acute hospital setting and at home.

Statistically significant changes in mean scores between T1 and T2 were found for the 6MWT (mean change 37.67m, 95% CI (-57.45, -17.89) p=0.01), TUAG and DGI and for the motor examination section (Part III) of the MDS-UPDRS.

Non-significant changes in mean scores between T1 and T2 were found for the ADL section (Part II) of the MDS-UPDRS and PDQ-39.

Conclusions and Implications of findings
A six week large-amplitude group exercise programme is feasible and safe and demonstrated significant changes in functional performance outcomes in PwPD. The author suggests that a more rigorous study design, that is adequately powered, is warranted to evaluate the efficacy of this exercise intervention in PwPD.
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LIST OF ABBREVIATIONS

ADLs  Activities of Daily Living
CI    Confidence Interval
DGI   Dynamic Gait Index
H&Y   Hoehn and Yahr Scale
HRQOL Health-related quality of life
IRQ   Interquartile Range
LSVT BIG Lee Silverman Voice Training-BIG
MCID  Minimally Clinical Important Difference
MDC   Minimal Detectable Change
MDS-UPDRS Movement Disorder Society-Unified Parkinson’s Disease Rating Scale
MRI   Magnetic Resonance Imaging
NGH   Naas General Hospital
PD    Parkinson’s disease
PET   Positron Emission Tomography
PI    Principal Investigator
PwPD  People with Parkinson’s disease
PWR!  Parkinson’s Wellness Recovery Programme
QOL   Quality of Life
RCT   Randomised Controlled Trial
SD    Standard Deviation
TUAG  Timed Up and Go
INTRODUCTION

Parkinson’s disease (PD) is a complex and highly prevalent neurodegenerative disorder characterised by disabling motor abnormalities such as bradykinesia, postural instability, and gait disorders that can lead to falls, increased risk of fractures, poor quality of life and reduced survival (Lo et al, 2009). Because of its unknown cause, dopamine-producing cells in the substantia nigra degenerate which are responsible for movement, balance and walking. The diagnosis is primarily based on clinical criteria. The clinical hallmarks of PD are tremor, rigidity, akinesia and postural instability (de Geode et al, 2001). A recent review showed worldwide prevalence rates of PD between 100 and 300 per 100,000 (Dorsey et al, 2007). Parkinson’s disease affects approximately 8,000 people in Ireland (Parkinson’s disease Association of Ireland 2008).

The management of PD has traditionally centred on pharmacological treatment, but even with optimal medical management, people with PD (PwPD) still experience a deterioration of body function, activities of daily living (ADLs) and participation in society. Functional physical performance outcomes such as balance and gait are commonly impaired in people with PD (PwPD) and are a major contributor to increased disability and decreased health-related quality of life (HRQOL) (Nicolien et al, 2013). This can lead to an increased dependence on others, depression, isolation and inactivity. The symptoms and physical impairments associated with PD make PwPD about one third less active than older adults without PD (van Nimwegen et al, 2011). Animal studies have shown that reduced physical activity may contribute to neuro-degeneration (Tilerson et al, 2002). However, exciting advances in neuroscience research have suggested that exercise induces neurochemical and
neuroplastic changes, which contributes to neuroprotection for the brain (Fisher et al, 2008).

There is a growing evidence base for exercise and physiotherapy interventions for PwPD (Tomlinson et al, 2012; Keus et al, 2014). The recent European Physiotherapy PD Guidelines (2014) recommended three modalities of care to target impairments and activity limitations experienced by PwPD. These include movement strategy training, practice and exercise. Exercise addresses physical capacity and functional mobility, focusing on balance, transfers and gait-related activities.

One particular novel exercise intervention which is gaining increased attention in the literature and is recommended in the European Physiotherapy PD Guidelines (2014) is the Lee Silverman Voice Training (LSVT) BIG (Farley et al, 2005). This exercise intervention uses a goal of intensive large-amplitude movement training combined with functional mobility training delivered in individual treatment sessions four times a week for four weeks (Ebersbach et al, 2010). However, this intense, individualised training programme could be a barrier for adherence for PwPD and is extremely demanding on hospital resources and expensive for the Health Service Executive (HSE) to administer. Another large-amplitude programme that is currently being developed is the Parkinson’s Wellness Recovery (PWR!) Programme (Krasteva et al, 2015) however, no randomised controlled trials (RCTs) have been conducted to establish its efficacy. The key difference between this programme and LSVT BIG is that PWR! incorporates group exercise into their programmes whereas LSVT BIG are very strict in maintaining individualised programmes. A group delivery format would significantly reduce the cost to implement making it more economically viable to deliver compared to individually delivered programmes.
Group exercise programmes have demonstrated positive improvements relating to functional mobility and health-related quality of life (HRQOL) in PwPD (Sage et al 2009). It is suggested that the benefits of group exercise programmes result from a combination of the physical intervention, social interactions and motivation of the group environment (Crizzle et al, 2005). The feasibility and efficacy of a large-amplitude group exercise training programme administered once a week over a shorter time period (six weeks) has yet to be investigated.

PD is a chronic progressive neurological condition with individuals facing an inevitable increasing disability and reduced activity. Despite a dramatic increase in research relating to exercise and PD, uncertainty prevails in the literature regarding optimal frequency, dose and intervention type (Keus et al, 2014). Physiotherapists play a vital role in delivering evidenced-based exercise interventions. Therefore, ongoing research is required into novel exercise interventions to assist with finding solutions to these unanswered questions.
1.1 Overview of Aetiology of Parkinson’s Disease

Parkinson’s Disease (PD) is a complex neurodegenerative disorder which affects the physical, psychological and functional status of individuals (Goodwin et al, 2008). Dopamine-producing cells in the substantia nigra progressively degenerate, affecting the control and regulation of movement, balance and walking (European Guidelines, 2014). Based on emerging evidence about the pathological changes, Stern et al (2012), have proposed a theory on the different stages involved in PD. The authors outlined three distinct stages of the disease process as the preclinical, premotor and motor stages. Motor symptoms indicate an advanced disease process. Rating scales are widely used in clinical practice and research to track disease progression. The Hoehn and Yahr (H&Y) rating scale is the most established which ranges from zero (no symptoms) to five (unable to walk) (Hoehn and Yahr, 1967). Mild to moderate PD represents stages zero to three on the H&Y scale.

1.1 Signs and Symptoms of Parkinson’s Disease

The signs and symptoms associated with PD are described in the categories of motor and non-motor symptoms. The cardinal motor signs of PD are resting tremor, bradykinesia, rigidity and postural instability. Motor disturbances related to PD can cause a decline in balance and mobility leading to a reduction in physical functional ability (Muslimovic et al, 2008). Non-motor symptoms such as depression, olfactory dysfunction and impaired executive function can be detrimental to health-related quality of life (HRQOL) of individuals (Martinez-Martin et al, 2011).
1.2 Treatment in Parkinson’s Disease

Medication is the first treatment choice in care for people with PD (PwPD). The largest advance in symptomatic management of rigidity, bradykinesia and tremor was the development of levodopa, a dopamine precursor that replaces the lost dopamine in the brain (Dunnett and Bjorklund, 1999). Levodopa is regarded as the gold standard in treatment of PD (Katzenschlager et al, 2008).

In addition to medication, neurosurgery is an option for some PwPD (Volkmann, 2007), involving the implantation of a deep brain stimulator into the thalamus, globus pallidus or subthalamic nucleus. This can help alleviate motor symptoms.

Even with optimal medical management, PwPD still experience a deterioration of body functions, activities of daily living (ADLs) and participation restrictions. This can lead to increased dependence on others, inactivity and social isolation, resulting in reduced quality of life. Therefore, there is a pressing need for non-medical treatment strategies, of which physiotherapy is the most applied and supported by scientific evidence (European Guidelines, 2014). Several high quality systematic reviews have evaluated the efficacy of physiotherapy and exercise in the management of PD (Keus et al, 2007; Tomlinson et al, 2012; Redecker et al, 2014). The number of publications addressing exercise for PD has tripled in the past decade, resulting in a dramatic increase in the number of exercise strategies available to PwPD (Nicolien et al, 2013).
1.4 Benefits of Different Exercise Strategies to Optimise Functional Physical Performance in PD

Functional independence and optimal physical performance is related to the capacity to perform ADLs independently (Gobbi et al, 2009). Balance and mobility are crucial to their performance. There is solid evidence that traditional exercise interventions such as balance and treadmill training improves functional ability in PwPD.

1.4.1 Balance Training

Postural instability is a cardinal feature of PD and distinguishes mild and moderate PD (Jacobs et al, 2006). Smania et al (2010) studied the effect of balance training on postural instability and found that balance training was superior to general exercise for improving balance, balance confidence and reducing number of falls. A meta-analysis of 16 trials carried out by Allen et al (2011), investigated the effect of exercise and motor training on balance and falls in PD. Results revealed that the impact of exercise and motor training indicated significantly improved balance-related activity performance especially involving programmes which included highly challenging balance training. However, the difference in effect sizes was not statistically significant (p=0.16). A Cochrane review of 39 trials found similar results to the above meta-analysis, where significant improvements in balance were achieved with physiotherapy. Despite this, it had no effect in decreasing the number of falls compared to no treatment (Tomlinson et al, 2013). Further research is required to inform therapists of the best method of balance training, its optimal dosage and its impact on falls rates.
1.4.2 Treadmill Training

The European Physiotherapy Guidelines (2014), reported strong recommendations for the use of treadmill training to improve walking speed and stride length and conveyed weak recommendations regarding walking distance and balance capacity. A Cochrane review of 10 trials supported recommendations for improved walking speed and stride length (Mehrholz et al, 2010). Treadmill training was also found to be a safe and feasible rehabilitation option (Herman et al, 2009). A recent randomised controlled trial (RCT) of 67 participants found that low intensity treadmill training (50 minutes at 40%-50% of heart rate reserve) was more effective than high intensity treadmill training (30 minutes at 70%-80% of heart rate reserve) for increasing walking capacity (Shulman et al, 2013). However, the results of this trial are only generalisable for people with mild to moderate PD and should be implemented into clinical practice with caution for people with moderate to advanced PD. Numerous trials failed to report any adverse events on the use of treadmill training which impacts on the methodological rigour of these studies.

Given the complex nature of PD-specific deficits that contribute to poor balance and gait, it is unlikely that one specific exercise type alone, such as balance or treadmill training, will necessarily improve physical performance adequately. There is a growing evidence-base investigating multifaceted exercise interventions such as Tai Chi (Hackney and Earhart, 2008), sensorimotor agility training (King and Horak, 2009) and dance (de Dreu et al, 2012) to target multiple aspects of disability.
1.4.3 Dance

Dance is receiving increased attention in the literature as it combines strategies from single exercise intervention types such as cueing, balance, strength, flexibility and aerobic exercise to form an interesting and enjoyable exercise strategy. As dance requires high-level multitasking and progressive motor skill learning, it is both physically and cognitively challenging (Duncan et al, 2012). Dance aims to improve gait, balance and mood (de Dreu et al, 2012). A wide range of international dance techniques have been researched, from American ballroom (Hackney and Earhart, 2009) to Argentine tango (Foster et al, 2013) to Irish set dancing (Volpe et al, 2013). The music provides an external rhythm, which can be considered as auditory cueing. However, dance may induce falling as it involves backward stepping. Therefore, the European Physiotherapy Guidelines for PD (2014) advise caution when selecting PwPD for tango classes. The therapist must employ sound clinical judgement, and if indicated must adapt the steps to the individuals’ impairments and activity limitations. Irish set dancing is deemed a safe and acceptable intervention (Volpe et al, 2013).

1.5 Exercise Intervention Components required for Neuroplastic Changes and Functional Physical Improvements

In addition to the benefits of traditional and multifaceted exercise interventions, there is emerging evidence indicating that exercise may also exert disease modifying effects in PD. This can be through neuroprotection or neurorestoration.

There is strong evidence from animal studies that aerobic training not only improves functional performance but also creates changes at the level of the brain itself.
Experimental rodent models of PD showed that high-intensity aerobic training increased postsynaptic D2 receptor mRNA expression and binding affinity, down regulated the dopamine transporter protein and reduced glutamate transmission and synaptic strength (Petzinger et al, 2010). Moreover, in both the 6-hydroxydopamine (6-OHDA) lesioned rat and the 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MDTP) which is a neurotoxin precursor that causes permanent symptoms in PD, high intensity treadmill training running, initiated before, during or after neurotoxicant exposure, showed an improvement in motor symptoms (Petzinger et al, 2007; Tillerson et al, 2013).

Neurochemical and neuroplastic changes are less straightforward when studying exercise interventions for humans. Nevertheless, a translational pilot study was recently published in which intensive aerobic exercise in four patients with early PD resulted in better postural control and increased postsynaptic D2 receptor binding potential on positron emission tomography (PET) imaging (Fisher et al, 2013). Functional magnetic resonance imaging (MRI) performed after a single bout of forced exercise revealed the same change in network activation pattern as that seen between medication states (Alberts et al, 2011). Similar results were observed in PwPD with transcranial magnetic stimulation after high-intensity treadmill training, whereby reduced cortical hyperexcitability (which is characteristic for the parkinsonian state) was found (Fisher et al, 2008).

Another indirect measure of neuroplasticity in dopaminergic signalling can be provided by changes in the levodopa-equivalent dose. One randomised controlled
study reported that a four week inpatient rehabilitation programme of 50 participants resulted in a long-lasting decrease in medication usage over a two year period (Frazzitta et al, 2012). These findings suggest that the natural worsening of symptoms associated with PD can be effectively counteracted by a properly designed intensive rehabilitation programme. However, further studies are warranted in this area to substantiate these results.

Generalisation of motor learning is another way of looking at cerebral motor plasticity. Three phases of motor learning are distinguished. Firstly, acquisition involves considerable improvement across several sessions of practice. Automatisation occurs when skilled behaviour requires minimal cognitive resources which are stable of time and resistance to interference such as dual tasking. Finally, retention is seen when motor skills are readily executed without further need of practice on the task. Even though limited, several studies have shown that PwPD are capable of motor learning (Nieuwbower et al, 2009; Rochester et al, 2010). The ability to learn a novel skill may be preserved by compensation of the basal ganglia dysfunction with activation of other brain structures such as the cerebellum (Pendt et al, 2011). The potential for learning is believed to diminish over the disease course, whereby the greatest potential for learning may be gained at H&Y stages one to three (Abbruzzese et al, 2009). In general, PwPD benefit from practice, but require an augmented training dose and intensity in comparison to their age-matched healthy counterparts (Soliveri et al, 1992).
1.6 Neuroplasticity-Principled Exercise Interventions that Optimise Functional Physical Improvements

Two novel treatment approaches called Lee Silverman Voice Training BIG (LSVT BIG) (Farley et al, 2008) and Parkinson’s Wellness Recovery (PWR!) (Krasteva et al, 2015), propose to translate data from animal models of PD to a neuroplasticity-principled model of rehabilitation for the treatment of human PD (Fox et al, 2012).

LSVT BIG uses training of big amplitude movements, high intensity, sensory recalibration, functional mobility training and patient specific salient goals as its focus for rehabilitation. It is designed to promote neuroplasticity and neuro-restoration (Farley et al, 2008; Fox et al, 2012). The delivery protocol for this programme constitutes 16 treatment sessions. The individual receives four individualised training sessions a week which is progressed over the course of four weeks (Farley et al, 2008). A recent perspective article which included 12 systematic reviews and meta-analysis (Nicolein et al, 2013) and the European Physiotherapy Guidelines for PD (2014), recommend this exercise approach for targeting gait, balance, transfers and physical capacity.

To date, only four studies on the effectiveness of LSVT BIG have been published. Farley et al (2005), conducted the first “Training BIG” trial, a noncontrolled study, which assessed the effects of two conditions of velocity on walking and reaching movements. The methodological quality of this study is severely inadequate. Firstly, the trial design is poor. An RCT which is the most scientifically rigorous method of hypothesis testing would have enhanced the robustness of this study. Eighteen
subjects volunteered to participate in the study, however, there is no reference as to why the authors chose this number, nor was a sample size calculation carried out. This inadequacy limits the validity of the study. The description of the Training BIG intervention is vague which impacts on the study’s reproducibility. None of the outcome measures utilised were PD-specific measures which is limiting. However, they were tested by blinded examiners which reduces bias to the results. Despite this, results revealed that training of amplitude in people with PD resulted in faster upper and lower limb movements especially in people with mild PD.

Ebersbach et al (2010), addressed the issue of poor trial design by carrying out the first RCT comparing LSVT BIG with Nordic walking and a domestic nonsupervised exercise programme. However, the methodology section is poorly described. Randomisation was conducted by “drawing lots” to one of the three intervention groups. The authors failed to mention vital information regarding the transparency of the randomisation process. There was no reference made to sequence generation, allocation concealment or who enrolled the participants. As seen in the previous study, the authors did not address how their sample size was determined or calculated. Thirdly, a bias was evident in favour of the LSVT BIG intervention which constituted one-to- one therapy time, whereas, the other interventions were in a group or nonsupervised setting. Despite several methodological discrepancies, the authors concluded that training LSVT BIG led to a clinically relevant improvement in motor performance in the primary outcome measure Unified Parkinson Disease Rating Scale (UPDRS-III) and also in secondary outcomes of gait speed and distance.
The same author conducted an RCT comparing LSVT BIG and a shorter training protocol of 10 treatment sessions (Ebersbach et al, 2014). Clinically significant results for the UPDRS-III were obtained for both protocols. However, the authors recommended that the higher intensity protocol was recommended as it was more effective in obtaining patient-perceived benefit. Once again, numerous methodological flaws are evident in this study as no changes were made to the methodological process from the previous study. The need for improvement of methodological quality of trials in physiotherapy for PD is highlighted in various systematic reviews (Tomlinson et al, 2012).

Dashtipour et al (2015) conducted a double-blinded RCT assessing the effects of LSVT BIG versus a general exercise programme on motor and non-motor symptoms of PD. This study did not adhere to numerous CONSORT recommendations which impacts greatly on the trial’s methodological quality. In this study, patients were randomly assigned to either the LSVT BIG group or the exercise group. No further explanation was provided regarding the randomisation method or procedure. An extremely small sample size of 11 participants was recruited, with no mention of how this sample size was determined. The authors attempted to improve on the bias seen in Ebersbach’s work by providing one to one therapy time for both groups. The trial was not able to detect a difference between the two exercise groups but showed that general exercise was as effective as LSVT BIG therapy in managing motor and non-motor symptoms.
Numerous limitations of the LSVT BIG programme have been highlighted (Fox et al, 2012). For example, additional dose-response relationships need to be established and also the practical feasibility of delivering 16 sessions in four weeks and for clients to be able to commit to this needs to be addressed.

The author and her colleague had previously carried out an individualised pilot LSVT BIG programme on one individual in an acute hospital setting which yielded positive outcomes on mobility, balance, dual-tasking and quality of life. However, there were numerous barriers to conducting this intensive individualised programme which supports the limitations outlined by Fox et al, (2012). The physiotherapy manager could not justify another programme to be conducted due to limited staff resources. This motivated the author to address a gap in the literature regarding the feasibility and efficacy of a group exercise large-amplitude class for people with mild to moderate PD.

1.7 Benefits of Group Exercise for People with Parkinson’s Disease

The European Physiotherapy Guidelines for PD (2014), recommend group exercise programmes as an effective mode of exercise delivery. A group delivery format significantly reduces both the burden on staffing levels and the cost to implement, making it economically viable to be delivered (Rodrigue et al, 2006). Group exercise studies in PwPD have shown efficacy in physical performance outcomes, high attendance rates and improved mood (Sage et al, 2009). An RCT comparing a home-based exercise intervention to a combined home and group exercise program over 12 weeks found that both groups improved their motor function and HRQOL but that the combined group had significantly greater improvements, especially in mental
health benefits (Helbostad et al, 2004). The positive elements from group programmes may be due to the physical exercise, the social interactions, motivation of the group environment or a combination of these factors. However, intervention delivered in a group format may not be as specific to the needs of the individual participant and attention from the instructor is reduced compared to individual therapy. One key benefit of group exercise programs is that they resemble the types of ongoing community programs that clients will likely participate in after completing an acute hospital-based programme (European Guidelines, 2014).

Another innovative neuroplasticity-principled exercise programme that has been gaining increased interest by the Movement Disorders Society and the literature is the Parkinson’s Wellness Recovery (PWR!) Programme. This programme was developed by the co-founder of LSVT BIG and is modelled on the LSVT BIG programme. However, the contrasting feature of the PWR! Programme is that it incorporates principles of group exercise training into its intervention. Dr. Becky Farley who is a co-founder of LSVT BIG opened a PWR! Gym in Arizona in 2012. Unfortunately, there has been no RCT carried out to date to determine the efficacy of this treatment approach. Preliminary research, although inadequate in its methodology and study design (quasi-experimental pre-post intervention study), demonstrated that the PWR! programme resulted in statistically significant increases in functional mobility and balance outcomes (p<0.01) as measured by the six minute walk test (6MWT), functional gait assessment (FGA) and the timed up and go test (TUAG). However, results were not maintained at a one month follow-up and there was an inadequate reporting of adverse events and drop-out rates (Krasteva et al,
This author was informed that an RCT incorporating elements of the PWR! Programme will be conducted in the immediate future. It is clear that the main limitation of the PWR! Programme is the lack of explicit research to determine its effectiveness and relevance in clinical practice.

1.8 Conclusion

Exercise is a proven beneficial adjunct in the management of PD and a wide range of exercise interventions are currently being adopted in clinical practice. Emerging evidence has demonstrated that neuroplasticity-principled approaches and novel restorative rehabilitation interventions such as LSVT BIG and PWR! are yielding improvements in functional physical outcomes. However, the number of published LSVT BIG trials are scarce and the methodological quality is inadequate. The European Physiotherapy Guidelines for PD strongly recommend that physiotherapists provide group exercise training for PwPD. It has the combined effects of being economically viable, improving physical performance outcomes, increasing attendance rates, improving mood and enhancing social engagement. Considering that LSVT BIG is an individualised and copyrighted protocol, and that PWR! requires additional scientific evaluation, the author proposed to test the feasibility and efficacy of a large-amplitude group exercise class adopting principles of both LSVT BIG and PWR! programmes.
CHAPTER 2                     METHODOLOGY

2.1 Aims and Objectives

The aim of this study was to assess the feasibility of a six week large-amplitude group exercise class on physical functional performance in individuals with mild-moderate PD.

Objectives

To determine if a one hour six weekly large amplitude group-exercise class incorporating a daily home exercise programme:

1) Is feasible and safe to carry out both in a hospital setting and a home environment as measured with an adverse events form.

2) Improves physical functional performance measures of balance, gait, functional mobility and exercise tolerance with mild to moderate PD as measured with the Six Minute Walk Test (6MWT), Dynamic Gait Index (DGI) and Timed Up and Go Test (TUAG).

3) Improves health related quality of life (HRQOL) using the Parkinson’s Disease Questionnaire-39 (PDQ-39).

4) Yields participant satisfaction as measured with a satisfaction questionnaire.

5) Facilitates exercise motivation and adherence as measured with a daily home exercise logbook.
2.3 Study Design

2.3.1 Study Design

A pretest-posttest single study pilot design was selected to address the research question. The reason for this choice of study design over a quasi-experimental design or an RCT, was due to the limited resources and participants available to the principal investigator (PI). The Physiotherapy Manager of Naas General Hospital (NGH) could not support the time for other members of staff to assist with the research study. Also, with a limited number of PwPD on the neurology database in the hospital, recruitment was not possible for the larger numbers required for an RCT.

2.3.2 Statistical Powering

A sample size of 24 participants was required to demonstrate a statistically significant treatment effect of the intervention. As there is no minimum clinically important difference (MCID) for the primary outcome measure of the 6MWT for PwPD, the PI utilised a sample size power calculation from a PD quasi-experimental study (Lauhoff et al, 2013). A sample size of 24 was sought to show an increase of 82 metres (minimal detectable change) on the 6MWT with an α of 5% and a power of 80%.
2.4 Participants

2.4.1 Recruitment

Individuals with mild to moderate PD were recruited from both the outpatient neurology waiting list and an established PD review database in NGH. Day Hospital patients were excluded from this study as they exhibited moderate to severe symptoms of PD. A substantial number of individuals from the PD database had attended for physiotherapy intervention and a PD class in the past, however, individuals who had received physiotherapy input for PD in the previous three months were excluded. The remaining individuals were newly diagnosed and had received no previous physiotherapy intervention. All potentially eligible participants were sent an invitation letter (Appendix 1) from the Deputy Physiotherapy Manager who acted as gatekeeper for the research study, inviting them to participate in the research programme. The invitation letter was accompanied by a patient information leaflet (Appendix 2) and consent form (Appendix 3) which outlined the purpose and nature of the study. The participants had seven days to decide whether they wished to participate in the research study. After one week, the PI contacted the potential participants by telephone to verify eligibility and to schedule baseline assessment appointments. Verbal consent was gained over the phone with formal written consent obtained at the baseline assessment. Recruitment took place over six weeks from early September to mid-October.

2.4.2 Inclusion and Exclusion Criteria

Inclusion Criteria:

- Diagnosis of Idiopathic PD diagnosed by a Consultant Neurologist.
• Disease severity measured on the Hoehn and Yahr Scale of 1-3 (Appendix 4)
• Independently mobile with or without a gait aid.
• Ability to give informed consent and follow simple commands.

Exclusion Criteria:

• Diagnosis of Non-Idiopathic PD.
• Unstable cardiovascular disease.
• Uncontrolled chronic condition including rheumatological and musculoskeletal conditions
• Confirmed diagnosis of a dementia or a PD related dementia.
• Any previous physiotherapy input for PD in the previous three months.

2.5 Ethical Considerations

2.5.1 Ethical Approval

Ethical approval was obtained from the Research Ethics Committee (REC) in NGH on the 29th June 2015 (Appendices 5 & 6). The Royal College of Surgeons of Ireland REC accepted the ethical approval granted by NGH for this study on the 1st September 2015; REC1118 (Appendix 7).

2.5.2 Ethical Issues

2.5.2.1 Informed Consent

The ability to give informed consent was stipulated in the inclusion criteria. Verbal consent was gained over the phone when the PI contacted potentially eligible
participants. Written consent (Appendix 3) was obtained at the baseline assessment meeting.

The patient information leaflet clearly outlined that no individual was under any obligation to partake in the research study. Participation was voluntary and participants had the opportunity to withdraw at any time. The routine management of those who did not wish to participate or those who withdrew from the class was not affected in any way.

2.5.2.2 Confidentiality

Confidentiality of participants’ identity was maintained throughout the course of the study. Appropriate measures were undertaken to ensure confidentiality of the collected data. All participants were provided with a unique identifier number. This was kept in a separate file and location to the hard data and electronic data. Only the PI had access to the “key” to these codes. All electronic data was coded and stored on the PI password protected computer in the physiotherapy department. The hard copy records of data were stored in a locked filing cabinet in the physiotherapy department in NGH.

2.5.2.3 Safety Considerations

As with any exercise intervention, there is a very small risk of falls or injury, however, the participants were supervised at all times and an environmental risk assessment was conducted as per usual care prior to each class. Group exercise classes are part of routine care for this cohort of patients.
2.6 Assessments

To minimise the possibility of assessor bias and a threat to instrument internal validity, a blinded assessor carried out baseline and post intervention assessments. As the Physiotherapy Manager could not support physiotherapy staff to carry out the assessments, a University College Dublin (UCD) undergraduate student, who was under the guidance of a hospital clinical tutor, was selected to act as blinded assessor. The same student was granted permission from UCD to return to NGH and carry out the post intervention assessments. Appropriate instructions and training for undertaking the outcome measures was provided by the PI. Assessments were carried out in the physiotherapy gym in NGH and took approximately 30-35 minutes to complete. Pre and post intervention assessments were carried out at the same time and on the same day to ensure consistency with the timing of medication dose and assessment time. This is in keeping with recommendations from research stating that there is an under-reporting from authors about medication and assessment timing, as true results may not be obtained if consistency is not adhered to (Kwakkel et al, 2007).

2.7 Outcome Measures

2.7.1 Feasibility Outcome Measures

A feasibility study is a small study for helping to design a further confirmatory study (Arnold et al, 2009). Thebane et al (2010) recommend that the outcome measures cited below are utilised when conducting feasibility studies.

1) Safety: This was monitored using weekly adverse events forms both during the exercise class and for participants to fill out at home (Appendix 8 and 9).
2) Exercise Compliance: This was assessed by monitoring the weekly compliance of the participants home exercise logbook (Appendix 10).

3) Adherence Rates: This was evaluated using weekly attendance records (Appendix 11).

4) Retention Rates: This was evaluated by comparing the proportion of participants who attended for baseline assessments against the proportion of participants who attended for post intervention assessment.

5) Participant Satisfaction: This was evaluated using a non-validated satisfaction questionnaire that was specifically designed for the research study (Appendix 12).

### 2.7.2 Clinical Outcome Measures

A variety of outcome measures that addressed the disability associated with PD at all levels of the International Classification of Functioning, Disability and Health (ICF) framework (Gubella and Andrew, 2002), were used in this study.

#### 2.7.2.1 Primary Outcome Measure

The primary outcome measure used in this study was the 6MWT which is a validated tool used to measure gait and exercise tolerance (American Thoracic Society, 2002) (Appendix 13). It reflects aerobic endurance, speed, balance and agility during ambulation (Garber and Friedman, 2003). It measures the maximal distance that a patient can walk at a self-paced speed, on a flat hard surface during a six-minute period. Participants were required to walk up and down a 10 metre corridor, incorporating the important functional component of turning during the assessment.
(Morris et al, 2001). The number of lengths completed was recorded, along with any additional distance covered at the end of the assessment. The 6MWT has been shown to have excellent test-retest reliability for PwPD, with an interclass correlation coefficient of 0.96 (Steffen and Seney, 2008). Unfortunately, there is no MCID or cut-off score established for this population. In a systematic review carried out by Tomlinson et al, (2012) the authors considered that a 13 metre increase in distance would probably be of clinically importance. However, it must be emphasised that this is only an educated opinion and that caution must be exercised when interpreting this information. A minimal detectable change (MDC) of 82 metres is established (Steffen and Saney, 2008).

2.7.2.2 Secondary Outcome Measures

Impairment

2.7.2.2.1 Movement Disorder Society-Unified Parkinson Disease Rating Scale Part II and III (MDS-UPDRS II & III)

The MDS-UPDRS is a common PD research tool that is used to assess the severity of motor symptoms (Goetz et al, 2008) (Appendix 14). It consists of four sections, whereby separate sections are commonly analysed in research (Goetz et al, 2008). In this study, part two (motor impact of experiences of daily living) and part three (motor examination) were measured. This scale has high internal consistency and high correlation with the original UPDRS scales. It has no established standard error of measurement, MDC, MCID or cut-off scores despite being recommended as the gold standard outcome measure for PD in research. However, normative data is available for the four separate sections (Goetz et al, 2008).
2.7.2.2 Timed Up and Go Test (TUAG)

The TUAG (Appendix 15) has been identified as a reliable and valid test of functional mobility in the elderly (Podsiadlo and Richardson, 1991) and has been shown to have both excellent test-retest reliability and inter-rater reliability when used with PwPD (ICC=0.99) (Morris et al, 2001). It requires an individual to stand up from a chair, walk a distance of three metres, turn around, walk back to the chair and sit down again. The time taken to complete this task is recorded with a stopwatch in seconds. However, there is ambiguity in the literature regarding its MDC. Dal Bello-Haas et al (2011) reported 4.85 seconds whereas, Steffen & Seney (2008) reported 11 seconds. This ambiguity may be attributed to the higher mean age and disease severity in the second study. This is a useful tool for predicting falls risk in the PD population with a cut-off score of 11.5 seconds (Nocera et al, 2013).

2.7.2.3 Dynamic Gait Index (DGI)

The DGI assesses an individual’s ability to modify balance while walking in the presence of external demands (Appendix 16). A maximum score of 24 points can be achieved. Eight tasks are assessed; steady state walking, walking with changing speeds, walking with head turns both horizontally and vertically, walking while stepping over and around obstacles, walking while stepping over and around obstacles and finally pivoting while stair climbing. It has an adequate discriminative ability between fallers and non-fallers based on a cut-off score < 19 (sensitivity = 0.64, specificity = 0.85) (Dibble et al, 2008). A MDC of 2.9 points has been
established (Huang et al, 2011). The DGI has been recommended for use by the European Physiotherapy Guidelines for PD (2014) for dynamic balance assessment.

**Participation Restriction**

2.7.2.2.4 Parkinson’s Disease Questionnaire-39

The PDQ-39 is a well-established and validated questionnaire that is used to evaluate the aspects of function and well-being that can be adversely affected by PD (Peto et al, 1998) (Appendix 17). The questionnaire includes 39 questions and involves 8 different dimensions. A total score of 156 can be achieved. A higher score indicates an increased impact of PD symptoms. The dimensions include mobility (10 items), activities of daily living (6 items), emotional well-being (6 items), stigma (4 items), social support (3 items), cognition (4 items), communication (3 items) and bodily discomfort (3 items). The Single Index Score (SI) indicates a global impact of PD symptoms on quality of life. The questionnaire is intended to be a self-completed instrument (Jenkinson et al, 1998). The PDQ-39 has been shown to have satisfactory internal consistency and reliability of the eight dimensions (Peto et al, 1995). Jenkinson et al, (1997) showed that internal consistency remains high. The MCID and normative data for each subsection have been established for this cohort group (Peto et al, 2008).

2.8 Intervention

The large-amplitude group exercise programme involved attendance of participants at one class a week for six weeks in the physiotherapy gym in NGH. The treatment
intervention lasted one hour and participants were encouraged to exercise at a high intensity (between 13-17 on the BORG Scale) for the duration of the class. The format of the class consisted of a warm up period, large-amplitude stretches, large-amplitude functional exercises, large-amplitude walking, and a cool down period. The PI conducted the exercise intervention. Exercises were progressed weekly in terms of intensity, frequency, speed and complexity. In this way, the exercise programme adhered to several key principles which are shown to enhance neuroplasticity in PD (Fox et al, 2006). The PI provided constant verbal feedback to encourage participants to use large amplitude movements for the duration of the class. Family members were permitted and encouraged to attend the class to ensure that the correct exercise technique was carried over at home. The European Physiotherapy Guidelines for PD (2014), recommend involving family members with goal planning and intervention sessions. Participants were also instructed to complete a daily home exercise logbook. Appropriate resources such as an exercise photo pack (Appendix 18), an exercise DVD and a YouTube video link (Appendix 19) were provided to assist with exercise motivation and compliance. A maximum of six participants took part in each class.

2.9 Statistical Methods

2.9.1 Data Collection

A data collection form was developed by the PI to record demographic details such as medical history, medications, functional status, falls history and previous physiotherapy treatment for PD. A list of the feasibility outcomes and a clinical
outcome measurement table was attached at the bottom of the form. The blinded assessor completed this section of the form (Appendix 20).

2.9.2 Statistical Analysis

Descriptive statistics were used to describe baseline demographic information and feasibility measures. To establish if there was a significant difference in clinical scores from pretest to post-test assessments, a paired t-test was used to assess parametric data and a Wilcoxon signed-rank test was used to evaluate non-parametric data. Statistical Package for the Social Sciences (SPSS) Version 22 software package was used for statistical analysis.
CHAPTER 3 RESULTS

3.0 Introduction

The aim of this study was to assess the feasibility of a six week large-amplitude group exercise class on physical functional performance in individuals with mild-moderate Parkinson’s Disease (PD). The objectives were to determine if this programme which incorporated an intensive home exercise programme (HEP) is feasible and safe to conduct in an acute hospital and in the participant’s home, improve functional mobility and balance, yield satisfaction and thus improve health-related quality of life (HRQOL).

The feasibility outcomes measures of interest were:

1) Safety: Monitored using adverse events forms in hospital and at home.
2) Exercise Compliance: Evaluated completion of daily exercise logbooks.
3) Adherence Rates: Evaluated weekly attendance records.
4) Retention Rates: Evaluated the proportion of participants who attended for post assessment against the proportion who attended for baseline assessment.
5) Satisfaction: Evaluated using a non-validated satisfaction questionnaire.

The primary clinical outcome measure was the Six Minute Walk Test (6MWT). The secondary clinical outcome measures of interest were:

1) Movement Disorder Society-Unified Parkinson’s Disease Rating Scale (MDS-UPDRS Part 2 (motor experiences of daily living ADLs) and Part 3 (motor examination).
2) Timed Up and Go Test (TUAG).
3) Dynamic Gait Index (DGI).
4) Parkinson’s Disease Questionnaire-39 (PDQ-39).
3.1 Screening and Eligibility

3.1.1 Screening

Recruitment took place from early September 2015 to mid-October 2015. In total, 35 individuals were invited to participate in the research study. Nine individuals declined to participate with reasons displayed in Figure 3.1.

3.1.2. Excluded Participants

Two participants were excluded as they did not fulfil the eligibility criteria. This was due to uncontrolled chronic musculoskeletal and psychiatric conditions. Two participants required one-to-one intervention due to a background of intellectual disability.

3.1.3. Withdrawal and Drop-Outs Prior to the Study

One participant agreed to participate but declined the day before commencement of the study.
Figure 3.1 Participant Flow Diagram

Invited to Participate (n=35)

Declined to Participate (n=9)
  • Transport issues (n=1)
  • Too busy with other hospital appointments (n=2)
  • Unwell (n=2)
  • Husband unwell and main carer (n=2)
  • Going on holidays (n=1)
  • Suffering with panic attacks (n=1)

Assessed for Eligibility (n=26)

Excluded (n=4)
  • Did not meet inclusion criteria (n=2)
  • Required 1:1 intervention (n=2)

Withdrawal (n=1)
  • Had not accepted PD Diagnosis and was not ready to join a PD Exercise Class

Study Group (n=21)

Analysed (n=18)

Lost to follow-up (n=3)
  Medically unwell
3.2 Baseline Characteristics of Participants

This section contains baseline descriptions of the 18 participants who completed post intervention assessments.

3.2.1 Gender

The study sample consisted of 13 males and 5 females.

3.2.2 Age

The mean age of the group was 69.17 years with a standard deviation (SD) of 7.91 years (range 56 to 83 years). The median age of the group was 72 years with an interquartile range of 13 years.

Figure 3.2: Age Statistics
3.2.3 Months since Diagnosis

The mean number of months since diagnosis was 74.22 with a SD of 55.96 months. The range varied significantly from 6 months to 19 years.

![Box plot showing months since diagnosis](image)

**Figure 3.3 Months since diagnosis**

3.2.4 Hoehn and Yahr Scale

Disease severity ranged from one to four on the Hoehn and Yahr (H&Y) PD rating scale. The mean H&Y score was 1.78 with a SD of 1.01. Table 3.1 describes the group in more detail.
Table 3.1 Hoehn and Yahr Scale

<table>
<thead>
<tr>
<th>Hoehn and Yahr Stage</th>
<th>Number of Participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 (55.5%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (17%)</td>
</tr>
<tr>
<td>3</td>
<td>4 (27.5%)</td>
</tr>
</tbody>
</table>

3.2.5 Medication

All participants were taking PD specific medication (Figure 3.4) with the majority of participants on a form of levodopa therapy (85%).

MAO-B: Monoamine oxidase-B. COMT: Catechol-O-methyl transferase

Figure 3.4 Use of PD specific medication in the study sample
3.2.6 Mobility Status

All participants were independently mobile. The majority of participants did not require any walking aid (88.88%). One participant who score a 3 on the H&Y Scale used a three-wheeled walker (6.11%) and one participant used a walking stick (6.11%) to aid their mobility.

![Mobility Status Chart]

**Figure 3.5 Mobility Status**

3.2.7 History of Falls in the six months prior to the study

A small minority of participants sustained a fall in the six months prior to commencing the study, whereby two participants (11%) reported sustaining one fall and one participant (5.5%) had sustained two falls.
3.3 Baseline Outcome Measures

The baseline outcome measures were administered by a third year physiotherapy student who was blinded to the study. The student had no affiliation to the study and all participants’ names were anonymous. The baseline descriptive statistics of the outcome variables are presented in Table 3.2 below.

Table 3.2 Baseline Outcome Measures

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Study Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>6MWT (metres)</td>
<td>367.61</td>
</tr>
<tr>
<td>MDS-UPDRS 2 (0-52)</td>
<td>10.70</td>
</tr>
<tr>
<td>MDS-UPDRS 3 (0-132)</td>
<td>23.44</td>
</tr>
<tr>
<td>TUAG (secs)</td>
<td>9.14</td>
</tr>
<tr>
<td>DGI (0-24)</td>
<td>19.50</td>
</tr>
</tbody>
</table>

6MWT: Six Minute Walk Test, MDS-UPDRS 2: Movement Disorder Society Unified Parkinson’s Disease Rating Scale (ADL Section), MDS-UPDRS 3: (Motor examination Section). TUAG: Timed Up and Go Test, DGI: Dynamic Gait Index.
### 3.3.1 Parkinson’s Disease Questionnaire-39

The PDQ-39 is a self-reported PD questionnaire of HRQOL. The baseline measures of each subsection and the index score are described in Table 3.3 below.

**Table 3.3 Baseline Parkinson’s Disease Questionnaire-39**

<table>
<thead>
<tr>
<th>PDQ-39 (0-156)</th>
<th>Study Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Mobility (40)</td>
<td>14.86</td>
</tr>
<tr>
<td>Activities of Daily Living (24)</td>
<td>18.71</td>
</tr>
<tr>
<td>Emotions (24)</td>
<td>12.93</td>
</tr>
<tr>
<td>Stigma (16)</td>
<td>7.30</td>
</tr>
<tr>
<td>Social Support (8)</td>
<td>8.78</td>
</tr>
<tr>
<td>Cognition (16)</td>
<td>17.70</td>
</tr>
<tr>
<td>Communication (12)</td>
<td>10.62</td>
</tr>
<tr>
<td>Body Discomfort (12)</td>
<td>23.57</td>
</tr>
<tr>
<td>Parkinson’s Disease Summary Index</td>
<td>14.27</td>
</tr>
</tbody>
</table>
3.4 Post Intervention Outcome Measures

3.4.1 Feasibility Outcome Measures

3.4.1.1 Safety

Weekly adverse events forms were completed by the Principal Investigator (PI) for the six week large-amplitude group exercise programme. Adverse events constituted any undesired outcome resulting from the large-amplitude training such as sustaining a fall, injuring a limb, laceration, pain and muscle soreness. No participant (0%) reported or sustained any adverse events as a result of carrying out the exercise programme in the acute hospital setting. Participants completed daily adverse events forms at home while carrying out their large-amplitude HEP. Results were calculated by measuring the number of adverse events reported over the total number of exercises logged in the exercise logbook. Table 3.4 displays these results.

Table 3.4 Adverse events carrying out the exercise programme at home

<table>
<thead>
<tr>
<th>No of Participants (n=18)</th>
<th>Adverse Events Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>5</td>
<td>20% (Muscle Soreness)</td>
</tr>
<tr>
<td>3</td>
<td>10% (Muscle Soreness)</td>
</tr>
</tbody>
</table>

3.4.1.2 Exercise Compliance

Exercise compliance encompassed compliance in completing both the daily home exercise logbook and daily use of the exercise resource pack (Photo pack, DVD and YouTube link). These were reviewed weekly by the PI. Results are displayed in Figures 3.6 and 3.7.
Figure 3.6 Compliance completing Home Exercise Logbook
Level of Compliance: Excellent=>80%, Very Good=70-80%, Good=60-70%, Satisfactory=50-60%, Poor=40-50%

Figure 3.7 Compliance utilising the Exercise Resource Pack
Level of Compliance: Excellent=>80%, Very Good=70-80%, Good=60-70%, Satisfactory=50-60%, Poor=40-50%
3.4.1.3 Adherence Rates

The mean number of classes attended by the study group was five. Attendance ranged from three to six classes. Figure 3.8 elaborates further on adherence rates.

![Figure 3.8 Adherence Rates](image)

3.4.1.4 Retention Rates

Twenty-one participants completed baseline assessments. Three participants had to withdraw during the course of the study due to medical and pre-existing musculoskeletal issues. Of the eighteen participants who completed the remaining classes 100% attended for post-treatment assessments.
### 3.4.1.5 Satisfaction

#### Table 3.5 Satisfaction Questionnaire of six week large-amplitude exercise class

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree or Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found the programme beneficial</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>44.44</td>
<td>55.56</td>
</tr>
<tr>
<td>I found the frequency of the class adequate (x1/week)</td>
<td>5.55</td>
<td>22.22</td>
<td>11.11</td>
<td>50</td>
<td>16.66</td>
</tr>
<tr>
<td>The duration of the class (1 hour) was too long</td>
<td>16.66</td>
<td>55.55</td>
<td>11.11</td>
<td>11.11</td>
<td>5.55</td>
</tr>
<tr>
<td>After the exercise programme, I am able to walk for longer distances</td>
<td>0</td>
<td>5.55</td>
<td>27.77</td>
<td>44.44</td>
<td>22.22</td>
</tr>
<tr>
<td>After the exercise programme, my ADLs such as doing the house chores and shopping are easier to manage</td>
<td>0</td>
<td>11.11</td>
<td>38.88</td>
<td>27.77</td>
<td>22.22</td>
</tr>
<tr>
<td>After the exercise programme, I feel steadier on my feet</td>
<td>0</td>
<td>5.55</td>
<td>22.22</td>
<td>50</td>
<td>22.22</td>
</tr>
<tr>
<td>My mood has improved after completion of the programme</td>
<td>0</td>
<td>5.55</td>
<td>37.77</td>
<td>38.88</td>
<td>22.22</td>
</tr>
<tr>
<td>The exercise resources (Photo-pack, DVD, YouTube link) motivated me to exercise at home</td>
<td>0</td>
<td>5.55</td>
<td>16.66</td>
<td>44.44</td>
<td>33.33</td>
</tr>
</tbody>
</table>

**Please Circle which Resource you found most beneficial:**

<table>
<thead>
<tr>
<th>Photo-Pack</th>
<th>DVD</th>
<th>YouTube Video</th>
<th>None Of the Above</th>
<th>27.77</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.55</td>
<td>50</td>
<td>11.111</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The Home Exercise Programme was difficult to carry out at home because it was too long to carry out</th>
<th>33.33</th>
<th>50</th>
<th>5.55</th>
<th>5.55</th>
<th>n/a</th>
</tr>
</thead>
<tbody>
<tr>
<td>I will continue to practice my daily home exercise programme when the programme has finished</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>55.55</td>
<td>44.44</td>
</tr>
<tr>
<td>I feel that exercising in a group setting is more enjoyable than exercising one-to-one (physiotherapist and individual)</td>
<td>n/a</td>
<td>16.66</td>
<td>5.55</td>
<td>38.88</td>
<td>33.3</td>
</tr>
<tr>
<td>I would recommend this exercise programme to others</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>33.33</td>
<td>66.66</td>
</tr>
<tr>
<td>My exercise habits are going to change after the programme</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>
3.4.2 Primary Outcome Measure: Six Minute Walk Test

The mean score for the 6MWT at baseline (T1) was 367.61 metres (m) with a SD of 88.64 (range 227-546m). The mean score for the 6MWT at post intervention assessment (T2) was 405.28m with a SD of 81.12 (range 250-540m).

A paired t-test was used to determine if there was a significant difference in the change in mean scores from T1 to T2 for the 6MWT. This statistical test was utilised as the data were normally distributed.

There was a statistically significant change between T1 and T2 (mean change -37.67m, SD=39.77, 95% CI, (-57.45, -17.89), p=0.01) for the 6MWT following the six week large-amplitude group exercise intervention programme. Figure 3.9 describes scores at T1 and T2.

Figure 3.9 6MWT Scores at T1 and T2 for the Study Group
3.4.3 Secondary Outcome Measures

3.4.3.1 Impairment MDS-UPDRS

The MDS-UPDRS is a PD rating scale designed to monitor the burden and extent of PD. Two sub-categories of the MDS-UPDRS were used in the study sample. Part Two measures self-reported motor experiences of daily living and consists of 13 items. A maximum score of 52 can be achieved. Part Three measures the motor examination and consists of 18 items. A maximum score of 132 can be achieved. The mean score for the MDS-UPDRS Part 2 at T1 was 10.67 with a SD of 4.83 (range 1-22). The mean score for the MDS-UIPDRS Part 2 at T2 was 10.00 with a SD of 5.27 (range 1-18).

A paired t-test was used to determine if there was a significant difference in the change in mean scores from T1 to T2 for the MDS-UPDRS Part 2. The mean change between T1 and T2 was 0.667 with a SD of 5.5, 95% CI, (-1.85, 3.18) and a p value of 0.583. This indicates that there was no statistically significant improvement in self-reported motor experiences of daily living. Figure 3.10 displays these scores.

Figure 3.10 MDS-UPDRS Part Two scores at T1 and T2
The mean score for the MDS-UPDRS Part 3 at T1 was 23.44 with a SD of 14.13 (range 8-58). The mean score for the MDS-UPDRS Part 3 at T2 was 19.72 with a SD of 12.69 (range 4-52).

A paired t-test was used to determine if there was a significant difference in the change in mean scores from T1 to T2 for the MDS-UPDRS Part 3. The mean change between T1 and T2 was 3.72 with a SD of 6.99, 95% CI, (.244, 7.2) and a p value of 0.04. This indicates that there was a statistically significant improvement with a p-value of <0.05. Figure 3.11 displays MDS-UPDRS Part 3 scores at T1 and T2.

Figure 3.11 MDS-UPDRS Part Three scores at T1 and T2
3.4.3.2 Activity Limitations

3.4.3.2.1 Timed Up and Go Test

The standard version of the TUAG test was included in this study. The median score for the TUAG in seconds at T1 was 8.99 with an interquartile range (IRQ) of 3.2 (range 5.59-15.22secs). The median score for the TUAG at T2 was 7.63 with an IRQ of 3.7 (range 5.12-14.97secs).

A Wilcoxon-signed rank test was used to determine if there was a significant difference in the change in median scores from T1 to T2 for the TUAG as data were not normally distributed.

The median change between T1 and T2 was p<0.01 which implies that there was a significant difference between T1 and T2 as a result of the intervention.

Figure 3.12 TUAG Scores at T1 and T2 for the Study Group
3.4.3.2.2. Dynamic Gait Index

The DGI assesses an individual’s ability to modify balance while walking in the presence of external demands. A maximum score of 24 can be achieved with a higher score indicating enhanced balance performance.

The median score for the DGI at T1 was 20 with an IRQ of 5 (range 14-24). The median score for the DGI at T2 was 22.5 with an IRQ of 4 (range 14-24).

A Wilcoxon-signed rank test was used to determine if there was a significant difference in the change in median scores from T1 to T2 for the DGI.

The median change between T1 and T2 was p<0.01 which implies that there was a significant difference between T1 and T2 as a result of the intervention.

Figure 3.13 DGI Scores at T1 and T2 for the Study Group
Summary of Outcome Measures at T2

Table 3.6 displays the change in mean or median scores between groups from T1 to T2 and the subsequent p-values and 95% Confidence Intervals (where indicated).

Table 3.6 Change in score from T1 to T2

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Mean (SD) change scores from T1-T2</th>
<th>Median (IRQ) change scores from T1-T2</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MWT</td>
<td>-37.67 (39.77)</td>
<td>N/A</td>
<td>-57.45,-17.88</td>
<td>0.01</td>
</tr>
<tr>
<td>MDS-UPDRS 2</td>
<td>0.667 (5.05)</td>
<td>N/A</td>
<td>-1.85,3.12</td>
<td>0.58</td>
</tr>
<tr>
<td>MDS-UPDRS 3</td>
<td>3.72 (6.99)</td>
<td>N/A</td>
<td>0.244,7.20</td>
<td>0.04</td>
</tr>
<tr>
<td>TUAG</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.01</td>
</tr>
<tr>
<td>DGI</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.01</td>
</tr>
</tbody>
</table>

6MWT: Six Minute Walk Test, MDS-UPDRS 2: Movement Disorder Society Unified Parkinson’s Disease Rating Scale (ADL Section) Part 3 (Motor examination), TUAG: Timed Up and Go Test, DGI: Dynamic Gait Index

3.4.3.3 Participation: Parkinson’s Disease Questionnaire 39

Both a paired t-test and the Wilcoxon-signed rank test were utilised to determine if a significant difference in mean and median scores existed between T1 to T2 for the PDQ-39 as data in the subsections were both normally and not normally distributed. There were no statistically significant differences in the change in mean and median
scores for all subsections of the PDQ-39. This also held true for the PDSI. Table 3.7 displays the subsections.

Table 3.7 Change in score from T1 to T2 for the PDQ-39

<table>
<thead>
<tr>
<th>PDQ-39</th>
<th>Mean (SD) change scores from T1-T2</th>
<th>Median (IRQ) change scores from T1-T2</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.14</td>
</tr>
<tr>
<td>Activities of Daily Living</td>
<td>-.46</td>
<td>N/A</td>
<td>-5.49,4.56</td>
<td>0.85</td>
</tr>
<tr>
<td>Emotions</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.78</td>
</tr>
<tr>
<td>Stigma</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.41</td>
</tr>
<tr>
<td>Social Support</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.50</td>
</tr>
<tr>
<td>Cognition</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.16</td>
</tr>
<tr>
<td>Communication</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.78</td>
</tr>
<tr>
<td>Bodily Discomfort</td>
<td>0.01</td>
<td>N/A</td>
<td>-5.85,5.85</td>
<td>1.00</td>
</tr>
<tr>
<td>Parkinson’s Disease Summary Index</td>
<td>N/A</td>
<td>=0</td>
<td>N/A</td>
<td>0.56</td>
</tr>
</tbody>
</table>

N/A= Not Appropriate. Mean values were used for data that were normally distributed, medoid values were used for data that were not normally distributed.
3.5 Summary of Findings

Feasibility Outcome Measures:

- Large-amplitude group exercise training is both feasible and safe to carry out in an acute hospital setting and at home.
- The majority of participants completed their daily home exercise logbook and the provision of an exercise DVD was the most popular resource which enhanced exercise compliance.
- The majority of participants found the large-amplitude group exercise class very beneficial and would recommend the class to other individuals with PD.

Primary Outcome Measure:

- There was a statistically significant change in mean scores in the study group between T1 and T2 for the primary outcome measure as measured by the 6MWT.

Secondary Outcome Measures:

- There were statistically significant differences in the change in mean scores for the outcome measures pertaining to activity limitations between T1 and T2 for the study group as measured by the TUAG and DGI.
- There was a significant change in mean score for the MDS-UPDRS 3 (motor examination) between T1 and T2 for the study group.
- There was no significant change in mean scores for the MDS-UPDRS 2 (ADL section) between T1 and T2 for the study group.
- There were no significant changes in HRQOL between T1 and T2 for the study group as measured with the PDQ-39.
CHAPTER 4    DISCUSSION

4.0 Introduction

Results demonstrated that participation in a six-week, large-amplitude group exercise class was feasible and safe to carry out in both an acute teaching hospital and in participants’ home environments. This intervention consisted of high intensity, large-amplitude stretches, large-amplitude functional exercises and large-amplitude walking which was progressed weekly in terms of intensity, frequency, speed and complexity. A blinded outcome assessor assessed participants at baseline and following the six week intervention. Large-amplitude group exercise training was found to have a statistically significant beneficial effect on exercise tolerance, functional mobility and dynamic balance in a sample of 18 community dwelling PD patients. Results also suggest that participation in this intervention led to a significant improvement in the motor examination section of the Movement Disorders Society-Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part Three. There was no significant change regarding the self-reported motor influence on daily living as measured by the MDS-UPDRS Part Two. There was no significant change regarding HRQOL as measured by the PDQ-39.

4.1 Results in the context of the current literature

4.1.1 Feasibility Outcomes

To the author’s knowledge, this is the first large-amplitude group exercise programme that has incorporated principles from both LSVT BIG (Farley et al, 2005) and PWR! (Krasteva et al, 2015) programmes for people with mild to moderate PD.
As it was possible that this novel exercise programme may have presented safety risks such as injuries or falls, the first aspect of feasibility considered was safety. No adverse events occurred carrying out the exercise programme in the acute hospital setting. The only adverse event reported from carrying out the programme at home was muscle soreness. This could be attributed to the fact a large proportion of people with PD (PwPD) are physically inactive (Nicolien et al, 2013) and muscle soreness was a direct result of augmented muscle conditioning and exercise. Similar results were noted for safety and adverse events in a feasibility RCT of progressive strength training and movement strategy training in 210 PwPD in an outpatient clinic (McGinley et al, 2012).

It has been well documented that PwPD are more physically inactive in comparison with their age-matched healthy counterparts (Goodwin et al, 2008). Therefore, identifying successful methods of getting PwPD to comply with exercise regimes and sustaining positive attitudes and behaviours towards exercise is particularly important given the growing number of people living with PD in Ireland (Irish Parkinson’s Association 2008). Exercise compliance is seldom reported in the literature (Thebane et al, 2010). Results in this study demonstrated that the majority of participants were either excellent or very good completing their daily home exercise logbook, and very good or good utilising their exercise resource pack. It is the opinion of the author that daily compliance with the exercise logbook was enhanced by the provision of the exercise resource pack (Photo pack, Exercise DVD and YouTube Link) especially in the first three weeks of the programme to facilitate learning and recall of the new exercises.

Adherence is a key variable that influences the outcome of a study (Cyarto et al, 2006), however, few trials of exercise programmes for PD have reported adherence
rates (Allen et al, 2010). The mean number of classes attended in this study was five out of a total six. The fact that participants saw the benefits of the programme and enjoyed attending the class may have influenced good adherence rates (Tomlinson et al, 2012).

A key factor in achieving meaningful results from a study is the ability to retain adequate participants. Retaining participants from any older population in a trial can be difficult (Wade et al, 2003). Retention rates in this study were very satisfactory at 100%. Similar satisfactory results were found for progressive strength training and movement strategy training whereby, 88% of participants attended for post intervention assessment (McGinley et al, 2012).

Interest is growing in the literature in the systematic evaluation of service delivery and the most significant feature of patient care that are likely to influence this is patient satisfaction (Cleary et al, 1991). There is no validated questionnaire that investigates levels of satisfaction with an exercise programme in PwPD, therefore the author developed a satisfaction questionnaire to gain insight into participants’ views and opinions regarding the class. Participants in this study were in complete agreement regarding the beneficial effects of the programme, recommending the programme to other PwPD, continuing the HEP on completion of the six week programme and positive behaviour change to exercise post intervention. There was less agreement amongst the study sample regarding frequency and duration of the class and whether the class improved outcomes such as mood and functional outcomes. Interestingly, there was disparity in the group regarding participants’ views of group exercise versus 1:1 intervention. Seventy two percent of participants found group exercise more enjoyable than 1:1 intervention, however, the remaining 28% of participants had no opinion or disagreed. The benefits of group exercise in
PwPD are well documented in the literature. In a meta-analysis de Goede et al (2001) investigated the effects of physical therapy in PD and reported on improvements of psychological well-being and the facilitation of several positive behavioural changes as additional effects of group exercise. In a systematic review of seven trials that investigated the beneficial effects of exercise in PwPD, the authors stated that therapy in a group setting helped with enhanced socialisation and provided a supportive environment for discussion for PwPD (Crizzle et al, 2006). More recently, Nicolien et al (2013), highlighted important considerations for therapists to consider when designing exercise programmes. Firstly, safety risks need to be considered as an increase in physical activity results in higher incidence of falls and injury in PwPD (Hackney and Earhart, 2011). Therapists need to be realistic with the timeframe of the class as this influences adherence. It was suggested in the European PD Physiotherapy Guidelines that one hour is a reasonable time period. Finally, barriers to exercise to as compliance and retention issues need to be addressed and therapists need to seek alternative ways to improve exercise participation on a permanent basis. The author of this study believes that the above recommendations were implemented in this study.

4.1.2. Exercise Tolerance

Parkinson’s Disease is a progressive neurodegenerative disorder which affects the physical, psychological and functional status of individuals (Goodwin et al, 2008). People with PD have a tendency towards a more inactive lifestyle (European Guidelines, 2014). Compared to their healthy counterparts, people with PD (PwPD) are about one-third less active (van Nimwegen et al, 2011). This is in part (24%)
predicted by disease severity, gait impairments and limitations in activities of daily living (van Nimwegen et al, 2011).

Parkinson’s Disease is a cause of immobility, and immobility is a cause for the progressive loss of exercise endurance and functional aerobic capacity (Delwaide et al, 1993). The effect of PD on endurance has been documented by Light et al, (1997) where they identified that individuals with moderate to advanced PD walked significantly shorter distances than their healthy contemporaries during three consecutive two-minute walk tests. The mean distance covered on initial assessment in this study was 367.61m. This value increased by 10% to 405.28m following the large-amplitude group exercise intervention. This equated to a statistically significant improvement of p<0.01. Unfortunately, there are no derived normative data or minimal clinically important difference (MCID) values for people with PD for the 6MWT. Nonetheless, this baseline value is less than that reported in previous PD studies, with literature reporting mean values ranging from 392m (Falvo and Earhart, 2009) to 546m (Canning et al, 2006). This variation in scores may be accounted for by factors such as age, disease severity and habitual physical activity. The study sample was older than in the above studies and included H&Y Stages I-IV; which may have contributed to the lower baseline 6MWT values. In a PD systematic review and meta-analysis of 39 trials of 1827 participants carried out by Tomlinson et al (2012), results demonstrated a mean increase in the distance walked in the 6MWT of 13.37m following physiotherapy compared with no intervention. The authors highlighted the issue of a lack of MCID value published for the 6MWT for this patient cohort. However, they stated that a 13m increase in distance walked would probably be considered clinically important for PwPD. Taking this probability into
consideration, the results obtained in this study exceeded three times this value (37.67m).

Steffen and Seney (2008) obtained a minimal detectable change (MDC) value of 82m in a sample of 37 community-dwelling older adults with Parkinsonism. The MDC value of 82m was larger than desired due to a large SD resulting from a wide range of disease severities of the participants on the H&Y Scale. In their study, people with all types of Parkinsonism were included whereas, the inclusion criteria in this current research study only accepted people with idiopathic PD. This may have accounted for the variation in MDC values between the two studies.

The optimal frequency and intensity of interventions in physiotherapy studies is a source of great debate in the PD literature (Redecker et al, 2014; European Guidelines 2014). Disparities are evident throughout the literature regarding optimal dosage. Ebersbach et al (2014), in an RCT compared the effects of the LSVT BIG standard protocol (16 individual sessions) with an amplitude-oriented training - shorter protocol (AOT-SP) comprising 10 sessions in 42 PwPD where the secondary outcome of interest was the 6MWT. Participants had a H&Y score of 1-3 and were less severely affected than the population in this study. The difference of 58m was statistically significant (p<0.01) for the LSVT BIG group, however a difference of 30m was not statistically significant (p=0.08) for the AOT-SP group. The reduced training intensity of AOT-SP may not have been sufficient enough to obtain statistically significant improvements on the 6MWT. However, the authors recognised that a key limitation of the study was the potential attention bias in the LSVT BIG group. In this study, the time frame of six weeks for a class intervention reflects a pragmatic approach to exercise delivery in the context of current clinical practice within an acute hospital setting. Despite a lower training intensity of six
sessions in this research, participants managed to achieve a statistically significant improvement (p<0.01). The addition of an intensive daily HEP and the provision of novel exercise resources may have proven influential in achieving these results.

As there is scant evidence pertaining to the effects of large-amplitude training on exercise tolerance, other modes of exercise interventions were evaluated from other exercise literature. In a systematic review and meta-analysis of 18 RCTs with 901 participants, Hai-Feng et al (2014) suggested that aerobic exercise showed significant effects compared with control therapies of home exercise programmes in the 6MWT (95% CI=0.08, 1.36, p=0.03). In contrast, Canning et al (2013) in a pilot RCT investigated the feasibility and effectiveness of six weeks of home-based treadmill training in 20 people with mild PD, where the primary outcome measure of efficacy of walking capacity was the 6MWT. Results indicated that treadmill training did not improve walking capacity compared to the control walking group (p>0.05). These results may have been influenced by a small sample size and high drop rate (26%). Shulman et al (2013) compared three types of physical exercise in an RCT: (1) A higher-intensity treadmill exercise (30 minutes at 70%-80% of heart rate reserve), (2) a lower-intensity treadmill exercise (50 minutes at 40%-50% of heart rate reserve), and (3) stretching and resistance exercises (2 sets of 10 repetitions on each leg on 3 resistance machines). These exercises were performed three times a week for three months. The primary outcome measure was the 6MWT. Results revealed that all three types of physical exercise resulted in improvements in the 6MWT: lower-intensity treadmill exercise (12% increase; \( p = .001 \)), stretching and resistance exercises (9% increase; \( p < .02 \)), and higher-intensity treadmill exercise (6% increase; \( p = .07 \)), with no between-group differences. Tai Chi is gaining increased attention in the PD literature not only for its significant impact on balance outcomes.
(Li et al, 2012), but also for its effect on enhancing gait outcomes. In an RCT by Hackney et al (2008) 33 people with PD were randomly assigned to either a Tai Chi group or a control group. The Tai Chi group participated in 20 one-hour long training sessions completed within 10–13 weeks; whereas, the control group had two testing sessions between 10 and 13 weeks apart without interposed training. The Tai Chi group improved more than the control group on the 6MWT, Berg Balance Scale, UPDRS and TUAG. This was the first study to examine 6MWT performance before and after Tai Chi. The improvement noted (p=0.04) in the Tai Chi group may reflect improved balance (Li et al, 2012). Alternatively, the improvement may reflect increased endurance, as Tai Chi has been shown to reduce systolic blood pressure, total cholesterol, heart rate and low-density lipoprotein cholesterol levels after as little as 10 weeks in Hong Kong Chinese women (Ko et al, 2006).

4.1.3. Disease Severity Scale

Two sub-categories of the MDS-UPDRS were used to establish the effect of large-amplitude group exercise training on disease severity in the study sample. Part two measures self-reported motor experiences of daily living and part three measures the motor examination. Goetz et al (2008), described normative data in 80 PwPD, whereby part two demonstrated a mean score of 16.0 (SD 10), and section three had a mean score of 36.8 (SD 18.4). In the current study, the mean score at baseline for the sample was 10.70 (SD 4.84) for section two and 23.44 (SD 14.13) for section three indicating milder symptoms for this study sample.
No statistically significant improvement was demonstrated in self-reported motor experiences of daily living (p=0.583) between pre and post intervention. In contrast, there was a statistically significant improvement in the motor examination post intervention (p=0.04).

No MDC, MCID or cut-off scores have been established for the MDS-UPDRS. However, there is disparity in the literature around possible MCID values. In a RCT carried out by Schrag et al (2006), the authors concluded that the minimally important difference was between two and three points for part two and five points for the motor score. In a cross-sectional study, Shulman et al (2010), found that a six point improvement on the MDS-UPDRS motor section suggested to indicate a moderate, clinically important change in motor-symptom severity based on the UPDRS. The high correlation between the motor section of the UPDRS and the MDS-UPDRS (Goetz et al, 2008) suggests they can be directly compared as done in a recent Cochrane review of 39 trials (Tomlinson et al, 2012). Taking the above recommendations into account, the mean improvement of 3.72 observed in this study is approaching these desired minimally important differences. The smaller mean differences may be attributed to the difference in homogeneity of the sample group in this study and the shorter intervention period.

The improvements made on the motor section of the UPDRS in the above studies are very similar to increased scores achieved by carrying out LSVT BIG training (Ebersbach et al, 2010). In this RCT, 60 patients with mild to moderate PD were randomly assigned to receive either LSVT BIG training (16 hours), group training of Nordic Walking (16 hours) or domestic non-supervised exercises. The primary efficacy measure was difference in change in the UPDRS motor score from baseline to follow-up at 16 weeks between groups. Results showed significant group
differences for UPDRS-motor score at final assessment (p<0.001). Mean improvement of UPDRS in the LSVT BIG group was -5.05 points (SD 3.91), whereas there was a mild deterioration of 0.58 (SD 3.17) in the Nordic Walking group and of 1.68 (SD 5.95) in the home group. This study sample demonstrated 1.33 points lower in comparison to this RCT. This difference may be attributed to the fact that disease severity was lower in this RCT and also a longer intervention period was conducted in the LSVT BIG study.

4.1.4. Functional Mobility

Functional mobility, as measured by the TUAG, was found to improve to a statistically significant degree (p=0.01). A median improvement of 1.36 seconds was noted following the large-amplitude group training, representing a decrease in the length of time taken to complete the task.

Huang et al (2011), derived an MDC value of 3.5 seconds for the TUAG from a convenience sample of 72 PwPD from a movement disorder clinic and the mean age of 67.5 years. This was not achieved in this study sample. Considering that the median score at baseline was 8.99 seconds, it would have been very difficult for participants’ to reduce their individual scores by one third in such a short timeframe. There are no floor/ceiling effects reported for PwPD, however, Rockwood et al (2000), have reported poor floor effects (29.3%) in elderly adults using the TUAG. The 1.36 second improvement is greater than the mean score of 0.63 second improvement conferred with other physiotherapy treatments reported in the Cochrane review (Tomlinson et al, 2012).
Results in this study are also greater than those reported by Ebersbach et al (2010), who saw statistically significant improvements (p=0.03) with a 0.75 second mean improvement in TUAG score having completed LSVT BIG intervention.

In contrast to these results, some physiotherapy interventions (Steffen and Seney, 2008) demonstrated significantly larger improvements (-4.5 seconds) than occurred in this study sample while others show no improvement at all. Nieuwboer et al (2007) conducted a randomised crossover trial of Rehabilitation in Parkinson’s disease: Strategies for Cueing (RESCUE) Trail with 153 participants, mean age 63.5 years with a H&Y stage of 2-4. Participants received 12 weeks of cueing training in their home environment and statistically significant results were seen in various impairment outcomes. However no significant change was demonstrated for the TUAG (p>0.6).

The cut-off score indicating risk of falls >11.5 seconds has been established for the TUAG in this patient population (Nocera et al, 2013). Results from this study indicated that two participants (11.11%) were a falls risk at baseline. Even though both these participants improved their TUAG over the six week intervention (median difference 1.81 seconds) they remained above the cut-off score.

4.1.5. Balance

The six week large-amplitude group exercise training also appeared to improve dynamic balance, measured using the DGI, which is also a key factor for falls risk. A median improvement of 2.5 points (p=0.01) was achieved between baseline and post intervention assessment.
Cakit et al (2007) derived normative baseline data for the DGI of 16.3 in a population of 31 PwPD with a H&Y stage 2-3. In this study, the median baseline DGI score obtained was 20 of a maximum 24. This may reflect the difference in population that are referred into the outpatient neurology physiotherapy service in comparison to those attending a rehabilitation unit. Also, the majority of participants in this study fell under a H&Y score of 1-2 indicating reduced severity of PD symptoms.

Dibble et al (2008) derived a cut-off score of <19 as a discriminative indicator for falls risk. In contrast to the results observed for the TUAG where two participants were a falls risk both pre and post intervention, eight participants (44.44%) had a score <19 points for baseline DGI assessment and only 2 participants (11.11%) had scores <19 post intervention. This indicates that one third of participants demonstrated a falls risk prior to participating in the six week programme to demonstrating minimal risk of falls post intervention. This may be likely attributed to the fact that the large-amplitude group exercise programme incorporated progressive dynamic balance exercises of large-amplitude stepping, twisting, rocking and turning which mimics challenging balance tasks for PwPD in their everyday lives.

Huang et al (2011) have derived an MDC value of 2.9 points for the DGI for PwPD. This study was very close to achieving this at 2.5 points.
4.1.6. Health-Related Quality of Life

This six week large-amplitude group exercise training programme did not have a significant positive influence on HRQOL as measured by the PDQ-39. In fact, there was no trend towards improvement on any subsection of the PDQ-39. The difference in the mean change in the PD Summary Index (PDSI) score was also non-significant (p=0.56). Physical function has been shown to be predictive of QOL which suggests that enhancing mobility will improve QOL in PwPD (Ellis et al, 2011). Considering that statistically significant scores were achieved for both balance and gait outcomes in this study (6MWT, TUAG, DGI, MDS-UPDRS 3), it could be assumed that this would translate positively in a self-reported questionnaire. In addition to this, 100% of participants either agreed or strongly agreed that they found the large-amplitude training beneficial and would recommend the exercise programme to others.

However, it has been acknowledged that a significant feature of answering the PDQ-39 relies on the accuracy of recall in the last month. It is difficult to determine whether study participants limited their answers purely to the previous month when completing the questionnaire (Jenkinson et al, 1997). The results obtained may not be a true reflection of the effect of the intervention on QOL in this study sample.

Despite this, results in this study are consistent with findings reported in the literature. In a Cochrane review of 39 trials, Tomlinson et al (2012) found no difference between treatment and control groups for mobility or the PDSI (p=0.73). Ebersbach et al (2010) found non-significant changes in the PDQ-39 following 16 sessions of LSVT BIG or Nordic walking. The authors suggested that their small sample size of 60 participants may have been under-powered to detect moderate improvements in QOL.
4.2 Strengths of the Study

- This feasibility study included relevant and recommended feasibility measures which are often under-reported in the literature.
- This novel group exercise programme addressed a gap in the evidence regarding large-amplitude exercise for PwPD.
- Validated primary and secondary outcome measures for PwPD were used to determine effectiveness across the International Classification of Functioning (ICF) of impairment, activity limitations and participation.
- Assessor bias was minimised utilising a blinded assessor who had no affiliation to the study.
- The study sample is representative of an outpatient PD service in an acute Regional teaching hospital.

4.3 Study Limitations

- Study Design: A pretest-posttest study design is less rigorous in comparison to the gold standard RCT or quasi-experimental design.
- Sample Size: The study was under-powered due to a limited number of PwPD on the outpatient Neurology Database in NGH. Of this, a substantial number refused to participate for various reasons or failed to meet the eligibility criteria.
- Resources: Service demands restricted colleagues in assisting with outcome measure assessment and class delivery.
- Study Duration: The study was of short duration of six weeks in comparison to more intensive programmes of 10 weeks recommended in the literature.
• Inadequate follow-up: The blinded outcome assessor was not available to complete follow-up assessments.

• Exercise Tolerance: Aerobic intensity was not measured for the 6MWT

4.5 Areas for Future Research

Due to the lack of research pertaining specifically to large-amplitude training in the treatment of PD, the author recommends that future research could be conducted that incorporates:

• A larger sample size to ensure that the study is adequately powered to infer statistically significant results.

• A more rigorous study design such as an RCT of large-amplitude group exercise training compared to usual physiotherapy care, incorporating an intervention phase greater than six weeks and an adequate follow-up period of one year to determine the maintenance of gains achieved.

• High quality studies investigating exercise-induced changes in the brain and their associated functional outcomes.

• Qualitative research methods such as semi-structured interviews to gain a deeper insight into the barriers, facilitators and motivators of exercise from the participant’s perspective. This knowledge will influence the structure of future exercise programmes and facilitate with exercise compliance over the longer term in this population.
CONCLUSION

A six week large-amplitude group exercise training programme for individuals with mild-moderate PD was feasible and safe to carry out in both a hospital setting and a home environment. Attendance rates and retention rates were very satisfactory. The provision of relevant exercise resources such as an exercise logbook, exercise photo pack, exercise DVD and a YouTube exercise link appeared to facilitate with increased compliance and satisfaction with the class. The majority of participants found the class very beneficial and preferred it to one-to-one intervention. The large-amplitude group exercise class also demonstrated statistically significant positive effects on functional physical performance outcomes of exercise endurance (6MWT), dynamic balance (DGI), functional mobility (TUAG) and PD-related motor severity in the study sample (MDS-UPDRS Part III). However, non-significant changes were noted for PD-related ADLs (MDS-UPDRS Part II) and HRQOL (PDQ-39). However, these results must be interpreted with caution as the primary and secondary clinical outcome measures were not powered to detect changes in these outcomes.

The study sample were recruited from the physiotherapy PD outpatient database in Naas General Hospital. Inclusion criteria deemed that participants needed to be independently mobile with or without a walking aid. The mean average H&Y for this study sample was 1.72 indicating a low disease disability. The duration and intensity of the intervention reflects current clinical practice in Ireland, but may not be sufficient to achieve sufficient changes in functional physical performance outcomes. Other studies have demonstrated more favourable outcomes with increased
frequency and duration of interventions. However, these interventions required 1:1 intervention and are not cost or resource effective in an Irish setting.

In conclusion, individuals with mild-moderate PD may benefit from regular participation in large-amplitude group exercise training as it may possibly improve exercise tolerance, functional mobility and dynamic balance. Further research is required to determine the efficacy of this intervention with a more rigorous study design, larger sample size and adequate follow-up of 1 year post intervention.

Word Count: 13,237
Appendix 1

Letter of Invitation to Participate in a Physiotherapy Research Study

“Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease:
A Pilot Intervention Study”

Dear ____________,

We are writing to you because you are either on a waiting list or our Parkinson’s Disease Outpatient Database for physiotherapy at Naas General Hospital. We wish to invite you to participate in a research study that is being conducted by one of our physiotherapists Eimear Manley. Eimear is carrying out the research as part of a Masters of Neurology and Gerontology Degree, through the Royal College of Surgeons in Ireland.

Enclosed please find the information about the study. Please take the time to read it carefully and discuss it with your family and friends. Please contact myself or Eimear if you have any queries or need further information on any aspect of the forms. Our contact number is 045-849941.

We will contact you over the coming weeks to see if you are willing to attend. You do not need to sign the enclosed consent now, they are merely for your information at this stage.

Thank you for taking the time to consider this research study.

Yours sincerely,

__________________________
Susan Curtis
Deputy Physiotherapy Manager
Appendix 2

Patient Information Leaflet

1. **Title of Study**: Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease: A Pilot Intervention Study

2. **Introduction**: The aim of this study is to establish the safety, satisfaction and effectiveness of a six-week, outpatient, large-movement group exercise programme on balance, walking ability and quality of life in individuals with mild-moderate Parkinson’s Disease (PD). It will involve attending Naas General Hospital on eight occasions. This includes attending for evaluation assessments before and after the six week exercise programme.

3. **Procedures**: If you chose to participate in the study, you will be asked some personal details regarding the length of time since your diagnosis, the medication you are taking and whether you have had any recent physiotherapy. We will assess your exercise tolerance, balance, walking ability and evaluate how your PD affects your quality of life. The assessment process will take approximately 35 minutes. The large-amplitude group exercise programme will take place in the physiotherapy gym in the old part of the hospital. The class will run once a week, on the same day and time, for 6 weeks and will last an hour. You will be supervised by a Chartered Physiotherapist.

4. **Benefits**: The study may help to improve your mobility and balance as well as your quality of life. A home exercise pack which will contain a home exercise diary and exercise DVD will be provided as a motivational tool to encourage you to exercise both during and after the exercise programme. There will be an opportunity to meet other people who have a similar condition as you and will give you the chance to discuss any issues or concerns that you have with one another. It is a great opportunity to exercise in a group setting and enjoy the benefits of social engagement.

5. **Risks**: There is a very small risk you may lose your balance and fall during the study. However, this is unlikely and you will be supervised by a physiotherapist at all times.

6. **Inclusion Criteria for the Exercise Programme**: A member of the Physiotherapy Staff will telephone you and ask a few screening questions to see if you are eligible to participate in the study.

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Telephone: 045 849500
www.naashospital.ie

*Naas General Hospital is an affiliated teaching hospital with the faculty of Health Sciences, Trinity College.*
7. **Exclusion from Participation:** Your doctor has told you that you cannot be in this study if any of the following are true: If you have an orthopaedic or heart condition that limits your ability to take part in the treatment. You must be able to give informed consent.

8. **Alternative treatment:** The study will not interfere with your hospital treatment.

9. **Confidentiality:** Your identity will remain confidential throughout the course of the study. Your name will not be published and will not be disclosed to anyone outside the hospital.

10. **Compensation:** The researchers and Physiotherapists in the study are covered by standard medical malpractice insurance. Nothing in this document restricts or curtails your rights.

11. **Voluntary Participation:** You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, the routine management of your PD condition will not be affected in any way.

12. **Permission:** Ethical Approval for this study will be granted by the Naas General Hospital Research Ethics Committee.

13. **Further Information:** You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Eimear Manley who can be contacted at 045-849941.
Appendix 3

Consent Form

Title of Study: Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease: A Pilot Intervention Study

For each statement below, please tick √ either Yes or No in the relevant box provided

<table>
<thead>
<tr>
<th>Statement:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have read and understood the information leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that I don’t have to take part in this study and that I can opt out at any time. I understand that I don’t have to give a reason for opting out and I understand that opting out won’t affect my future medical care in Naas General Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am aware of the potential risks of this research study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been given a copy of the information leaflet and this completed consent form for my records</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Storage and future use of information

I give permission for material/data to be stored for possible future research:

- a) Related to the current study to research ethics committee approval
- b) Related to the current study only if consent is obtained at the time of the future research subject to research ethics committee approval

I give permission for material/data to be stored for possible future research related to the current study without further consent being required subject to research ethics committee approval

I give permission for material/data to be stored for possible future research unrelated to the current study without further consent being required subject to research ethics committee approval

Telephone: 045 849500
www.naishospital.ie

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Participants Name (Block Capitals): __________________________

Participants Signature: __________________ Date: ______________

Keep the original of this form in the participants’ records, give one copy to the participant, keep one copy in the investigators records.
### Appendix 4: Hoehn and Yahr Clinical Rating Scale for Parkinson’s Disease

<table>
<thead>
<tr>
<th><strong>Hoehn and Yahr Scale</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Only Unilateral involvement, usually with minimal or no functional disability</td>
</tr>
<tr>
<td>2</td>
<td>Bilateral or midline involvement without impairment of balance</td>
</tr>
<tr>
<td>3</td>
<td>Bilateral disease; mild to moderate disability with impaired postural reflexes; physically independent</td>
</tr>
<tr>
<td>4</td>
<td>Severely disabling disease; still able to walk or stand unassisted</td>
</tr>
<tr>
<td>5</td>
<td>Confinement to bed or wheelchair unless aided</td>
</tr>
</tbody>
</table>
Appendix 5: Ethical Approval Letter Naas General Hospital

29/6/15

Ms. Eimear Manley,
Physiotherapy Dept.,
Naas General Hospital.

Re: Research Study - Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease: A Pilot Intervention Study.

Dear Eimear,

I am happy to inform you that the above study has been approved by the hospital’s Ethics Committee.

Publications arising from research conducted in Naas General Hospital as approved by the Ethics Committee should include an acknowledgement to NGH as a research site. The hospital supports the International Committee of Medical Journal Editors (ICMJE) criteria for authorship and contributors and expects all principle investigators to adhere to these principles.

Yours sincerely,

Alice Kinsella
A/General Manager

Telephone: 045 849900
www.naashospital.ie

Naas General Hospital is an affiliated teaching hospital with the faculty of Health Sciences, Trinity College.
Appendix 6: Ethics Form

Version 5.5 May 2011

STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study:
Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease: A Pilot Intervention Study

Principal Investigator:
Eimear Manley

For Official Use Only – Date Stamp of Receipt by REC:
This Application Form is divided into Sections.

Sections A, B, C, D, E, J, K, L are **Mandatory**.
Sections F, G, H, and I are optional. Please delete Sections F, G, H, and I if these sections do not apply to the application being submitted for review.

**IMPORTANT NOTE:** Please refer to Section I within the form before any attempt to complete the Standard Application Form. Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.
SECTION A IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

A1 Title of the Research Study:

| Large-Amplitude Group Exercise Training for Individuals with Parkinson’s Disease: A Pilot Intervention Study |

A2 Principal Investigator(s):

| Title: Ms. | Name: Eimear Manley |
| Qualifications: BSc (Hons) Physiotherapy |
| Position: Staff Grade Physiotherapist |
| Dept: Physiotherapy |
| Organisation: Naas General Hospital |
| Address: Naas, Co Kildare |
| Tel: 045-849941 | E-mail: Eimear.manley@hse.ie |

A3 (a) Is this a multi-site study?  No

A3 (b) Please name each site where this study is proposed to take place and state the lead investigator for each site:

| Site: PHYSIOTHERAPY DEPARTMENT, NAAS GENERAL HOSPITAL, NAAS, CO. KILDARE | Lead Investigator: EIMEAR MANLEY |

A3 (c) For any of the sites listed above, have you got an outcome from the research ethics committee (where applicable)?

No
A4. Co-Investigators:

Name of site

Royal College of Surgeons

Title: Dr. Name: HELEN FRENCH
Qualifications: PhD, MSc, B.Physio, Dip Stat
Position: Lecturer in Physiotherapy
Organisation: Royal College of Surgeons
Address: School of Physiotherapy, 123 St Stephens Green, Dublin 2
Role in Research: Supervisor

A4. Co-Investigators:

Name of site

Naas General Hospital

Title: Dr. Name: MARY MARTIN
Position: Consultant Geriatrician
Organisation: Naas General Hospital
Address: Naas, Co Kildare
Role in Research: Co-Investigator

A5. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Title: Ms. Name: Eimear Manley
Address: Physiotherapy Department, Naas General Hospital
Tel (work): 045-849941 Tel (mob.): 087-1257242
E-mail: Eimear.manley@hse.ie

A6. Please provide a lay description of the study.

The aim of the study is to assess the feasibility and efficacy of a six week group exercise programme on physical performance outcomes in individuals with mild-moderate Parkinson’s Disease (PD). Gait and balance disturbance is extremely common in PD and is a major contributor to increased disability and decreased health-related quality of life. Therefore, treatment strategies such as exercise to treat mobility and balance impairments in PD are paramount. Various exercise strategies have been developed to target these deficits. One such
rehabilitation approach which has shown to be effective is Lee Silverman Voice Training (LSVT) BIG. This is a unique approach in the fact that it targets (BIG) movement amplitude as a single treatment parameter. However, this rehabilitation approach is standardised, consisting of 4 1-hourly individualised treatment sessions, 4 times a week. This intensity of training is not feasible in an acute hospital setting. The researcher proposes to incorporate principles of LSVT BIG/large amplitude training into a group setting to assess its feasibility and potential efficacy.

A7 (a) Is this study being undertaken as part of an academic qualification? **Yes**

A7 (b) If yes, please complete the following:
- **Student Name:** Eimear Manley
- **Course:** MSc Physiotherapy (Neurology and Gerontology)
- **Institution:** Royal College of Surgeons of Ireland
- **Academic Supervisor:** Dr. Helen French

5  SECTION B  STUDY DESCRIPTORS

**SECTION B IS MANDATORY**

B1. Provide information on the study background.

Parkinson’s Disease (PD) is a complex, chronic and progressive neurodegenerative disorder. It consists of a constellation of motor and nonmotor symptoms affecting the physical, psychological, social and functional status of individuals (Goodwin et al, 2008). In the course of the disease, most people with PD face mounting mobility deficits including difficulties with transfers, posture, balance and walking, which leads to a loss of independence, injury, inactivity resulting in social isolation and increased risk of osteoporosis and cardiovascular disease (Keus et al, 2007). There are approximately 9,000 people in Ireland living with PD (Parkinsons.ie).

Pharmacological therapy is the primary treatment modality for PD and serves to slow the onset of disease progression and limit the clinical manifestations of the condition (Katzenschlager et al, 2008). Unfortunately, current pharmacologic and surgical treatment options for gait and balance disturbances are limited (Vu TC et al, 2012). Therefore, there is a pressing need for other (nonpharmacologic) treatment strategies such as exercise to treat mobility impairments in PD.
Several comprehensive meta-analyses and Cochrane reviews (Keus et al, 2006; Goodwin et al, 2008; Tomlinson et al, 2012) have been published on this topic over the last few years. A great advancement in recent literature for PD has been the publication of the 2015 European Physiotherapy Guidelines for PD.

Exercise has become an established and beneficial therapeutic adjunct in the management of PD. Numerous types of exercise models and strategies have been advocated for people with PD targeting mobility and balance impairments such as: Progressive resistance training (Falvo et al, 2008; Sage et al, 2011), treadmill training (Herman et al, 2008), various forms of dance (Duncan and Earhart, 2010), Tai Chi (Li F et al, 2012), boxing (Combs et al, 2011) sensoriaility training (King and Horak, 2008). Various models of rehabilitation often use compensatory strategies to bypass the basal ganglia as the basis of their therapeutic management (Nieuwboer et al, 2008). In contrast, there is a growing body of evidence favouring a neuroplasticity-principled rehabilitation model (Farley et al, 2008).

One particular exercise model that incorporates the latter restorative approach is Lee Silverman Voice Therapy (LSVT BIG). Developed in 2005 (Farley et al, 2005), LSVT BIG is an intensive high-amplitude standardised exercise protocol. The recent European guidelines have recommended this exercise approach for training balance and mobility impairments.

This standardised exercise protocol was piloted with one individual in January 2014 in Naas General Hospital which produced excellent results. A Case Study of this pilot intervention programme was published in the Irish Society of Chartered Physiotherapists (ISCP) Firsthand Magazine highlighting its efficacy. However, the authors highlighted numerous limitations with this protocol regarding time, staff time, staff resources and feasibility issues for the participant to commit to such high doses of intensity of training.

To overcome these barriers, the researcher proposes to adopt principles from LSVT BIG training incorporating elements of motor learning principles in the form of a six week (once weekly) group-based exercise programme for people with mild-moderate PD.
B2. List the study aims and objectives.

<table>
<thead>
<tr>
<th>Aims:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To assess the feasibility and efficacy of a six week large-amplitude group exercise class on physical performance in individuals with PD.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objectives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To determine if a one hour-weekly large-amplitude group exercise plus independent daily intensive home exercise programme is:</td>
</tr>
<tr>
<td>1 Feasible and Safe?</td>
</tr>
<tr>
<td>2 Improves physical performance measures in mild-moderate PD</td>
</tr>
<tr>
<td>3 Improves health related quality of life</td>
</tr>
<tr>
<td>3 Yields patient satisfaction and facilitates with exercise compliance</td>
</tr>
</tbody>
</table>

B3. List the study endpoints (if applicable).

The primary outcomes are to evaluate the feasibility and efficacy of a large-amplitude group exercise class on physical performance measures with mild-moderate PD

B4. Provide information on the study design.

Pretest-Posttest Pilot Experimental Design

B5. Provide information on the study methodology.

<table>
<thead>
<tr>
<th>Study Design:</th>
</tr>
</thead>
</table>
| A pretest-posttest pilot intervention design of one patient group will be conducted to ascertain the feasibility and efficacy of a large-amplitude group exercise class on individual with mild-moderate PD living in Kildare/West Wicklow. This study design type was deemed most appropriate by the investigator to address the research question and primary outcomes of feasibility and clinical efficacy. All eligible and willing
participants will receive the intervention. People with moderate-severe PD are excluded from the programme but this will not affect their routine care and treatment offered from the outpatient neurology service.

Subject Recruitment:
The participants will be recruited from the outpatient neurology waiting list and PD review database. Patients from the database may have attended for physiotherapy intervention and a PD class in the past. However, participants will be excluded if they have attended for physiotherapy in the previous 3 months – which allows for a washout period of treatment effect. If recruitment is posing difficult, potential Day Hospital clients may be invited to participate in the study. This will not affect their routine care in Day Hospital.

The participants will be sent an invitation letter (Appendix 1) from the Deputy Physiotherapy Manager who will act as gatekeeper for the trial inviting them to participate in the research programme. The invitation letter will be accompanied by a patient information leaflet (Appendix 2) and consent form (Appendix 3) which will outline the purpose and nature of the study. The participants will have at least seven days to digest this information and decide whether they wish to partake in the research study or not. Participants will then be contacted by the principal investigator to ensure eligibility and baseline assessments will be scheduled at this time. Verbal consent will be made over the phone with written consent provided at the baseline assessments.

To minimise the possibility of assessor bias and reduce threats to instrumentation internal validity, a blinded assessor will carry out baseline and post intervention assessments (UCD undergraduate student on clinical placement. This student will be under the direction and supervision of a Senior Clinical Tutor). The researcher will ensure that optimal training will be provided to the Undergraduate student prior to outcome assessment to minimise the threats of novice error.

Due to staffing resources in the physiotherapy department, the physiotherapy manager could not justify the time for the neurology service to carry out the quantity of assessments, therefore, this is another reason why this blind assessor has been selected.

Assessments will take place in the physiotherapy gym. It will take approximately 30-35 minutes to complete assessments.
Inclusion Criteria:
1. Diagnosis of Ideopathic Parkinson’s Disease diagnosed by a Consultant Neurologist
2. Hoehn and Yahr Scale 1-3 (Appendix 4)
3. Independent Mobile
4. Ability to give informed consent and follow simple commands

Exclusion Criteria:
1. Non-Ideopathic PD
2. Unstable Cardiovascular Disease
3. Uncontrolled Chronic Condition
4. Confirmed Diagnosis of Dementia/PD Related Dementia
5. Received Physiotherapy for PD in the last 3 months

Intervention:
The large-amplitude exercises classes will take place in the front physiotherapy gym. The treatment intervention shall consist of a 5 minute warm up, followed by large amplitude stretches and movement sequences (x15minutes), large-amplitude task specific exercises (x30mins) and a cool down of 5 minutes. A progression of the exercises will be three times over the course of the six week programme.

A maximum of 6 participants will partake in each class.

If successful recruitment of the target sample size of 24 is achieved, this correlates to 4 exercises classes per week over a 6 week period.

Likewise, if a reduced number is recruited (eg 18 participants) 3 exercise classes will take place.

The PI has discussed the justification and the feasibility of time and resources with the physiotherapy manager for conducting the intervention.

Safety procedures will be adhered to with all staff involved having CPR certification and access to the cardiac arrest trolley located in the nearby endoscopy department.
Outcome Measures:

**Feasibility Outcomes:**

For the purpose of this study, feasibility is adopted as an umbrella term, encompassing the constructs of safety, exercise compliance, adherence rates, retention rates and participant satisfaction with the exercise programme.

Safety during the intervention phase will be monitored by structured weekly screening by the intervention therapist for any new soreness lasting longer than 48 hours related to therapy and by recording of any adverse events (injury, near-miss accident, fall) both during the intervention and carrying out the intensive home exercise programme (Appendices 6 and 7).

Exercise compliance will be monitored by weekly review of a completed home exercise logbook (Appendix 8).

Adherence will be evaluated using weekly attendance records at the intervention session (Appendix 9).

Retention rates will be evaluated by comparing the proportion of participant who attend for baseline assessment V the proportion who attend for post intervention assessment.

Participant Satisfaction with the programme will be evaluated using a non-validated Questionnaire (Appendix 10).

**Primary Outcome Measure:**

Six minute walk test: Individuals walk up and down a 10m walkway for six minutes, as quickly as the subject can as long as they feel safe and comfortable. They may have as many seated rests as required over the course of the six minutes (American Thoracic Society, 2002)(Appendix 11)

**Secondary Outcome Measures:**

Timed Up and Go Test: this test requires the individual to stand up from a chair, walk a 3 metre distance, turn around, return and sit down again. The functional mobility performance is timed (Podsialdo and Richardson, 1991)(Appendix 12)
Dynamic Gait Index: this is a test of dynamic balance when there are threats to external demands. It is recommended as the best evaluating tool for measuring balance in PD (European Guidelines, 2015) (Appendix 13)

MDS-UPDRS: An impairment measurement of disease severity.

Motor ADL (Section II) and Motor Examination (Section III) will be evaluated (Goetz et al, 2008) (Appendix 14)

PDQ-39: This is a disease specific measure of quality of life (Peto et al, 1995) and has been shown to be sensitive to changes that matter to the individuals.

B6. What is the anticipated start date of this study?

Early September

B7. What is the anticipated duration of this study?

September 2015 – April 2016: (8 months)

B8 (a) How many research participants are to be recruited in total?

24

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.

Descriptive statistics will be used to describe baseline demographic information (Appendix 5) and feasibility measures.

To determine if there is a significant difference in clinical scores from pretest to posttest intervention a paired t-test will be used to assess parametric results and a Wilcoxon signed-rank test will be used to evaluate non-parametric tests.
B8 (c) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

As there is no Minimum Clinically Important Difference (MCID) for the primary outcome measure of the Six minute walk test for PD the researcher is adopting a sample size power calculation from a previous similar study using this primary outcome measure in this cohort of participants. A sample size of 24 was sought to show an increase of 82 metres on the Six Minute Walk Test (MDC) with an alpha of 5% and a power of 80%.

B8 (d) Where sample size calculation is impossible (e.g. It is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

See Above

6 SECTION C study PARTICIPANTS

SECTION C IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

7 SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1. 1 How many research participants are to be recruited? At each site (if applicable)? And in each treatment group of the study (if applicable)?
### C1.2 How will the participants in the study be selected?

The participants will be recruited from the physiotherapy department outpatient neurology waiting list and physiotherapy review PD database. If recruitment is posing difficult, potential PD participants from the Day Hospital may be invited to partake in the study.

### C1.3 How will the participants in the study be recruited?

The participants will be sent an invitation letter (Appendix 1) from the Deputy Physiotherapy Manager who will act as gatekeeper for the trial inviting them to participate in the research programme. The invitation letter will be accompanied by a patient information leaflet (Appendix 2) and consent form (Appendix 3) which will outline the purpose and nature of the study. The participants will have considerable amount of time to digest this information and consider if they wish to volunteer for the study or not. Participants will then be contacted by the principal investigator to ensure eligibility and baseline assessments will be scheduled at this time. Verbal consent will be gained over the phone with written consent provided at baseline assessments.

### C1.4 What are the main inclusion criteria for research participants? (please justify)

1. Diagnosis of Ideopathic Parkinson’s Disease diagnosed by a Consultant Neurologist
2. Hoehn and Yahr Scale 1-3 as any stage greater than this will require a lot of supervision (Appendix 4)
3. Independent Mobile with or without a gait aid
4. Ability to give informed consent and follow simple commands

C1.5 What are the main exclusion criteria for research participants? (please justify)

1. Non-Ideopathic PD
2. Unstable Cardiovascular Disease
3. Uncontrolled Chronic Condition
4. Doctor confirmed Diagnosis of Dementia/PD Related Dementia – this was discussed with the co-investigator Dr. Mary Martin.
5. Attended Physiotherapy intervention in the last 3 months – This timeframe is adopted in numerous PD published trials.

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project? **No**

8 SECTION C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? **Yes**

C2.1 (c) If yes, how will informed consent be obtained and by whom?

Potential participants will receive an information pack containing a study invitation letter, patient information leaflet and consent form from the gatekeeper. Potential participants will be contacted after a cooling period of at least one week after they receive documentation to determine consent. Verbal consent will be acknowledged over the phone, however, written consent will be obtained at baseline assessment.

C2.1 (d) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?

Yes. It is stated clearly in the patient information leaflet that there is no obligation to participate in the study and that participants may withdraw at any time without affecting their care.
The investigator will also be guided by her professional code of conduct as stipulated by the ISCP.

C2.1 (f) Will there be a time interval between giving information and seeking consent? Yes

C2.1 (g) If yes, please elaborate.

Participants will be given a cooling off period of at least 7 days to make a decision regarding participation into the research study.

9 SECTION C3 adult participants - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes, as this is stipulated in the inclusion criteria

C3.1 (b) If no, please elaborate

C3.1 (c) If no, is this research of such a nature that it can only be carried out on adults without capacity? No

C3.1 (d) What arrangements are in place for research participants who may regain their capacity?

Not Applicable

10 SECTION C4 participants under the age of 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

11 SECTION C5 PARTICIPANTS - CHECKLIST

Please confirm if any of the following groups will participate in this study. This is a quick checklist for research ethics committee
members and it is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity.

C5.1 Patients  Yes
C5.2 Unconscious patients  No
C5.3 Current psychiatric in-patients  No
C5.4 Patients in an emergency medical setting  No
C5.5 Relatives / Carers of patients  No
C5.6 Healthy Volunteers  No
C5.7 Students  No
C5.8 Employees / staff members  No
C5.9 Prisoners  No
C5.10 Residents of nursing homes  No
C5.11 Pregnant women  No
C5.12 Women of child bearing potential  No
C5.13 Breastfeeding mothers  No
C5.14 Persons with an acquired brain injury  No
C5.15 Intellectually impaired persons  No
C5.16 Persons aged > 65 years  Yes

C5.17 If yes to any of the above, what special arrangements have been made to deal with issues of consent and assent (if any)?

Refer to C2.1 c

12  SECTION D  research PROCEDURES

SECTION D IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

D1. What research procedures or interventions (over and above those clinically indicated and/or over and above those which are part of routine care) will research participants undergo whilst participating in this study?
Research participants will undergo a 6 week (once-weekly) large-amplitude group exercise class in the physiotherapy department.

The primary focus of the intervention is on feasibility and clinical efficacy outcomes regarding physical performance.

**D2. If there are any potential harms resulting from any of the above listed procedures, provide details below:**

The participants will be participating in a group exercise class. Group exercises classes are a routine component of physiotherapy intervention. As with any group exercise class there is a small risk of falls or injury, however, the participants will be supervised at all times and an environmental risk assessment will be conducted as per usual care prior to each class.

An adverse events form will be documented completed weekly (Appendix 6)

In the rare case of an incident, the investigator will adhere to hospital protocol regarding completion of an incident recording form and report any adverse events to members of the research ethics committee as outlined in the policy for undertaking research in Naas General Hospital.

**D3. What is the potential benefit that may occur as a result of this study?**

Participation in the class may improve physical performance measures of enhance mobility, balance, confidence, quality of life.

Social engagement and peer support

**D4 (a) Will the study involve the withholding of treatment?**

**No**

**D4 (b) Will there be any harms that could result from withholding treatment?**

**N/A**

**D5. How will the health of participants be monitored during and after the study?**

The participants will be monitored as part of usual care by the therapist taking the class.

The validated outcome measures will be used to evaluate health improvements over the course of the 6 weeks.
Safety evaluation forms will be completed during the intervention and by the participants at home while carrying out their home exercise programme.

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? [Not Applicable as this is not a Randomised Controlled Trial]

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Not Applicable

D7. Please comment on how individual results will be managed.

Results and outcomes of the study will be sent to the referring Dr and also to the participant’s Consultant Neurologist (Appendix 16)

This is part of routine clinical practice

D8. Please comment on how aggregated study results will be made available.

- Results will be submitted as part of a Masters thesis to RCSI.
- Dissemination at key conferences and peer reviewed journals – if this occurs, Naas General Hospital will be acknowledged as a publication site for research
- The results will also be submitted to the Physiotherapy Manager as part of a Quality Improvement Project.
- Power Point Presentation will be provided to all Physiotherapy Staff at a General In-Service Training.
- Power Point Presentation will be provided at the Hospitals Research and Education Forum.

D9. Will the research participant’s general practitioner be informed the research participant is taking part in the study (if appropriate)? [If the GP is the referring Doctor then a letter explaining that the participant is partaking in the study and a brief outline of the study will be issued]

D10. Will the research participant’s hospital consultant be informed the research participant is taking part in the study (if appropriate)?
13 SECTION E  Data Protection

SECTION E IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

SECTION E1  data processing - consent

E1.1 (a) Will consent be sought for the processing of data? Yes

SECTION E2 data processing - GENERAL

E2.1 Who will have access to the data which is collected?

The hard copy records of data will be stored in a locked filing cabinet in the physiotherapy department accessibly only to the principle investigator (PI) and physiotherapy manager.

All electronic data will be coded and anonymous and stored on the PI password protected computer in the physiotherapy department.

E2.2 What media of data will be collected?

Computerised spreadsheets and hard copy paper forms

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

Coded and Anonymous

E2.3 (b) If ‘coded’, please confirm who will retain the ‘key’ to re-identify the data?
The PI will retain the “key” which will remain in a locked filing cabinet in the physiotherapy department – this will be kept separately from the original data, therefore, only the PI will be able to identify the data optimises confidentiality.

Electronic data will be stored on a password protected computer which is unique to the PI.

### E2.4 Where will data which is collected be stored?

- Hard copy records will be stored in a locked filing cabinet in the physiotherapy department, where the PI and the Physiotherapy manager only will have access to.
- Electronic data will be stored on the principal investigator’s password protected computer in the physiotherapy department.

### E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

- All of the above
- Also, the investigator has reviewed relevant hospital and HSE data protection policies to ensure full knowledge and awareness of adequate security measures:
  1. Data Protection and Freedom of Information Legislation – Guidance for Health Service Staff
  2. Data Protection – Its Everyone’s Responsibility; An Introductory guide for Health Service Staff

### E2.6 (a) Will data collected be at any stage leaving the site of origin?

No

### E2.7 Where will data analysis take place and who will perform data analysis (if known)?

- In Naas General Hospital by the Principal Investigator
- This will be conducted out of work hours

### E2.8 (a) After data analysis has taken place, will data be destroyed or retained?


Retained for a period of 5 years in accordance with Data Protection Legislation, after which time it will be destroyed

**E2.8 (b) Please elaborate.**

Clinical data will be retained as part of participant healthcare records as per routine clinical practice. This is outlined in the Data Protection Records Retention Policy.

Research data will be destroyed.

**E2.8 (c) If destroyed, how, when and by whom will it be destroyed?**

How: Shredding of Confidential Data using on site HSE shredding – this shredded paper can be recycled as part of a recyclables collection (Data Protection Policy)

Whom: The PI

**E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?**

Hard data in a locked filing cabinet in the physiotherapy department, electronic data on a password protected computer in the physiotherapy department for five years after the period of data collection.

This timeframe is stipulated by the Royal College of Surgeons in Ireland with respect to good research practice when conducting a research study.

**E2.9 Please comment on the confidentiality of collected data.**

The following measures will be taken to ensure confidentiality of data:

1. Participants will be provided with a unique identifier number. This will be kept in a separate file to the hard data of electronic data and will be stored separately
2. Names and other details that may identify the participants will be removed
3. Only the investigator will have access to and be aware of the “key” to these codes
4. All data collected will be saved in a password protected computer of the PI
5 This password is unique and has a minimum of 8 characters in length with a combination of letters and numbers to increase complexity (Data Protection Policy).

5 All hard copies of written documentation will be secured in a locked filing cabinet.

6 Access to the study data will be restricted to the PI.

**E2.10 (a)** Will any of the interview data collected consist of audio recordings / video recordings? **No**

**E2.11 (a)** Will any of the study data collected consist of photographs/ video recordings? **No**

**SECTION e3  ACCESS TO HEALTHCARE RECORDS**

**E3.1 (a)** Does the study involve access to healthcare records (hard copy / electronic)? **No**; information regarding indications for treatment, PMedHx and Meds should be provided by referring source. If this is not explicit, the principal investigator will contact the referring source for this information.

**E3.1 (b)** If yes, please elaborate.

**Not applicable**

**E3.1 (c)** Who will access these healthcare records?

**Not Applicable**

**E3.1 (d)** Will consent be sought from patients for research team members to access their healthcare records? **Yes / No**

**E3.2 (a)** Who or what legal entity is the data controller in respect of the healthcare records?

**Not applicable**
**E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?**

Not applicable

---

**16 SECTION f  HUMAN BIOLOGICAL MATERIAL**

**17 f1 Bodily Tissue / Bodily Fluid Samples - general**

**F1 1 (a) Does this study involve human biological material?  **No**

If answer is No, Please delete following questions in Section F.

---

**18 section G radioactive material / diagnostic or therapeutic ionising radiation**

**19 G1 radioactive material / diagnostic or therapeutic ionising radiation - general**

**G1.1 (a) Does this study/trial involve exposure to radioactive materials or does this study/trial involve other diagnostic or therapeutic ionising radiation?  **No**

If the answer to question G1.1(a) is No, please delete the following questions in this Section.
SECTI0N H  MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device?  [No]

If the answer to question H1 (a) is No, please delete the following questions in this Section.

SECTION I  MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product. Section I is optional. Please delete if this section does not apply.

SECTION I.1  NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product?  [No]

If the answer to question I1.1 (a) is No, please delete the following questions in this Section.

SECTION I.2  COSMETICS

I2.1 (a) Does this study involve a cosmetic?  [No]
If the answer to question I 2.1 (a) is No, please delete the following questions in Sub-Section I 2.

SECTION I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

If the answer to question I 3.1 (a) is No, please delete the following question in Sub-Section I 3.

25.1 SECTION j INDEMNITY

SECTION J IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

J1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? Yes

J2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? Yes. The investigator carrying out this piece of research is an employee of Naas General Hospital and a qualified chartered physiotherapist. She is covered under the indemnity of Naas General Hospital

J3 (a) Who or what legal entity is the sponsor of this research study?

Pending Ethical Approval from Naas General Hospital Research Ethics Committee
J3 (b) What additional indemnity arrangements has the sponsor put in place for this research study in case of harm being caused to a research participant (if any)?

This research is conducted as part of the requirements of a MSc in Neurology and Gerontology from the Royal College of Surgeons of Ireland. The researcher, a registered student at RCSI is also covered by the indemnity by provided by RCSI

SECTION k COST AND RESOURCE IMPLICATIONS and funding

SECTION K IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

K1 (a) Are there any cost / resource implications related to this study?  No

K2 (a) Is funding in place to conduct this study?  No

K2 (d) Is the study being funded by an external agency?  No
K2 (e) Is the external agency a ‘for profit’ organisation?  No

K2 (g) Please provide additional details in relation to management of funds.

N/A
K3. Please provide details of any payments (monetary or otherwise) to investigators.

N/A

K4. Please provide details of any payments (monetary or otherwise) to participants.

N/A

SECTION 1 ETHICAL ISSUES

SECTION L IS MANDATORY

L1. Please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.

The PI feels that all potential ethical issues that this project raises from recruitment, Consent, Data collection and protection, exclusion criteria, safety issues and adverse events; have all been discussed and addressed in various sections of the application form.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.
Appendix 7: Ethical Approval Royal College of Surgeons of Ireland

Royal College of Surgeons in Ireland
The Research Ethics Committee
121 St. Stephen’s Green, Dublin 2, Ireland.
Tel.: 081 4509705 Email: recsinfo@rcsi.ie

Dr David Smith, Acting Chair
Dr Niamh Clarke, Governor

1st September 2014

Ms Eimear Marley,
Physiotherapy Department,
Naas General Hospital,
Naas,
Co. Kildare

<table>
<thead>
<tr>
<th>Ethics Reference No.</th>
<th>Project Title</th>
<th>Researchers Name (lead applicant)</th>
<th>Principal Investigator on the project</th>
<th>Other individuals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECI118 (accepted from Naas Hospital)</td>
<td>Large-Amplitude Group Exercise Training for individuals with Parkinson's Disease: A Pilot Intervention Study</td>
<td>Ms Eimear Marley</td>
<td>Dr Helen French</td>
<td>Dr Mary Martin (Consultant Geriatrician, Naas General Hospital)</td>
</tr>
</tbody>
</table>

Dear Ms Marley,

Thank you for your Research Ethics Committee (REC) application. The RCSI REC accepts the ethical approval granted by the Naas Hospital REC for the research study (details above) submitted by Ms Eimear Marley.

This letter provides approval for data collection for the time requested in your application and for an additional 6 months. This is to allow for any unexpected delays in proceeding with data collection; therefore this research ethics approval will expire on 1st October 2016.

Where data collection is necessary beyond this point, approval for an extension must be sought from the Research Ethics Committee.

This ethical approval is given on the understanding that:

- All personnel listed in the approved application have read, understand and are thoroughly familiar with all aspects of the study.
- Any significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the REC, and an ethical amendment submitted where appropriate.
- Please submit a final report to the REC upon completion of your project.

We wish you all the best with your research.

Yours sincerely,

[Signature]

PP Dr Niamh Clarke (Convenor)
Dr David Smith (Acting Chair)
Appendix 8: Adverse Events Form during Intervention Programme:

Participant ID:_____________________

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<tr>
<th></th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Explanation</th>
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<td>Injury Sustained</td>
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<td>Near-Miss Accident</td>
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<td>Fall Sustained</td>
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**Appendix 9: Adverse Events Form carrying out Home Exercise Programme:**

Participant ID: __________________

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<th>Wednesday</th>
<th>Thursday</th>
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<th>Saturday</th>
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<td>Near-Miss Accident</td>
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<td>Fall Sustained</td>
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Appendix 10: Exercise Compliance:

Exercise Logbook (Home Exercise Diary and DVD Compliance Log)

*Please Circle the times of the day when you carried out your 7 Core Exercises:*

<table>
<thead>
<tr>
<th>Exercises</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
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<tr>
<td>Ex #5</td>
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<tr>
<td>Ex #6</td>
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<td>Ex #7</td>
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</tr>
</tbody>
</table>

*Please Tick the Days You Used the Exercise DVD to assist you while Exercising:*

<table>
<thead>
<tr>
<th>DVD USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Appendix 11: Adherence Rates: Attendance Sheet

Large-Amplitude Group Exercise Programme

Attendance Sheet

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Class 1 Date</th>
<th>Class 2 Date</th>
<th>Class 3 Date</th>
<th>Class 4 Date</th>
<th>Class 5 Date</th>
<th>Class 6 Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
**Appendix 12: Participant Satisfaction:**

*The researcher would like to know your feedback from the exercise programme. Please place one tick under the statement which best reflects your answer.*

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree or Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found the programme beneficial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I found the frequency of the class adequate (x1/week)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The duration of the class (1 hour) was too long</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After the exercise programme, I am able to walk for longer distances</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After the exercise programme, my ADLs such as doing the house chores and shopping are easier to manage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After the exercise programme, I feel steadier on my feet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My mood has improved after completion of the programme</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercise resources (Photo-pack, DVD, YouTube link) motivated me to exercise at home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Please Circle which Resource you found most beneficial:</strong></td>
<td>Photo-Pack</td>
<td>DVD</td>
<td>YouTube Video</td>
<td>None Of the Above</td>
<td></td>
</tr>
<tr>
<td>The Home Exercise Programme was difficult to carry out at home because it was too long to carry out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I will continue to practice my daily home exercise programme when the programme has finished</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel that exercising in a group setting is more enjoyable than exercising one-to-one (physiotherapist and individual)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>I would recommend this exercise programme to others</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My exercise habits are going to change after the programme</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Appendix 13: Six Minute Walk Test

**Description:** The 6-Minute Walk test is a measure of exercise capacity and endurance.

**Equipment:** Stopwatch, Tape Measure, Track/loop Walkway, Portable Chair

**Instructions to participant:**

“When I say “go”, I want you to walk as quickly as you can, as you feel comfortable and safe, for six minutes, up and down this walkway, doing laps. I will walk with you. If you get tired, short of breath, have chest pain, leg pain, or any other symptoms, we will stop and have you rest until you feel ready to go again. While you rest, we let the stopwatch run, and then when you are through resting you can continue to walk for what is left of the remaining 6 minutes. You can begin when I say “go”.

- Be sure to walk slightly BEHIND the participant so you are not unintentionally coaxing them to go faster than they would choose otherwise.
- Inform the patient of the time elapsed at the end of each minute.
- Keep talking to a minimum to conserve participants’ pulmonary function.

At the end of the 6 minutes:

- Have the participant sit down (portable chair).
- Calculate and record the distance walked.

<table>
<thead>
<tr>
<th>Time</th>
<th>Document Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minute 1</td>
<td></td>
</tr>
<tr>
<td>Minute 2</td>
<td></td>
</tr>
<tr>
<td>Minute 3</td>
<td></td>
</tr>
<tr>
<td>Minute 4</td>
<td></td>
</tr>
<tr>
<td>Minute 5</td>
<td></td>
</tr>
<tr>
<td>Minute 6</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 14: Permission to Use MDS-UPDRS for Research Project:

Name: Eimear Manley

Company / Organization Name: Naas General Hospital

Address: Physiotherapy Department, Naas General Hospital City: Kildare State: Leinster

Country: Ireland

Telephone: 00353871257242. Email: Eimear.manley@rcsi.ie

Intended use of materials: I am currently carrying out an MSc in the Royal College of Surgeons in Ireland.

As part of my research project, I would like to use the MDS-UPDRS as one of my outcome measures.

My study is a small feasibility study which aims to assess the clinical effectiveness and feasibility of a movement-amplitude training programme in people with Parkinson’s Disease.

I am receiving no funding/grants for this small scale study. Total: $0 USD

By submitting this request to MDS, you agree to the following: I understand that all of the International Parkinson and Movement Disorder Society (MDS) Rating Scales may only be used for the purposes described above. I also understand that reproduction, translation, modification, sale, or distribution of any portion of the MDS Rating Scales is strictly prohibited and, specifically, that the MDS Rating Scales may not be incorporated into clinical trials, training or certification programs or materials, software programs, or otherwise except through use of the Permissions Request form and payment of applicable fees.

Dear Dr. Manley,

Thank you for contacting MDS regarding permission to use the MDS-UPDRS in your research project. I have reviewed your request and am pleased to grant you permission to use the MDS-UPDRS in your research project, free of charge. Please let me know if you have any questions or if there is anything further I can assist you with. Thank you.

Best Regards,

Megan Campbell
Program Manager
International Parkinson and Movement Disorder Society (MDS)
555 E. Wells Street, Suite 1100
Appendix 14: Movement-Disorder Society-Unified Parkinson’s Disease Rating Scale

MDS-UPDRS

The Movement Disorder Society (MDS)-sponsored new version of the UPDRS is founded on the critique that was formulated by the Task Force for Rating Scales in Parkinson's disease (Mov Disord 2003;18:738-750). Thereafter, the MDS recruited a Chairperson to organize a program to provide the Movement Disorder community with a new version of the UPDRS that would maintain the overall format of the original UPDRS, but address issues identified in the critique as weaknesses and ambiguities. The Chairperson identified subcommittees with chairs and members. Each part was written by the appropriate subcommittee members and then reviewed and ratified by the entire group. These members are listed below.

The MDS-UPDRS has four parts: Part I (non-motor experiences of daily living), Part II (motor experiences of daily living), Part III (motor examination) and Part IV (motor complications). Part I has two components: IA concerns a number of behaviors that are assessed by the investigator with all pertinent information from patients and caregivers, and IB is completed by the patient with or without the aid of the caregiver, but independently of the investigator. These sections can, however, be reviewed by the rater to ensure that all questions are answered clearly and the rater can help explain any perceived ambiguities. Part II is designed to be a self-administered questionnaire like Part IB, but can be reviewed by the investigator to ensure completeness and clarity. Of note, the official versions of Part IA, Part IB and Part II of the MDS-UPDRS do not have separate on or off ratings. However, for individual programs or protocols the same questions can be used separately for on and off. Part III has instructions for the rater to give or demonstrate to the patient; it is completed by the rater. Part IV has instructions for the rater and also instructions to be read to the patient. This part integrates patient-derived information with the rater's clinical observations and judgments and is completed by the rater.

The authors of this new version are:

Chairperson: Christopher G. Goetz
Part I: Werner Poewe (chair), Bruno Dubois, Anette Schrag
Part II: Matthew B. Stern (chair), Anthony E. Lang, Peter A. LeWitt
Part III: Stanley Fahn (chair), Joseph Jankovic, C. Warren Olmstead
Part IV: Pablo Martinez-Martín (chair), Andrew Lee, Olivier Rascol, Bob van Hilten
Development Standards: Glenn T. Stebbins (chair), Robert Holloway, David Nyenhuis
Appendices: Cristina Sampalo (chair), Richard Dodel, Jaime Kulisevsky
Statistical Testing: Barbara Tilley (chair), Sue Leurgans, Joan Teresi
Consultant: Stephanie Shaftman, Nancy Lapelle

Contact person: Christopher G. Goetz, MD
Rush University Medical Center
1725 W. Harrison Street, Suite 755
Chicago, IL USA 60612

Telephone 312-942-8016
Email: cgoetz@rush.edu

July 1, 2008
### Part II: Motor Aspects of Experiences of Daily Living (M-EDL)

#### 2.1 SPEECH

Over the past week, have you had problems with your speech?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: Not at all (no problems).</td>
</tr>
<tr>
<td>1</td>
<td>Slight: My speech is soft, slurred or uneven, but it does not cause others to ask me to repeat myself.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: My speech causes people to ask me to occasionally repeat myself, but not everyday.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: My speech is unclear enough that others ask me to repeat myself every day even though most of my speech is understood.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Most or all of my speech cannot be understood.</td>
</tr>
</tbody>
</table>
### 2.2 SALIVA & DROOLING

Over the past week, have you usually had too much saliva during when you are awake or when you sleep?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I have too much saliva, but do not drool.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I have some drooling during sleep, but none when I am awake.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>I have some drooling when I am awake, but I usually do not need tissues or a handkerchief.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>I have so much drooling that I regularly need to use tissues or a handkerchief to protect my clothes.</td>
</tr>
</tbody>
</table>

### 2.3 CHEWING AND SWALLOWING

Over the past week, have you usually had problems swallowing pills or eating meals? Do you need your pills cut or crushed or your meals to be made soft, chopped or blended to avoid choking?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>No problems.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I am aware of slowness in my chewing or increased effort at swallowing, but I do not choke or need to have my food specially prepared.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I need to have my pills cut or my food specially prepared because of chewing or swallowing problems, but I have not choked over the past week.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>I choked at least once in the past week.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Because of chewing and swallowing problems, I need a feeding tube.</td>
</tr>
</tbody>
</table>
### 2.4 EATING TASKS

Over the past week, have you usually had troubles handling your food and using eating utensils? For example, do you have trouble handling finger foods or using forks, knives, spoons, chopsticks?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all (No problems).</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I am slow, but I do not need any help handling my food and have not had food spills while eating.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I am slow with my eating and have occasional food spills. I may need help with a few tasks such as cutting meat.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>I need help with many eating tasks but can manage some alone.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>I need help for most or all eating tasks.</td>
</tr>
</tbody>
</table>

### 2.5 DRESSING

Over the past week, have you usually had problems dressing? For example, are you slow or do you need help with buttoning, using zippers, putting on or taking off your clothes or jewelry?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I am slow but I do not need help.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I am slow and need help for a few dressing tasks (buttons, bracelets).</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>I need help for many dressing tasks.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>I need help for most or all dressing tasks.</td>
</tr>
</tbody>
</table>
### 2.6 HYGIENE

Over the past week, have you usually been slow or do you need help with washing, bathing, shaving, brushing teeth, combing your hair or with other personal hygiene?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal:</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight:</td>
<td>I am slow but I do not need any help.</td>
</tr>
<tr>
<td>2: Mild:</td>
<td>I need someone else to help me with some hygiene tasks.</td>
</tr>
<tr>
<td>3: Moderate:</td>
<td>I need help for many hygiene tasks.</td>
</tr>
<tr>
<td>4: Severe:</td>
<td>I need help for most or all of my hygiene tasks.</td>
</tr>
</tbody>
</table>

### 2.7 HANDWRITING

Over the past week, have people usually had trouble reading your handwriting?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal:</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight:</td>
<td>My writing is slow, clumsy or uneven, but all words are clear.</td>
</tr>
<tr>
<td>2: Mild:</td>
<td>Some words are unclear and difficult to read.</td>
</tr>
<tr>
<td>3: Moderate:</td>
<td>Many words are unclear and difficult to read.</td>
</tr>
<tr>
<td>4: Severe:</td>
<td>Most or all words cannot be read.</td>
</tr>
</tbody>
</table>

### 2.8 DOING HOBBIES AND OTHER ACTIVITIES

Over the past week, have you usually had trouble doing your hobbies or other things that you like to do?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal:</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight:</td>
<td>I am a bit slow but do these activities easily.</td>
</tr>
<tr>
<td>2: Mild:</td>
<td>I have some difficulty doing these activities.</td>
</tr>
<tr>
<td>3: Moderate:</td>
<td>I have major problems doing these activities, but still do most.</td>
</tr>
<tr>
<td>4: Severe:</td>
<td>I am unable to do most or all of these activities.</td>
</tr>
</tbody>
</table>
### 2.9 TURNING IN BED

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I have a bit of trouble turning, but I do not need any help.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I have a lot of trouble turning and need occasional help from someone else.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>To turn over I often need help from someone else.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>I am unable to turn over without help from someone else.</td>
</tr>
</tbody>
</table>

### 2.10 TREMOR

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all. I have no shaking or tremor.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>Shaking or tremor occurs but does not cause problems with any activities.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>Shaking or tremor causes problems with only a few activities.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>Shaking or tremor causes problems with many of my daily activities.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Shaking or tremor causes problems with most or all activities.</td>
</tr>
</tbody>
</table>

### 2.11 GETTING OUT OF BED, A CAR, OR A DEEP CHAIR

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight</td>
<td>I am slow or awkward, but I usually can do it on my first try.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>I need more than one try to get up or need occasional help.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>I sometimes need help to get up, but most times I can still do it on my own.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>I need help most or all of the time.</td>
</tr>
</tbody>
</table>
2.12 WALKING AND BALANCE

Over the past week, have you usually had problems with balance and walking?

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal:</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight:</td>
<td>I am slightly slow or may drag a leg. I never use a walking aid.</td>
</tr>
<tr>
<td>2: Mild:</td>
<td>I occasionally use a walking aid, but I do not need any help from another person.</td>
</tr>
<tr>
<td>3: Moderate:</td>
<td>I usually use a walking aid (cane, walker) to walk safely without falling. However, I do not usually need the support of another person.</td>
</tr>
<tr>
<td>4: Severe:</td>
<td>I usually use the support of another persons to walk safely without falling.</td>
</tr>
</tbody>
</table>

2.13 FREEZING

Over the past week, on your usual day when walking, do you suddenly stop or freeze as if your feet are stuck to the floor.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal:</td>
<td>Not at all (no problems).</td>
</tr>
<tr>
<td>1: Slight:</td>
<td>I briefly freeze but I can easily start walking again. I do not need help from someone else or a walking aid (cane or walker) because of freezing.</td>
</tr>
<tr>
<td>2: Mild:</td>
<td>I freeze and have trouble starting to walk again, but I do not need someone’s help or a walking aid (cane or walker) because of freezing.</td>
</tr>
<tr>
<td>3: Moderate:</td>
<td>When I freeze I have a lot of trouble starting to walk again and, because of freezing, I sometimes need to use a walking aid or need someone else’s help.</td>
</tr>
<tr>
<td>4: Severe:</td>
<td>Because of freezing, most or all of the time, I need to use a walking aid or someone’s help.</td>
</tr>
</tbody>
</table>

This completes the questionnaire. We may have asked about problems you do not even have, and may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this questionnaire.
Part III: Motor Examination

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

At the top of the form, mark whether the patient is on medication for treating the symptoms of Parkinson’s disease and, if on levodopa, the time since the last dose.

Also, if the patient is receiving medication for treating the symptoms of Parkinson’s Disease, mark the patient’s clinical state using the following definitions:

- **ON**: The typical functional state when patients are receiving medication and have a good response.
- **OFF**: The typical functional state when patients have a poor response in spite of taking medications.

The investigator should “rate what you see”. Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), use the notation “UR” for Unable to Rate. Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

| 3a | Is the patient on medication for treating the symptoms of Parkinson’s Disease? □ No □ Yes |
| 3b | If the patient is receiving medication for treating the symptoms of Parkinson’s Disease, mark the patient’s clinical state using the following definitions:
  | □ ON: The typical functional state when patients are receiving medication and have a good response.
  | □ OFF: Off is the typical functional state when patients have a poor response in spite of taking medications.
| 3c | Is the patient on Levodopa? □ No □ Yes |
|    | 3.C1 If yes, minutes since last levodopa dose:          |

July 1, 2003
### 3.1 SPEECH

**Instructions to examiner:** Listen to the patient’s free-flowing speech and engage in conversation if necessary. Suggested topics: ask about the patient’s work, hobbies, exercise, or how he got to the doctor’s office. Evaluate volume, modulation (prosody) and clarity, including slurring, paillalia (repetition of syllables) and tachypnea (rapid speech, running syllables together).

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No speech problems.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Loss of modulation, diction or volume, but still all words easy to understand.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Loss of modulation, diction, or volume, with a few words unclear, but the overall sentences easy to follow.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Speech is difficult to understand to the point that some, but not most, sentences are poorly understood.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Most speech is difficult to understand or unintelligible.</td>
</tr>
</tbody>
</table>

### 3.2 FACIAL EXPRESSION

**Instructions to examiner:** Observe the patient sitting at rest for 10 seconds, without talking and also while talking. Observe eye-blink frequency, masked facies or loss of facial expression, spontaneous smiling and parting of lips.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: Normal facial expression.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Minimal masked facies manifested only by decreased frequency of blinking.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: In addition to decreased eye-blink frequency, Masked facies present in the lower face as well, namely fewer movements around the mouth, such as less spontaneous smiling, but lips not parted.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Masked facies with lips parted some of the time when the mouth is at rest.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Masked facies with lips parted most of the time when the mouth is at rest.</td>
</tr>
</tbody>
</table>
### 3.3 RIGIDITY

**Instructions to examiner:** Rrigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No rigidity.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Rigidity only detected with activation maneuver.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.</td>
</tr>
</tbody>
</table>

### 3.4 FINGER TAPPING

**Instructions to examiner:** Each hand is tested separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to tap the index finger on the thumb 10 times as quickly AND as big as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No problems.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement, b) slight slowing, c) the amplitude decrements near the end of the 10 taps.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Any of the following: a) 3 to 5 interruptions during tapping, b) mild slowing, c) the amplitude decrements midway in the 10-tap sequence.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement, b) moderate slowing, c) the amplitude decrements starting after the 1st tap.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.</td>
</tr>
</tbody>
</table>
### 3.5 HAND MOVEMENTS

**Instructions to examiner:** Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to make a fist with the arm bent at the elbow so that the palm faces the examiner. Have the patient open the hand 10 times as fully and as quickly as possible. If the patient fails to make a tight fist or to open the hand fully, remind him/her to do so. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No problem.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.</td>
</tr>
</tbody>
</table>

### 3.6 PRONATION-SUPINATION MOVEMENTS OF HANDS

**Instructions to examiner:** Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to extend the arm out in front of his/her body with the palms down; then to turn the palm up and down alternately 10 times as fast and as fully as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No problems.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing c) the amplitude decrements starting after the 1st supination-pronation sequence.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.</td>
</tr>
</tbody>
</table>
3.7 TOE TAPPING

**Instructions to examiner:** Have the patient sit in a straight-backed chair with arms, both feet on the floor. Test each foot separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the heel on the ground in a comfortable position and then tap the toes 10 times as big and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>No problem.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the first tap.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Cannot or can only barely perform the task because of slowing, interruptions or decrements.</td>
</tr>
</tbody>
</table>

3.8 LEG AGILITY

**Instructions to examiner:** Have the patient sit in a straight-backed chair with arms. The patient should have both feet comfortably on the floor. Test each leg separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the foot on the ground in a comfortable position and then raise and stomp the foot on the ground 10 times as high and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>No problems.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the first tap.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Cannot or can only barely perform the task because of slowing, interruptions or decrements.</td>
</tr>
</tbody>
</table>
3.9 ARISING FROM CHAIR

Instructions to examiner: Have the patient sit in a straight-backed chair with arms, with both feet on the floor and sitting back in the chair (if the patient is not too short). Ask the patient to cross his/her arms across the chest and then to stand up. If the patient is not successful, repeat this attempt a maximum up to two more times. If still unsuccessful, allow the patient to move forward in the chair to arise with arms folded across the chest. Allow only one attempt in this situation. If unsuccessful, allow the patient to push off using his/her hands on the arms of the chair. Allow a maximum of three trials of pushing off. If still not successful, assist the patient to arise. After the patient stands up, observe the posture for Item 3.13.

0: Normal: No problems. Able to arise quickly without hesitation.
1: Slight: Arising is slower than normal; or may need more than one attempt; or may need to move forward in the chair to arise. No need to use the arms of the chair.
2: Mild: Pushes self up from arms of chair without difficulty.
3: Moderate: Needs to push off, but tends to fall back; or may have to try more than one time using arms of chair, but can get up without help.
4: Severe: Unable to arise without help.

3.10 GAIT

Instructions to examiner: Testing gait is best performed by having the patient walking away from and towards the examiner so that both right and left sides of the body can be easily observed simultaneously. The patient should walk at least 10 meters (30 feet), then turn around and return to the examiner. This item measures multiple behaviors: stride amplitude, stride speed, height of foot lift, heel strike during walking, turning, and arm swing, but not freezing. Assess also for “freezing of gait” (next item 3.11) while patient is walking. Observe posture for Item 3.13.

0: Normal: No problems.
1: Slight: Independent walking with minor gait impairment.
2: Mild: Independent walking but with substantial gait impairment.
3: Moderate: Requires an assistance device for safe walking (walking stick, walker) but not a person.
4: Severe: Cannot walk at all or only with another person’s assistance.
### 3.11 Freezing of Gait

**Instructions to examiner:** While assessing gait, also assess for the presence of any gait freezing episodes. Observe for start hesitation and stuttering movements especially when turning and reaching the end of the task. To the extent that safety permits, patients may NOT use sensory tricks during the assessment.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>No freezing.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>Freezes on starting, turning or walking through doorway with a single halt during any of these events, but then continues smoothly without freezing during straight walking.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>Freezes on starting, turning or walking through doorway with more than one halt during any of these activities, but continues smoothly without freezing during straight walking.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>Freezes once during straight walking.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Freezes multiple times during straight walking.</td>
</tr>
</tbody>
</table>

### 3.12 Postural Stability

**Instructions to examiner:** The test examines the response to sudden body displacement produced by a quick, forceful pull on the shoulders while the patient is standing erect with eyes open and feet comfortably apart and parallel to each other. Test retropulsion. Stand behind the patient and instruct the patient on what is about to happen. Explain that s/he is allowed to take a step backwards to avoid falling. There should be a solid wall behind the examiner, at least 1-2 meters away to allow for the observation of the number of retropulsive steps. The first pull is an instructional demonstration and is purposely milder and not rated. The second time the shoulders are pulled briskly and forcefully towards the examiner with enough force to displace the center of gravity so that patient MUST take a step backwards. The examiner needs to be ready to catch the patient, but must stand sufficiently back so as to allow enough room for the patient to take several steps to recover independently. Do not allow the patient to flex the body abnormally forward in anticipation of the pull. Observe the number of steps backwards or falling. Up to and including two steps for recovery is considered normal, so abnormal ratings begin with three steps. If the patient fails to understand the test, the examiner can repeat the test so that the rating is based on an assessment that the examiner feels reflects the patient's limitations rather than misunderstanding or lack of preparedness. Observe standing posture for item 3.13.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: Normal</td>
<td>No problems: Recovers with one or two steps.</td>
</tr>
<tr>
<td>1: Slight</td>
<td>3-5 steps, but subject recovers unaided.</td>
</tr>
<tr>
<td>2: Mild</td>
<td>More than 5 steps, but subject recovers unaided.</td>
</tr>
<tr>
<td>3: Moderate</td>
<td>Stands safely, but with absence of postural response; falls if not caught by examiner.</td>
</tr>
<tr>
<td>4: Severe</td>
<td>Very unstable, tends to lose balance spontaneously or with just a gentle pull on the shoulders.</td>
</tr>
</tbody>
</table>
3.13 POSTURE

Instructions to examiner: Posture is assessed with the patient standing erect after arising from a chair, during walking, and while being tested for postural reflexes. If you notice poor posture, tell the patient to stand up straight and see if the posture improves (see option 2 below). Rate the worst posture seen in these three observation points. Observe for flexion and side-to-side leaning.

0: Normal: No problems.
1: Slight: Not quite erect, but posture could be normal for older person.
2: Mild: Definite flexion, scoliosis or leaning to one side, but patient can correct posture to normal posture when asked to do so.
3: Moderate: Stooped posture, scoliosis or leaning to one side that cannot be corrected voluntarily to a normal posture by the patient.
4: Severe: Flexion, scoliosis or leaning with extreme abnormality of posture.

3.14 GLOBAL SPONTANEITY OF MOVEMENT (BODY BRADYKINESIA)

Instructions to examiner: This global rating combines all observations on slowness, hesitancy, and small amplitude and poverty of movement in general, including a reduction of gesturing and of crossing the legs. This assessment is based on the examiner’s global impression after observing for spontaneous gestures while sitting, and the nature of arising and walking.

0: Normal: No problems.
1: Slight: Slight global slowness and poverty of spontaneous movements.
2: Mild: Mild global slowness and poverty of spontaneous movements.
3: Moderate: Moderate global slowness and poverty of spontaneous movements.
4: Severe: Severe global slowness and poverty of spontaneous movements.

3.15 POSTURAL TREMOR OF THE HANDS

Instructions to examiner: All tremor, including re-emergent rest tremor, that is present in this posture is to be included in this rating. Rate each hand separately. Rate the highest amplitude seen. Instruct the patient to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other. Observe this posture for 10 seconds.

0: Normal: No tremor.
1: Slight: Tremor is present but less than 1 cm in amplitude.
2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.
3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.
4: Severe: Tremor is at least 10 cm in amplitude.
### 3.16 KINETIC TREMOR OF THE HANDS

**Instructions to examiner:** This is tested by the finger-to-nose maneuver. With the arm starting from the outstretched position, have the patient perform at least three finger-to-nose maneuvers with each hand reaching as far as possible to touch the examiner’s finger. The finger-to-nose maneuver should be performed slowly enough not to hide any tremor that could occur with very fast arm movements. Repeat with the other hand, rating each hand separately. The tremor can be present throughout the movement or as the tremor reaches either target (nose or finger). Rate the highest amplitude seen.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No tremor.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: Tremor is present but less than 1 cm in amplitude.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: Tremor is at least 1 but less than 3 cm in amplitude.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: Tremor is at least 3 but less than 10 cm in amplitude.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: Tremor is at least 10 cm in amplitude.</td>
</tr>
</tbody>
</table>

### 3.17 REST TREMOR AMPLITUDE

**Instructions to examiner:** This and the next item have been placed purposefully at the end of the examination to allow the rater to gather observations on rest tremor that may appear at any time during the exam, including when quietly sitting, during walking and during activities when some body parts are moving but others are at rest. Score the maximum amplitude that is seen at any time as the final score. Rate only the amplitude and not the persistence or the intermittency of the tremor. As part of this rating, the patient should sit quietly in a chair with the hands placed on the armrests of the chair (not in the lap) and the feet comfortably supported on the floor for 10 seconds with no other directives. Rest tremor is assessed separately for all four limbs and also for the lip/jaw. Rate only the maximum amplitude that is seen at any time as the final rating.

**Extremity ratings**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No tremor.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: &lt; 1 cm in maximal amplitude.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: &gt; 1 cm but &lt; 3 cm in maximal amplitude.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: 3 - 10 cm in maximal amplitude.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: &gt; 10 cm in maximal amplitude.</td>
</tr>
</tbody>
</table>

**Lip/Jaw ratings**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal: No tremor.</td>
</tr>
<tr>
<td>1</td>
<td>Slight: &lt; 1 cm in maximal amplitude.</td>
</tr>
<tr>
<td>2</td>
<td>Mild: &gt; 1 cm but &lt; 2 cm in maximal amplitude.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: &gt; 2 cm but &lt; 3 cm in maximal amplitude.</td>
</tr>
<tr>
<td>4</td>
<td>Severe: &gt; 3 cm in maximal amplitude.</td>
</tr>
</tbody>
</table>
### 3.18 Constancy of Rest Tremor

**Instructions to examiner:** This item receives one rating for all rest tremor and focuses on the constancy of rest tremor during the examination period when different body parts are variously at rest. It is rated purposefully at the end of the examination so that several minutes of information can be coalesced into the rating.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:</td>
<td>Normal: No tremor.</td>
</tr>
<tr>
<td>1:</td>
<td>Slight: Tremor at rest is present &lt; 25% of the entire examination period.</td>
</tr>
<tr>
<td>2:</td>
<td>Mild: Tremor at rest is present 26-50% of the entire examination period.</td>
</tr>
<tr>
<td>3:</td>
<td>Moderate: Tremor at rest is present 51-75% of the entire examination period.</td>
</tr>
<tr>
<td>4:</td>
<td>Severe: Tremor at rest is present &gt; 75% of the entire examination period.</td>
</tr>
</tbody>
</table>

### Dystonia Impact on Part III Ratings

A. Were dystonias (chorea or dystonia) present during examination?  
   - No  
   - Yes

B. If yes, did these movements interfere with your ratings?  
   - No  
   - Yes

### Hoehn and Yahr Stage

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:</td>
<td>Asymptomatic.</td>
</tr>
<tr>
<td>1:</td>
<td>Unilateral involvement only.</td>
</tr>
<tr>
<td>2:</td>
<td>Bilateral involvement without impairment of balance.</td>
</tr>
<tr>
<td>3:</td>
<td>Mile to moderate involvement; some postural instability but physically independent; needs assistance to recover from pull test.</td>
</tr>
<tr>
<td>4:</td>
<td>Severe disability; still able to walk or stand unassisted.</td>
</tr>
<tr>
<td>5:</td>
<td>Wheelchair bound or bedridden unless aided.</td>
</tr>
</tbody>
</table>
Appendix 15: Timed Up and Go Test

Directions:

- The Time “Up and Go” Test measures, in seconds, the time taken for an individual to stand up from a standard arm chair (approximate seat height of 46cm, arm height 65cm), walk a distance of 3 metres, turn, walk back to the chair and sit down.
- The subject wears their regular footwear and uses their customary aid (none, cane, walker) at hand.
- They are instructed that, on the work “go” they are to get up and walk at a comfortable and safe pace to a line on the floor 3 metres away, turn, return to the chair and sit down again.
- The subject walks through the test once before being timed in order to become familiar with the test.
- Either a stopwatch or a wristwatch with a second hand can be used to time the trial.

Instructions to the patient:

Timed Up and Go: Walk as quickly and safely as possible to the marked line, turn around, walk back to the chair and sit down”.

Time: ___________________________

Mobility Aid Used: Yes/No

If yes what aid: ___________________________
Appendix 16: Dynamic Gait Index

DYNAMIC GAIT INDEX

DATE: ________________

Grading: record the lowest category that applies.

1. Gait level surface. Instructions: Walk at your normal speed from here to the next mark (20').
   (3) Normal: walks 20', no assistive devices, good speed, no evidence for imbalance, normal gait pattern.
   (2) Mild impairment: walks 20', uses assistive devices, slower speed, mild gait deviations.
   (1) Moderate impairment: walks 20', slow speed, abnormal gait patterns, evidence for imbalance.
   (0) Severe impairment: cannot walk 20' without assistance, severe gait deviations or imbalance.

2. Change in gait speed. Instructions: Begin walking at your normal pace (for 5'), when I tell you "go", walk as fast as you can (for 5'). When I tell you "slow", walk as slowly as you can (for 5').
   (3) Normal: Able to smoothly change walking speed without loss of balance or gait deviation.
   Shows significant difference in walking speeds between normal, fast and slow paces.
   (2) Mild impairment: is able to change speed but demonstrates mild gait deviations, or no gait deviations but unable to achieve a significant change in velocity, or uses as assistive device.
   (1) Moderate impairment: Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations, or changes speed but loses balance but is able to recover and continue walking.
   (0) Severe impairment: Cannot change speeds, or loss balance and has to reach for a wall or be caught.

3. Gait with horizontal head turns. Instructions: Begin walking at your normal pace. When I tell you to "look right", keep walking straight, but turn your head to the right. Keep looking to the right until I tell you "look left", then keep walking straight and turn your head to the left. Keep your head to the left until I tell you, "look straight", then keep walking straight, but return your head to the centre.
   (3) Normal: Performs head turns smoothly with no change in gait.
   (2) Mild impairment: Performs head turns smoothly with slight change in gait velocity, i.e. minor disruption to smooth gait path or uses walking aid.
   (1) Moderate impairment: Performs head turns with moderate change in gait velocity, slows down, stagers, but recovers, can continue to walk.
   (0) Severe impairment: Performs task with severe disruption of gait, i.e. stagers outside 15" path, loses balance, stops, reaches for wall.

4. Gait with vertical head turns. Instructions: Begin walking at your normal pace. When I tell you to "look up", keep walking straight, but tip your head and look up. Keep looking up until I tell you, "look down", then keep walking straight and turn your head down. Keep looking down until I tell you, "look straight", then keep walking straight, but return your head to the centre.
   (3) Normal: Performs head turns smoothly with no change in gait.
   (2) Mild impairment: Performs head turns smoothly with slight change in gait velocity, i.e. minor disruption to smooth gait path or uses walking aid.
   (1) Moderate impairment: Performs head turns with moderate change in gait velocity, slows down, stagers, but recovers, can continue to walk.
   (0) Severe impairment: Performs task with severe disruption of gait, i.e. stagers outside 15" path, loses balance, stops, reaches for wall.
5. Gait and pivot turn. Instructions: Begin walking at your normal pace. When I tell you, "turn and stop", turn as quickly as you can to face the opposite direction and stop.

(3) Normal: Pivot turns safely within 3 seconds and steps quickly with no loss of balance.
(2) Mild impairment: Pivot turns safely in >3 seconds and steps with no loss of balance.
(1) Moderate impairment: Treads slowly, requires verbal cuing, requires several small steps to catch balance following turn and stop.
(0) Severe impairment: Cannot turn safely, requires assistance to turn and stop.

6. Step over obstacle. Instructions: Begin walking at your normal speed. When you come to the shoebox, step over it, not around it, and keep walking.

(3) Normal: Is able to step over box without changing gait speed; no evidence for imbalance.
(2) Mild impairment: Is able to step over shoe box, but must slow down and adjust steps to clear box safely.
(1) Moderate impairment: Is able to step over box but must stop, then step over. May require verbal cuing.
(0) Severe impairment: Cannot perform without assistance.

7. Step around obstacles. Instructions: Begin walking at normal speed. When you come to the first cone (about 6' away), walk around the right side of it. When you come to the second cone (6' past first cone), walk around it to the left.

(3) Normal: Is able to walk safely around cones safely without changing gait speed; no evidence of imbalance.
(2) Mild impairment: Is able to step around both cones, but must slow down and adjust steps to clear cones.
(1) Moderate impairment: Is able to clear cones but must significantly slow speed to accomplish task, or requires verbal cuing.
(0) Severe impairment: Unable to clear cones, walks into one or both cones, or requires physical assistance.

8. Steps. Instructions: Walk up these stairs as you would at home. (i.e. using a rail if necessary. At the top, turn around and walk down.

(3) Normal: Alternating feet, no rail
(2) Mild impairment: Alternating feet, must use rail
(1) Moderate impairment: Two feet to a stair, must use rail
(0) Severe impairment: Cannot do safely.

TOTAL SCORE

Admission: ___________________ Date: ___________________

Discharge: ___________________ Date: ___________________

Signature ___________________ Designation: ___________________
### PDQ-39 QUESTIONNAIRE

Please complete the following

Please tick one box for each question

Due to having Parkinson's disease, how often during the last month have you...

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or cannot do at all</th>
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Please check that you have ticked one box for each question before going on to the next page.

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142
<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or cannot do at all</th>
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</thead>
<tbody>
<tr>
<td><strong>Due to having Parkinson's disease, how often during the last month have you...</strong></td>
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<td>14 Had problems writing clearly?</td>
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<td>15 Had difficulty cutting up your food?</td>
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<td>16 Had difficulty holding a drink without spilling it?</td>
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<td>17 Felt depressed?</td>
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<td>18 Felt isolated and lonely?</td>
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<td>19 Felt weepy or tearful?</td>
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<td>20 Felt angry or bitter?</td>
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<td>21 Felt anxious?</td>
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<td>22 Felt worried about your future?</td>
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<td>23 Felt you had to conceal your Parkinson's from people?</td>
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<td>24 Avoided situations which involve eating or drinking in public?</td>
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<td>25 Felt embarrassed in public due to having Parkinson's disease?</td>
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<tr>
<td>26 Felt worried by other people's reaction to you?</td>
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<td>27 Had problems with your close personal relationships?</td>
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<tr>
<td>28 Lacked support in the ways you need from your spouse or partner?</td>
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<tr>
<td>If you do not have a spouse or partner tick here</td>
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<tr>
<td>29 Lacked support in the ways you need from your family or close friends?</td>
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</tbody>
</table>

Please check that you have ticked one box for each question before going on to the next page.
<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
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</thead>
<tbody>
<tr>
<td>Unexpectedly fallen asleep during the day?</td>
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<td>Had problems with your concentration, e.g. when reading or watching TV?</td>
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<td>Felt your memory was bad?</td>
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<td>Had distressing dreams or hallucinations?</td>
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<td>Had difficulty with your speech?</td>
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<td>Felt unable to communicate with people properly?</td>
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<td>Felt ignored by people?</td>
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<tr>
<td>Had painful muscle cramps or spasms?</td>
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<td>Had aches and pains in your joints or body?</td>
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<tr>
<td>Felt unpleasantly hot or cold?</td>
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</table>

*Please check that you have ticked one box for each question before going on to the next page*

Thank you for completing the PDQ 39 questionnaire
Appendix 18: Home Exercise Photo pack

Large-Amplitude Home Exercise Programme

Exercise 1 – Out Down Up and Around
Sit BIG
Out BIG

Exercise 1 – Out Down Up and Around
Down BIG
Up and Around BIG

Exercise 1 – Out Down Up and Around
Finish BIG!!!
Repeat x10

Exercise 2 – Sit To Stand
Sit BIG

Exercise 2 – Sit To Stand
Stand BIG

24/04/2015
Exercise 4 – Lawnmower Exercise
Step Forward BIG (L) x10
Pull Back BIG x10
Repeat x50

Exercise 4 – Lawnmower Exercise
Stand BIG

Exercise 4 – Lawnmower Exercise
Step Forward BIG (R) x10
Pull Back BIG x10
Repeat x50

Exercise 5 – Step Back Arms Up
Stand BIG
Step Back BIG (L) Arms Up

Exercise 5 – Step Back Arms Up
Finish BIG
Repeat x10

Exercise 5 – Step Back Arms Up
Stand BIG
Step Back BIG (R) Arms Up
Exercise 7 – Heel/Toe Rock

BIG Arm Swings

Repeat on both sides

BIG Arm Swings
Appendix 19: Exercise YouTube Link

Copy/type this link into the toolbar at the top of your internet page and press enter.

A YouTube link, “large-amplitude exercises for Parkinson’s Disease” should appear with a video of Eimear carrying out the exercises.

Follow along with the video while practicing your exercises OR review the video first to refresh your memory and practice on your own.

https://youtu.be/-ajvOlaAI2k
Appendix 20: Data Collection Form

Appendix 5

Demographic Data Collection Form

Data Collection Form #1

Office Use:

Participant ID:
Date of Assessment:
Time of Assessment:
Medication Taken At:

Age: __________________________ Date of Birth: __________________________

Gender: Male □ Female □

Past Medical History:
1)
2)
3) 
4)
5)
6)
7)
8)

Length of Time since diagnosis: __________________________

Hohn and Yahr Scale: __________________________

Medication:

<table>
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<tr>
<th>Name</th>
<th>Dosage</th>
<th>Time Taken</th>
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<tbody>
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</table>

Social History:
Lives with: __________________________
Next of Kin: __________________________
House Details: __________________________
Other Details: __________________________
**Mobility Status:**
Indoors: Independent ☐ With Supervision ☐ Mobility Aid ☐
Outdoors: Independent ☐ With Supervision ☐ Mobility Aid ☐

If uses mobility aid describe: __________________________________________

**Falls History:**
Have you sustained a fall in the past 6 months?
Yes ☐ No ☐
If Yes, how many? __________________________________________

**Previous Physiotherapy Treatment due to Parkinson's Disease?**
Yes ☐ No ☐

Please indicate most recent physiotherapy intervention: ______________________

**Feasibility Outcomes:**
1) Safety: Adverse Events Form
2) Compliance with Exercise: Home Exercise Logbook
3) Adherence Rates: Attendance Sheet
4) Retention Rates: No who complete baseline assessment V No who complete post intervention assessment
5) Participant Satisfaction Questionnaire

**Clinical Outcomes:**

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Baseline Assessment</th>
<th>Post Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Six Minute Walk Test</td>
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<tr>
<td>Timed Up and Go</td>
<td></td>
<td></td>
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<tr>
<td>Dynamic Gait Index</td>
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<tr>
<td>MDS-UPDRS: ADL Section</td>
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<tr>
<td>MDS-UPDRS: Motor Section</td>
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<td>PDQ-39</td>
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</tbody>
</table>
Appendix 21: Doctor Information Letter

RE: ____________________________

Dear Dr. ____________,

I am writing to you to inform you that ____________ has agreed to participate in a pilot intervention study as part of an MSc in Neurology and Gerontology.

The study intervention is a six week, large-amplitude group-based exercise class, which is based on the principles of the evidenced-based rehabilitation approach LSVT (Lee Silverman Voice Training) BIG.

The aims of the study are to evaluate both the feasibility and efficacy of this exercise class on physical performance outcomes.

I will forward you a discharge report following the intervention. Attached are the outcomes that will be evaluated.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Baseline Assessment</th>
<th>Post Intervention</th>
</tr>
</thead>
<tbody>
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<td>Six Minute Walk Test</td>
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<tr>
<td>Timed Up and Go Test</td>
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<td>Dynamic Gait Index</td>
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<td>PDQ-39</td>
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</tbody>
</table>

If you have any queries in relation to the above, please don’t hesitate to contact me at 045-849941.

Yours Sincerely,

Fimear Manley
MISCP

Telephone: 045 849900
www.naashospital.ie
Appendix 22: Doctor Discharge Letter

Discharge Letter

Eimear Manley,
Naas General Hospital,
Naas,
Co. Kildare
Date:

RE: ____________________________

Dear Dr. ________________

I am writing to you to inform you that ________________ has just participated in and completed a six week “large-amplitude group exercise pilot intervention programme” as part of an MSc Neurology and Gerontology Research Project.

I would like to update you of ________________ progress following the intervention:

<table>
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<th>Outcome Measure</th>
<th>Baseline Assessment</th>
<th>Post Intervention</th>
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<tbody>
<tr>
<td>Six Minute Walk Test</td>
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</table>

Clinical Implications:

___________________________________________________________________________

Yours Sincerely,

Eimear Manley
MISCP

Telephone: 045 849500
www.naashospital.ie
Naas General Hospital is an affiliated teaching hospital with the faculty of Health Sciences, Trinity College.
REFERENCES


European Physiotherapy Guidelines for Parkinson’s Disease 2015


Nocera JR, Stegemoller EL, Malatey IA, Okun M, Marsiske M, Haas C (2013). Using the timed up & go test in a clinical setting to predict falling in Parkinson's disease" *Archives of physical medicine and rehabilitation*; 94(7):1300-1305.


www.parkinsons.ie (accessed 21/03/2016)