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# Respiratory Muscle Training and Maintenance Program Impact on Cardiopulmonary Function in Parkinson's Disease: Pilot Study

Kristen P. Barta[1]*, Germaine Ferreira[2], Nicole P. Borman[3], Ashley H. Campbell[3]

[1]University of North Texas Health Science Center, 3500 Bowie Blvd, Fort Worth, TX 76107.
[2]Baylor University, One Bear Place #97193, Waco, TX 76798.
[3]University of St. Augustine for Health Sciences, 5401 La Crosse Ave Austin, TX 78739.

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***Correspondence:**
Kristen P. Barta, 1University of North Texas Health Science Center, 3500 Bowie Blvd, Fort Worth, TX 76107;
Email: Kristen.Barta@unthsc.edu.



## Abstract

**Introduction:** Parkinson's disease (PD) leads to motor symptoms that can contribute to difficulties with traditional exercise leading to a decline in cardiopulmonary function. Research has shown that intensive inspiratory muscle training (IMT) can have a positive impact on respiratory function yet have limited long-term benefits when the training was discontinued. The purpose of this study was to determine an appropriate maintenance program to sustain improvements made after an intensive IMT. Methods: Nine people with PD completed the intensive and maintenance IMT programs. The dependent variables of maximum inspiratory pressure (MIP), maximum expiratory pressure, six-minute walk test distance, and fatigue were assessed using a one-way repeated ANOVA. Results: The results showed that the intensive IMT program significantly improved MIP $F(2,16) = 7.88$, $p = 0.004$. Post hoc analysis showed a significant change between initial testing and completion of the intensive program ($p = .048$) and completion of the maintenance program ($p = .015$). There was not a significant difference between the intensive and maintenance programs ($p = .59$) indicating that the improvements were maintained. Conclusion: The results of this intervention protocol support the benefits of an IMT protocol and that a maintenance program can be beneficial in keeping the gains achieved.

The study is registered at www.clinicaltrails.gov NCT05287243.

## Introduction

Parkinson's disease (PD) is the second leading neurodegenerative disease in the United States resulting from dysfunction of the basal ganglia. This progressive condition affects over 2% of people over 65 years old. Resting tremor, rigidity, bradykinesia, and postural instability are the four cardinal signs of PD. These symptoms often negatively impact one's ability for independence in mobility and activities of daily living[1]. Additionally, motor impairments can hinder a person with PD's ability to participate in traditional exercise. Van Nimwegen et al[2], found that people with PD have a 29% reduction in physical activity compared to older adults due to disease severity, difficulties with ADLs, gait, and other unexplained factors. Cavanaugh et al[3], reported that people with PD can demonstrate an 11% reduction in ambulation participation over the course of a year.

In addition to the motor symptoms observed in people with PD, multiple non-motor symptoms may occur as well. These symptoms can present as dysfunction in metabolic, autonomic, and cardiovascular systems[4]. A study by King et al[5], found that 60.5% of people with PD reported a respiratory comorbidity which correlated to impaired cardiovascular endurance on walking measures. Additionally, people with PD have been shown to demonstrate abnormal pulmonary function compared to healthy age-matched counterparts[6]. Furthermore, cardiovascular disease has been associated with higher levels of mortality and decreased levels of quality of life in people with PD[7,8].

Respiratory muscle training (RMT) is a technique used to improve respiratory muscle strength through the use of specific exercises. Inspiratory muscle training (IMT) is one exercise method that can be used to improve respiratory muscle function and is a form of resistance training where breathing techniques are practiced against an external inspiratory load that is provided by an inspiratory muscle device[9,10]. The goal of IMT is to increase respiratory muscle strength. Literature suggests several different IMT protocols, using parameters of repetitions, intensity, and time are common methods for dosing this intervention. Seixas et al[9], suggests utilizing mild to moderate intensity or a time of 15 to 30 minutes, 5-7 times per week for 4 weeks. Research by Huang et al 2020[11] suggested that after three months of IMT, subjects demonstrated improved forced expiratory volume, forced vital capacity, maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP). The average MIP values are 75±27 cm H2O and the MEP values are 96.4±36 cm H2O in healthy individuals[10,12,13]. Currently, literature on the efficacy of IMT with longer durations is limited[10,13].

People with PD have lower cardiopulmonary function than healthy age-matched peers. This decline can further impair a person's ability to participate in exercise and daily activities[4]. Additionally, the limitations in cardiopulmonary function can have a severe impact on mortality[7]. There is evidence that IMT can have a positive impact on the cardiopulmonary function in people with PD[11]. Through intensive daily exercise people with PD have shown improvements in MIP and MEP. These improvements are critical to the long-term health and function of this population[14]. Despite the positive changes in cardiopulmonary status achieved through IMT, many programs are discontinued, which results in a loss of the gains made during training. Non-compliance to exercise programs is thought to impact as much as two-thirds of patients in physical therapy[15]. Multiple factors impact the successful continuation of an exercise program. High intensity exercise programs have higher rates of non-compliance long-term[16].

The purpose of this study was to determine if improvements in inspiratory muscle strength could be sustained with a maintenance IMT program. It was hypothesized that there would be a significant difference in MIP from baseline at the three and six-month follow-ups. This study provides necessary information for therapists to make evidence-based recommendations for continued respiratory training after the course of rehabilitation has been completed. To the investigators' knowledge, there are no current studies guiding the recommendations for post intensive IMT.

## Methods

### Subjects

The participants were a convenience sample of 12 people with PD. Julious[17] states that 12 subjects are an appropriate sample size for a pilot study based on feasibility and precision. The inclusion criteria for participation were a physician's diagnosis of PD and a stable regimen of medications throughout the study. The exclusion criteria were active smoking, presence of a pacemaker, recent diagnosis of chronic obstructive pulmonary disease, bronchial asthma, active pulmonary disease within 1 month, or hospitalization within 2 months of time of study. All participants completed an IRB-approved informed consent prior to the start of data collection.

### Procedures

A convenience sample of 12 individuals with PD in the same geographical area was recruited for this study. The study was approved by a university Institutional Review Board and all participants signed an informed consent.

This study utilized a repeated measures design that assessed changes in respiratory muscular strength, walking endurance, and self-reported fatigue. The participants completed testing at three separate points during the 24-week study and were tested within 2 hours of taking their regularly scheduled medications for PD (ON phase). The testing times included a pretest prior to initiating the training protocol, a posttest after 12 weeks of intensive training, and a final posttest after 12 weeks of the maintenance program. The following measures were recorded: heart rate, blood pressure, respiratory rate, MIP, MEP, six-minute walk test (6MWT), and Parkinson's Disease Fatigue Scale (PFS-16)[18,19]. The 6MWT is a valid tool used to assess walking capacity in people with PD[20]. The MicroRPM Respiratory Meter was used to measure the MIP and MEP during the three testing periods[21]. All participants maintained their current level of fitness throughout the study timeframe. There were no additional exercises introduced during the study other than the intensive and maintenance IMT protocols.

After the initial pretest was completed, participants, and caregivers, if necessary, were educated on how to complete the intensive IMT program at home using an inspiratory muscle trainer. Each participant was issued their own device for use at home. The participants were provided a paper log and recorded their daily completion of the intensive IMT throughout the 24 weeks. Additionally, investigators contacted participants weekly through text messages or phone call for follow-up on compliance and questions. The dosage of the IMT program was set to three times per day for 20 repetitions each with resistance set at 30% of baseline maximum for 12 weeks based on previous research[9-10]. The intensive training portion of the study was necessary to improve inspiratory muscle strength initially in order to determine if the following maintenance program helped sustain these improvements. All participants were able to complete the training protocol at 30% of the baseline maximum. After 12 weeks of intensive IMT training, the investigators completed the first posttest which included the same initial assessments: MIP, MEP, heart rate, blood pressure, respiratory rate, 6MWT, and PFS-16 in person. The participants, and caregivers, if necessary, were then educated on the maintenance IMT program and included the same exercise with a reduced dosage. The maintenance program was 33% of their intensive IMT program, which included completion of the IMT once a day for 20 repetitions with resistance set at 30% of the baseline maximum at the first posttest. The participants continued the maintenance program for 12 more weeks at home. The daily log weekly for follow-up was continued. Participants were contacted either through email, text, or phone call, depending on their preference. After the 12 weeks of maintenance IMT, the investigators completed the second posttest which included the following assessments: MIP, MEP, heart rate, blood pressure, respiratory rate, 6MWT, and PFS-16 in person.

## Data analysis

All statistical analyses were calculated using SPSS Statistics version 29 software (IBM Corporation, Armonk, New York). Descriptive statistics for participants' baseline characteristics to include age (years), gender (male, female or other), disease duration (years), and disease severity scale. A one-way repeated measures ANOVA evaluated the significance of the intensive and maintenance IMT programs on cardiovascular function in people with PD at the group level. The level of significance was set at $p < 0.05$ to show a statistically significant change in the dependent variables[22].

## Results

A total of 10 people completed the intensive training protocol and nine of these completed the subsequent maintenance program. See Table 1 for the sample population demographics. Two participants did not complete the study and only completed baseline testing and 1 week of the intervention before reporting that the intensive program was too time consuming. Neither participant was scheduled for posttest 1. The other participant completed baseline testing and posttest 1 but was not able to be reached for scheduling posttest 2. This participant's results were included in the pretest posttest 1 analysis, but not the posttest 2. See Table 2 for individual participant dependent variable changes.

**Table 1:** Participant characteristics (N = 10)

| Characteristic | Mean (SD) | |
|---|---|---|
| Gender (male, female) | 5,5 | |
| Age | 68.9 (6.4) | |
| Years with PD | 9 (5.4) | |
| Hoehn and Yahr stage[a] (n) | | |
| I | | 1 |
| II | | 5 |
| III | | 2 |
| IV | | 2 |
| Assistive device (n) | | |
| Rolling walker | | 2 |

[a]Stage remained unchanged throughout the study

**Table 2:** Individual participant dependent variable changes

| Participant | MIP[a] | MEP[b] | 6MWT[c] | PFS-16[d] |
|---|---|---|---|---|
| 1 | | | | |
| Pretest[e] | 30 | 45 | 1494 | 44 |
| Posttest 1[f] | 36 | 58 | 1600 | 31 |
| Posttest 2 | 42 | 63 | 1638 | 40 |
| 2 | | | | |
| Pretest | 86 | 151 | 1083 | 34 |
| Posttest 1 | 94 | 95 | 942 | 44 |
| Posttest 2 | 95 | 122 | 1473 | 33 |
| 3 | | | | |
| *Pretest* | 18 | 50 | 1837 | 55 |
| *Posttest 1* | 17 | 39 | 1040 | 37 |
| *Posttest 2* | 19 | 28 | 16396 | 37 |
| 4 | | | | |
| *Pretest* | 75 | 63 | 825 | 38 |
| *Posttest 1* | 89 | 87 | 1085 | 49 |
| *Posttest 2* | 70 | 59 | 1085 | 38 |
| 5 | | | | |
| *Pretest* | 72 | 117 | 560 | 51 |
| *Posttest 1* | 106 | 135 | 1628 | 50 |
| *Posttest 2* | 105 | 108 | 1178 | 67 |
| 6 | | | | |
| Pretest | 15 | 21 | 699 | 50 |
| Posttest 1 | 27 | 29 | 780 | 41 |
| Posttest 2 | 25 | 27 | 870 | 53 |
| 7 | | | | |
| *Pretest* | 36 | 52 | 769 | 53 |
| *Posttest 1* | 46 | 65 | 819 | 40 |
| *Posttest 2* | 45 | 60 | 725 | 42 |
| 8 | | | | |
| *Pretest* | 33 | 40 | 1245 | 55 |
| *Posttest 1* | 45 | 66 | 1250 | 32 |
| *Posttest 2* | - | - | - | - |
| 9 | | | | |
| *Pretest* | 42 | 68 | 1350 | 36 |
| *Posttest 1* | 75 | 124 | 1715 | 31 |
| *Posttest 2* | 60 | 73 | 1618 | 22 |
| 10 | | | | |
| *Pretest* | 20 | 47 | 1469 | 26 |
| *Posttest 1* | 20 | 38 | 1350 | 21 |
| *Posttest 2* | 26 | 52 | 1410 | 20 |

[a]MIP-Minimum Inspiratory Pressure in cm H20, [b]MEP-Maximum Expiratory
Pressure in cm H20, [c]6MWT-Six Minute Walk Test in feet, [d]PFS-16-Parkinson's
Disease Fatigue Scale
[e]Intensive program set at 30% of the MIP at pretest for all participants
[f]Maintenance program set at 30% of the MIP at posttest 1 for all participants

**Table 3:** Imapct of inspiratory muscle training on dependent variables

| Variable | Baseline | Posttest 1 N=10 12-week intensive | Posttest 2 N=9 12-week maintenance | Baseline, Posttest1, 95% CI[a] | Posttest 1, Posttest 2 | Baseline, Posttest 2 |
|---|---|---|---|---|---|---|
| MIP[b] | 43.7 (27.1) | 56.7 (34.5) | 65.8 (32.0) | p = .048[c] (-25.7,-.12) | p = .015* (-39.2,-4.6) | p=.59 (-28.6,10.4) |
| MEP[d] | 68.2 (40.4) | 74.8 (38.5) | 65.8 (32.0) | p=.71 | - | - |
| 6MWT[e] | 1120.6 (437.5) | 1217.7 (363.2) | 1292.9 (344.3) | p=.98 | - | - |
| PFS-16[f] | 42.6 (10.2) | 38.2 (9.4) | 39.1 (14.5) | p=.42 | - | - |

[a]95%CI-95% Confidence Interval [b]MIP-Minimum Inspiratory Pressure in cm H20, [c]p<.05
[d]MEP-Maximum Expiratory Pressure in cm H20, [e]6MWT-Six Minute Walk Test in feet, [f] PFS-16-Parkinson's Disease Fatigue Scale
Values given in mean (standard deviation)

Mauchly's test indicated sphericity was met. The results showed that the intensive IMT program significantly improved MIT at $F(2,16) = 7.88$, $p = 0.004$. Post hoc analysis showed a significant change between initial testing and completion of the intensive program ($p = .048$) and completion of the maintenance program ($p = .015$). Additionally, there was not a significant difference between the intensive and maintenance programs ($p = .59$) indicating that the improvements made were maintained. The results of the remaining variables after the intensive program were not significant; MEP at $F(2,16) = .71$, $p = .51$, 6MWT at $F(2,16) = .98$, $p = .39$, PFS-16 $F(2,16) = .92$, $p = .42$. The benefits of a maintenance program were not able to be assessed for the remaining variables because there was not a significant change after the intensive program. See Table 3 for impact of the training programs.

## Discussion

People with PD demonstrate limitations beyond the motor impairments associated with the disease progression. Multiple non-motor symptoms that occur can present as dysfunction in metabolic, autonomic, abnormal pulmonary function and impaired cardiovascular endurance[4,5]. Decreased participation in physical activity can further exacerbate the deleterious effects of PD on the cardiopulmonary system.

The results of this study aligned with previous research that supports positive changes in MIP in individuals with PD after participation in an intensive IMT program. The novelty of this pilot study is reflected in the maintenance of MIP improvements with an individualized protocol. Maintenance programs are essential in rehabilitation as many people often discontinue exercise at intense levels[16]. Furthermore, research suggests that detraining will occur in inspiratory musculature when IMT is not continued[14]

Maximum inspiratory pressure was the only variable that improved significantly. Interestingly, the device used during the study only created resistance during the inspiratory portion of the exercise. During exhalation, the individual simply blew through the device without additional overpressure. This could explain the nonsignificant change in MEP from baseline that was observed. It is worth noting that both IMT at home and in-person measurements of MIP and MEP were dependent on appropriate technique when using the MicroRPM Respiratory Meter and inspiratory muscle trainer. Differences in techniques across patients may have impacted the quality of home training and assessment results.

There was an overall improvement in walking distance, despite the change not being statistically significant. The participants of the study were asked to continue their normal routines with the addition of the IMT intensive program over the initial 12 weeks, there was not a walking program completed alongside the IMT exercises. The study wanted to focus on the true impact of IMT on MIP at intense and maintenance levels and incorporation of a walking program could have impacted the results. Future research should incorporate a walking program alongside an IMT program to assess if the combination can lead to a significant improvement in walking tolerance in people with PD. The results of the PFS-16 also demonstrated a similar pattern to the MEP and walking distance. There was an improvement in the rate of perceived daily fatigue within the study's participants over the 12-week intensive program and a slight decline in the rating after completion of the maintenance program. Fatigue was self-reported and not formally addressed within the training protocol. There is potential that the lack of additional exercise intervention lead to the changes in self-perceived fatigue being nonsignificant.

Huang et al[11], completed the training program at an intensity range of 30-60% of the maximum MIP at baseline and trained at a frequency of 60 breaths per day. The present study utilized a consistent intensity of 30% of maximum MIP for all participants across both training and maintenance portions. It is possible that this intensity did not pose a great enough challenge for some participants and possibly hindered the potential for greater improvements. Future studies should increase the training protocol to challenge the cardiopulmonary system of people more aggressively with PD.

## Limitations

There were several limitations to the pilot study. The nature of the study was to explore the potential impact of an intensive IMT protocol followed by a maintenance program in a person with PD. While the analysis of the ANOVA was robust, the sample size was small. It is possible that the length of the study contributed to a small recruitment sample and non-compliance of the protocol for some participants. The intensive portion of the study showed the highest rate of missed sessions. The majority of the participants were Hoehn and Yahr Stage II. Given the sedentary nature of the IMT program, it would be beneficial to assess changes specifically in individuals with more progression from PD to determine the impact on their respiratory strength. Finally, the inspiratory trainer used in this study only provided resistance during the inhalation phase of breathing. There is a potential that the type of device could have limited the potential for change in the participant's MEP after training.

## Conclusion

Identifying effective alternative methods for people with PD to improve cardiopulmonary function is necessary. The results of this intervention protocol support the benefits of an intensive IMT program to improve MIP and possibly a subsequent maintenance program to sustain the gains achieved in the PD population.

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