

**STUDY OF AN EARLY WELLNESS PROGRAM IN PARKINSON'S DISEASE: IMPACT ON QUALITY
OF LIFE AND EARLY INTERVENTION GUIDANCE**

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in partial fulfillment of the requirements for the Degree of Doctor of Medicine

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Abstract

Background and Significance – Previous studies have shown that Parkinson’s disease (PD) patients are at an increased risk for a variety of complications impacting health related quality of life (HRQoL). Additionally, these various complications often lead to increased healthcare utilization. Wellness intervention in PD has shown to be effective in improving HRQoL and objective measures of disease burden such as motor functioning. What has not been demonstrated to date is whether patients who are given the opportunity to participate in regularly administered classes in these modalities will continue to attend and whether benefits will continue to be realized outside the strict confines of a controlled trial.

Objective and Hypothesis – This study examined whether intervening early in PD with a comprehensive Wellness Program is feasible and promotes lasting habits that will continue to provide sustained benefit. It was hypothesized that intervening early in PD with an intensive program involving structured exercise, socialization and PD specific education would serve to maintain or improve subject’s quality of life while decreasing healthcare utilization.

Methods – Twenty-one consenting ambulatory adult subjects diagnosed with PD within the last five years completed various screenings at baseline and following a required 6-month Wellness Program intervention. Subjects were assessed at 12 and 18 months if they continued to participate. Patient demographics, disease specific quality of life, objective mobility, healthcare utilization and falls were assessed. Data were collected at Banner Sun Health Research Institute, located in Sun City, Arizona. All p-values were 2-tailed and $P < 0.05$ was considered statistically significant. All data analyses were conducted using STATA-14.

Results – Twenty of twenty-one subjects completed the required 6-month intervention. Continued participation was 70% at 12 months and 60% at 18 months. Overall HRQoL was stable at 18 months. Significant improvement was seen in patient reported mobility and emotion sub-areas at 12 months. Communication specific HRQoL was significantly worsened at 12 months. Subjects demonstrated a stable level of physical activity while fatigue

was significantly decreased. All objective measures were significantly improved from baseline. Healthcare utilization was decreased by 18 months. A total of 5 falls were reported by 3 subjects during the 6-month interventional period.

Conclusion and Impact – This pilot study demonstrates that comprehensive wellness intervention in early PD is feasible, effective, safe and valuable in establishing long-term beneficial habits while potentially reducing healthcare utilization. The significant long-term subject participation observed in this study establishes that wellness intervention may be practical for large scale implementation. The results also highlight the importance of addressing communication specific symptoms early in the course of the disease. Ultimately, this study will aid the design and implementation of future PD wellness interventions.

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Introduction and Significance

Background

Parkinson's disease (PD) is a chronic, progressive neurodegenerative disease that mainly affects older individuals. It is the second most common neurodegenerative disease in the world, after Alzheimer's disease, and is estimated to currently affect as many as one million Americans.^{1,2} As the average age of the population continues to increase, the number of individuals diagnosed with PD is expected to double by the year 2040.² PD is classically associated with stereotypical motor symptoms and motor impairments. The cardinal symptoms of the disease include tremor, bradykinesia, gait freezing, rigidity and postural instability. These symptoms lead to progressively impaired overall mobility and functional impairment.

In addition to the motor symptoms of the disease a variety of non-motor disease complications are common and often substantially impact patients' health-related quality of life (HRQoL).^{3,4,5,6} HRQoL is defined by the Center for Disease Control as "an individual's or group's perceived physical and mental health over time."⁷ For example, PD also commonly adversely affects mood, activities of daily living and frequently leads to social isolation due to a variety of physical and psychosocial factors.^{8,9} Current standards of PD treatment include medications to improve motor function, primarily via cerebral dopaminergic modulation. However, treatments designed to address the myriad of other disease related complications remain relatively incomplete.

Previous studies have shown that those who suffer from PD are at an increased risk for a variety of complications including depression, generalized fatigue, reduced quality of life, recurrent falls and injury due to falls. For example, Kerr et al found that 48% of predominantly early stage PD patients, averaging 6.1 years since diagnosis, reported a fall within the previous 6 months and 24% reported multiple falls over that time period.¹⁰ Additionally, the risk of fall associated fracture has been reported to be elevated at a five-fold higher rate in PD than for non-PD age and sex matched individuals.¹¹

Depression is a common psychological complication of PD with rates as high as 76% and ranges typically reported between 20% to 70% within the general PD population.^{12,13} These

rates are thought to be higher in PD patients than in the general elderly population. This is significant since depression has been shown to negatively impact PD HRQoL nearly twice as much as the motor symptoms of the disease.¹⁴

Additionally, these various detrimental complications of PD account for much of PD patient's healthcare utilization and related financial expenditures. It is estimated that up to 75% of PD associated falls will result in additional healthcare utilization and consequent financial costs.¹⁵ When hospitalized, PD patients have a greater length of stay on average as compared to age and sex matched non-PD patients.¹⁶ All of these complications contribute significantly to the economic burden of the disease and necessitate a closer examination in order to identify successful strategies aimed at better addressing the non-motor disease symptoms, improving HRQoL and reducing PD associated healthcare costs.

Recently, studies investigating the impact of various wellness interventions in PD, such as exercise and dance, have shown to be effective in improving HRQoL as well as in improving objective measures of disease burden, such as gait and motor functioning.^{8, 17, 18} Furthermore, Ellis et al. demonstrated that a structured, outpatient physical exercise program in combination with pharmacologic treatment may yield the greatest benefit to PD patients. Ellis showed significant improvement in mobility, walking speed and activities of daily living in PD patients who completed 12 sessions of structured group format exercise over 6 weeks.¹⁹ These findings demonstrate that a comprehensive, socially-based approach to PD treatment may lead to improved patient outcomes. What has not been demonstrated to date is whether patients who are given the opportunity to participate in regularly administered classes in these modalities will continue to attend and whether benefits will continue to be realized outside the confines of a clinical study.

Previous studies have also shown that PD patients' psychological adjustment to the disease has a significant impact on their HRQoL.²⁰ Therefore, it seems reasonable to target newly diagnosed PD based on the theory that these patients may achieve a significant benefit from an early, comprehensive wellness program as they adjust to the disease.

This study was designed to examine the impact of an early PD Wellness Program on HRQoL in a retirement-aged PD community located in Sun City, Arizona. The Wellness Program

was structured to include regular group-format PD specific exercise, PD specific education and to promote social support among the study participants. A survey battery, specifically designed to assess the various known complications of the disease commonly impacting quality of life, was administered at baseline and then recurring on a 6-month follow-up basis for a total study duration of 18 months. Additionally, various objective assessments were obtained at baseline, 6-months and 12-months. Falls and healthcare utilization were also documented.

Study Goals

The primary goal of this study is to determine if intervening early in PD with a comprehensive Wellness Program is feasible. The results will allow us to determine if patients given the opportunity to participate in such a program are likely to continue attending following the conclusion of their formal study participation. Secondary goals include evaluating the program's impact on quality of life, mood, fatigue, number of falls and healthcare utilization within the study group. Therefore, this study will allow us to determine if intervening earlier with specific program offerings in PD is beneficial. Also, the results from this study will allow us to better design and implement future PD wellness programs that may improve quality of life for PD patients while improving care and reducing costs to the patient and healthcare system.

Study Hypothesis

The overall hypothesis is that implementation of a comprehensive wellness intervention in early PD, specifically in those with a diagnosis of less than five years' duration, is feasible. Additionally, we hypothesize that intervening earlier in PD with an intensive program involving structured exercise, PD specific education and group socialization will serve to maintain or improve quality of life, self-efficacy, fatigue and mood while reducing healthcare utilization.

Research Materials and Methods

Overall Study Design

This was an open-label, single site pilot study conducted over an 18-month time period. Data was collected from consenting adult patients who had been diagnosed by a physician with PD. Study subjects were limited to those with early PD which was defined by this study as PD of less than five years' duration from the time of physician diagnosis. Patients were recruited from the Banner Sun Health Research Institute's Center for Parkinson Research clinic during a regular office visit. The study design called for 20 subjects to allow for adequate assessment of the intervention's feasibility and determination of the efficacy of this type of intervention. Consenting subjects were required to participate in various screenings and interventions during the first 6 months of the study to be included in the data analysis. Consenting subjects were followed up at 12 and 18 months if they continued to participate in the study. However, there were no formal Wellness Program participation requirements after the initial 6-month interventional period and subjects were free to participate ad lib.

Subject inclusion criteria included a signed and dated Institutional Review Board (IRB) approved written consent, PD diagnosed by a clinician, PD diagnosis of less than 5 years' duration and the ability and willingness to participate in all required study interventions. Additionally, study subjects were also required to attain a medical release from the subject's treating physician stating that the subject is physically able to participate in a moderate intensity exercise program.

Subjects were excluded from the study if they were determined to have cognitive dysfunction such that they were unable to complete the required assessments without assistance, had any medical or psychiatric condition that could impair their ability to participate in the interventions, or if subject had known pregnancy or was planning to become pregnant at any point during the study period.

Study subjects were free to self-withdraw from the study at any time for any reason without prejudice. Subjects were withdrawn by the study administrator if any of the following events occurred: 1) subject developed a health condition that would interfere with continued participation in the study, 2) subject was non-compliant with the protocol, defined as less than

70% attendance in the fitness classes or non-attendance for greater than 2 consecutive weeks in the absence of illness or injury within the 6-month period of active intervention, 3) subject withdrew consent to participate. Subjects who withdrew from the study within the first 6 months after the first subject was enrolled were replaced.

Setting and Patient Population

The study was conducted at Banner Sun Health Research Institute (BSHRI), located in Sun City, Arizona. The Center for Parkinson Research and affiliated ambulatory clinic serves as a care provider to a large, local PD patient population. Study subjects were free to utilize maximum medical management for their symptoms and were also allowed to change medications and or adjust medication dosages as per their treating physician throughout the study period.

Wellness Program Intervention

The Wellness Program intervention included the following: 1) regular fitness program attendance of at least twice weekly, 2) one time consult with a mental health professional for baseline assessment, 3) attendance at three scheduled lectures held at BSHRI which were designed to educate study subjects about PD. Other, optional interventions which were made available to study subjects included attendance at weekly PD support groups and attendance at other PD specific classes offered on site at BSHRI.

The fitness programs were taught by a certified fitness instructor with experience in PD. All fitness classes were offered at the study site (BSHRI). Classes were offered 2-3 times per day three times per week, of which subjects were free to choose from. Class offerings consisted of various disease specific, whole-body, exercise programs including: circuit training, resistance and aerobic exercise training, and stretching.²¹ Subjects were also free to attend other ad hoc classes offered at the study site such as Tai Chi, Yoga, music therapy, speech classes and crafting which were all specific to PD and consistent with an overall wellness program. Subject attendance at all classes was documented. The mental health consult was performed by an on-site clinical social worker with extensive behavioral health experience in PD, Alzheimer's

disease and in the elderly. Subjects with any identified mental health needs were referred to appropriate resources outside of the study. The lecture series consisted of 3 separate lectures given by an experienced neurologist who specializes in PD and other movement disorders.

Subjects were required to come in to the clinic (BSHRI) for formal assessments at baseline and 6 months. If the subject wished to continue participating in the intervention following the mandatory initial 6 months they were also formally assessed at 12 months and 18 months. Subject assessment data was collected at each of these formal visits across the 18 months of participation. Visits occurring at 12 and 18 months were primarily utilized to assess long term compliance with the Wellness Program, factors affecting compliance and whether any gains made within the first 6 months of the Wellness Program continued to be maintained. Subjects were also required to maintain a monthly fall diary throughout their participation in the study.

Study Instrument

Study data was collected via a self-administered survey packet which was completed by each subject during a formal study visit at BSHRI occurring at baseline, 6 months, 12 months and 18 months. The survey packet consisted of seven distinct, self-administered surveys including: Parkinson's Disease Questionnaire-39 (PDQ-39)^{22,23}, Geriatric Depression Scale (short form)²⁴, Healthcare Utilization survey, Falls survey, Self-efficacy Scale, Fatigue Severity Scale²⁵ and the Physical Activity Scale for the Elderly (PASE). These surveys have been validated in PD and were chosen to address the study goals. Specifically, the survey questions were designed to assess the significance and prevalence of known complications of PD, assess HRQoL within our study population and to assess the efficacy of the Wellness Program intervention as related to outcome measures. Surveys were chosen based on their proven validity for use in PD or geriatric assessment.

For example, the PDQ – 39 has consistently been shown to be a reliable and valid tool for assessing quality of life in PD. The survey consists of 39 items aimed at evaluating PD patient's functioning and overall well-being. The 39 items are divided into eight categories which include: mobility (10 items), activities of daily living (6 items), emotional well-being (6

items), disease stigma (4 items), social support (3 items), cognition (4 items), communication (3 items) and bodily discomfort (3 items). The Parkinson's Disease Summary Index (PDQ39-SI), which is a single index score accounting for the eight categories, was also calculated. Possible scores range from 0 to 100 with higher scores indicating a lower HRQoL.

In addition to the PDQ-39, the GDS and FSS have also been independently validated as reliable measures.^{24,25} Although the Falls survey and Healthcare Utilization have not been validated, they were reviewed by Dr. Christine Savi, Ph.D., former Director of Assessment and Evaluations for the University of Arizona College of Medicine – Phoenix. Each of the surveys utilized in this study can be found in Appendix A.

Additionally, objective assessments completed during each of the formal study visits included: Timed Up and Go score, 30-second chair stand score, 2-minute step test and 6-minute walk tests. Objective assessments were completed and documented by either a certified fitness instructor with experience in PD or the principal investigator.

Ethical Research Practice and Data Handling

As this study utilized human subjects, IRB approval was obtained. All study subjects were required to read and sign an IRB approved consent form. All subject data was de-identified by the study coordinator or by the principal investigator. Data was manually entered by the study coordinator or principal investigator onto an onsite computer with a secure server. Only study personnel could access the de-identified subject data.

The entire study was overseen by a study coordinator experienced in PD management who facilitated completion of the study's survey assessments, documented subject program attendance and served as a resource for any issues which arose throughout the duration of the subject's study participation.

Statistical Analysis

Clinical characteristics were assessed using medians and interquartile ranges for continuous variables. The Friedman test was conducted to ascertain any differences in the medians between the time points of the repeated measures. If the overall global test was

statistically significant, a pairwise comparison with the Wilcoxon Signed Rank was conducted to assess difference in the covariates between each time point. All p-values were 2-tailed and $P < 0.05$ was considered statistically significant. P-values between 0.05 and 0.10 were also noted and considered to indicate a marginal difference. All data analyses were conducted using STATA version 14 (College Station, TX).

Results

Baseline Characteristics of Study Subjects

Mean subject age at baseline was 72 years (SD 7.1 years). The average time since PD diagnosis was 24.3 months (SD 17.9 months) at baseline. Of the 20 subjects 12 were male (60%) and 8 were female. All subjects were treated with PD medications at baseline. Subject PD medications included: levodopa (10), monoamine oxidase inhibitor (MAOI) (2), levodopa plus MAOI (2), levodopa plus dopamine agonist (3) and levodopa plus MAOI plus dopamine agonist (3). Major subject comorbidities included: hypertension (6), diabetes mellitus (3), hypothyroidism (3) and CAD (1). Table 1 shows the baseline characteristics of the study population.

Primary Outcome: feasibility

A total of 21 subjects were recruited to participate in the Wellness Program intervention. All but one subject completed the required 6-month interventional period. One subject dropped out early due to relocating their primary residence away from the study site which made regular attendance unfeasible. Thus, a total of 20 subjects were included in the final data analysis.

Attendance across the required initial 6-month interventional period was good with all subjects completing the required two group fitness classes per week. Most subjects attended greater than the minimum of two required fitness classes per week. All study subjects also successfully completed the three-part PD lecture series which was a requirement for study participation. Subject participation following the required 6-month interventional period remained high with 14 subjects (70%) continuing to participate at 12 months and 12 subjects (60%) continuing to participate at 18 months.

Table 1: Baseline Subject Demographics and PD Medications

Characteristic	N = 20
Age ^a - years	72 ± 7.1
Sex - male	N = 12 (60%)
Time Since Diagnosis ^a - months	24.3 ± 17.9
Antiparkinsonian Medications Taken	Number of Subjects
Levodopa	10 (50%)
MAOI	2 (10%)
Levodopa + MAOI	2 (10%)
Levodopa + DA	3 (15%)
Levodopa + MAOI + DA	3 (15%)

^a Mean ± SD; MAOI = monoamine oxidase inhibitor; DA = dopamine agonist

Secondary Outcomes

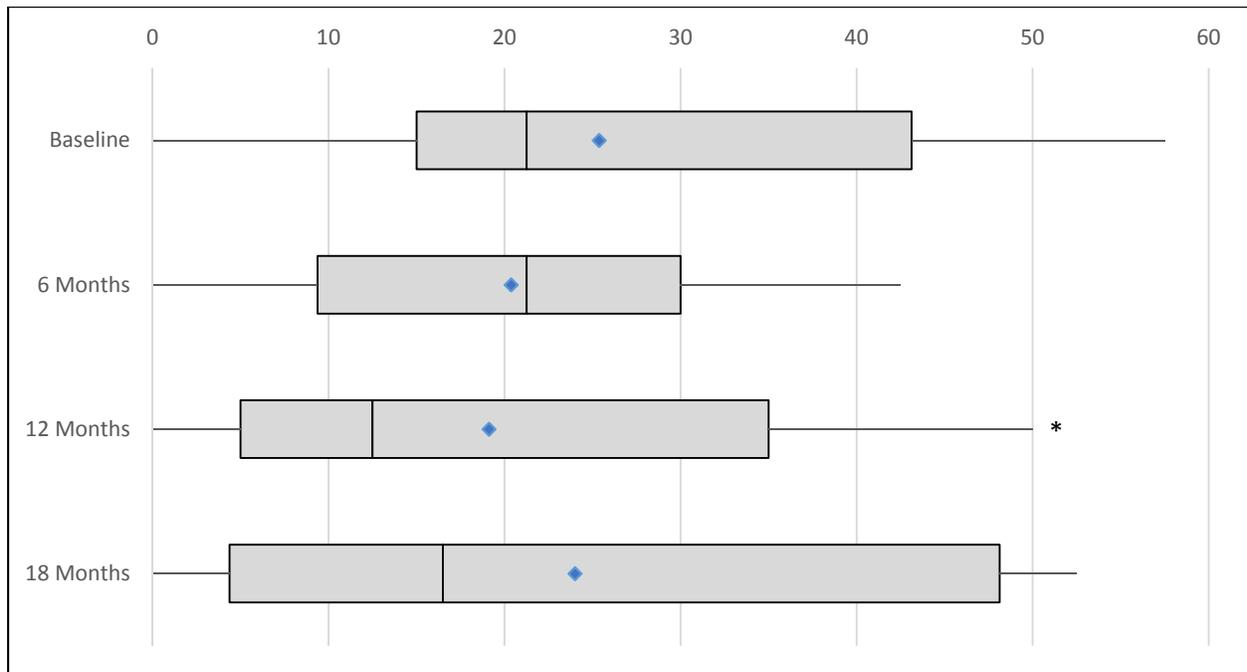
Disease Specific Quality of Life: PDQ-39

Wellness Program participants overall HRQoL, as measured by the PDQ39-SI, remained stable over the 18-month duration of the study. There were no significant changes at any of the study intervals when compared to baseline PDQ39-SI scores. PDQ39-SI scores at baseline, 6, 12 and 18 months were 20.1 (IQR 11.8, 29.4), 21.7 (IQR 13.7, 25.7), 19.2 (IQR 13.0, 21.8) and 22.2 (IQR 6.9, 29.6), respectively. When analyzing the PDQ-39 sub-areas both mobility and emotions showed statistically significant improvement ($p < 0.05$) from baseline to 12 months. Mobility scores improved from a median of 21.25 (IQR 15, 43.8) at baseline to 12.5 (IQR 5, 35) at 12 months, an 8.75-point improvement. Emotion scores improved from a median of 20.85 (IQR 8.3, 37.5) at baseline to 12.5 (IQR 8.3, 29.2) at 12 months, an 8.35-point improvement. Activities of daily living trended towards improvement (p -value between 0.05 and 0.10) from a median of 18.75 (IQR 16.7, 29.2) at baseline to 14.6 (IQR 8.3, 22.9) at 6 months. Social support also trended towards improvement (p -value between 0.05 and 0.10) from a median of 8.3 (IQR 0, 16.7) at baseline to 0 (IQR 0, 8.3) at 12 months. HRQoL sub-areas which remained stable over the duration of the study included disease stigma, cognition, and bodily discomfort. Communication, as measured by the PDQ-39, was significantly worsened ($p < 0.05$) from a median of 16.7 (IQR 8.3, 33.3) at baseline to 25 (IQR 16.7, 41.7) at 12 months, an 8.3-point worsening. Communication continued to trend towards worsened when compared to baseline at 18 months (20.85; IQR 8.3, 41.7). PDQ-39 single index and sub-area data is reported in Table 2. Figures 1 through 4 display PDQ-39 Single Index, Mobility, Emotions, and Communication scores from baseline through 18 months, respectively.

Table 2: Parkinson's Disease Questionnaire-39 (PDQ-39) Single Index and Sub-areas

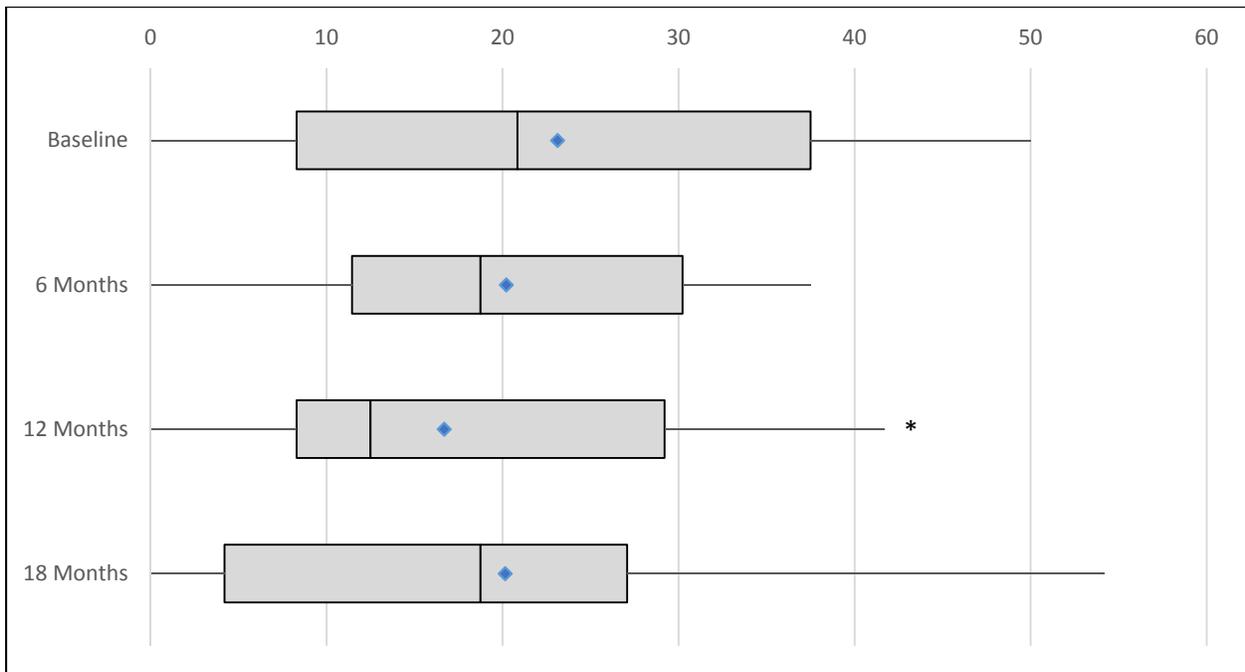
Outcomes	Baseline Median (IQR)	6 months Median (IQR)	12 Months Median (IQR)	18 Months Median (IQR)
<u>PDQ-39 Single Index</u>	20.1 (11.8, 29.4)	21.7 (13.7, 25.7)	19.2 (13.0, 21.8)	22.2 (6.9, 29.6)
<u>PDQ-39 Sub-Areas</u>				
<i>Mobility</i>	21.25 (15.0, 43.8)	21.25 (8.75, 30.0) ^{1*}	12.5 (5, 35) ²	16.5 (3.75, 48.75) ^{6*}
<i>ADL</i>	18.75 (16.7, 29.2)	14.6 (8.3, 22.9) ^{1*}	8.3 (8.3, 20.8)	16.65 (6.25, 29.2)
<i>Emotions</i>	20.85 (8.3, 37.5)	18.75 (10.4, 31.25)	12.5 (8.3, 29.2) ²	18.75 (4.2, 19.15)
<i>Stigma</i>	6.3 (0, 12.5)	3.15 (0, 25)	6.3 (0, 12.5)	0 (0, 18.8)
<i>Social Support</i>	8.3 (0, 16.7)	8.3 (0, 25)	0 (0, 8.3) ^{4*}	8.3 (0, 16.7)
<i>Cognition</i>	18.8 (18.8, 31.3)	25 (12.5, 31.3)	25 (12.5, 31.3)	28.15 (12.5, 31.3)
<i>Communication</i>	16.7 (8.3, 33.3)	25 (14.6, 33.3) ^{1*}	25 (16.7, 41.7) ²	20.85 (8.3, 41.7) ^{3*}
<i>Bodily Discomfort</i>	25 (8.3, 33.3)	29.15 (16.7, 41.7)	25 (16.7, 41.7)	16.7 (8.3, 41.7)
<p>Pairwise comparison: 1= Baseline vs. 6 months, 2= baseline vs. 12 months, 3= baseline vs. 18 months, 4= 6 months vs. 12 months, 5= 6 months vs. 18 months, 6= 12 months vs. 18 months. If there is a number, then the pairwise comparison was statistically significant using the Wilcoxon Sign Rank (p<0.05). An (*) indicates the p-value was between 0.05 and 0.10 thus a marginal difference. ADL = Activities of daily living.</p>				

Figure 1: PDQ-39 Mobility Scores



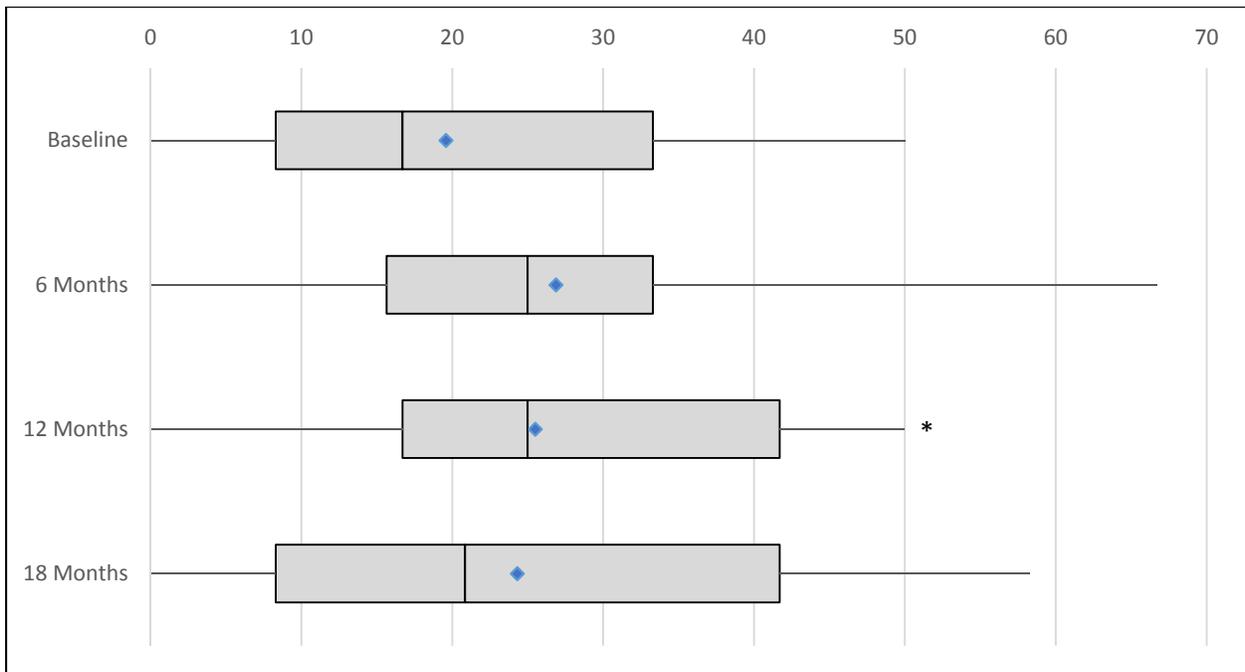
* indicates significant difference ($p < 0.05$) from baseline

Figure 2: PDQ-39 Emotions Scores



* indicates significant difference ($p < 0.05$) from baseline

Figure 3: PDQ-39 Communication Scores



* indicates significant difference ($p < 0.05$) from baseline

Fatigue, Physical Activity and Mood

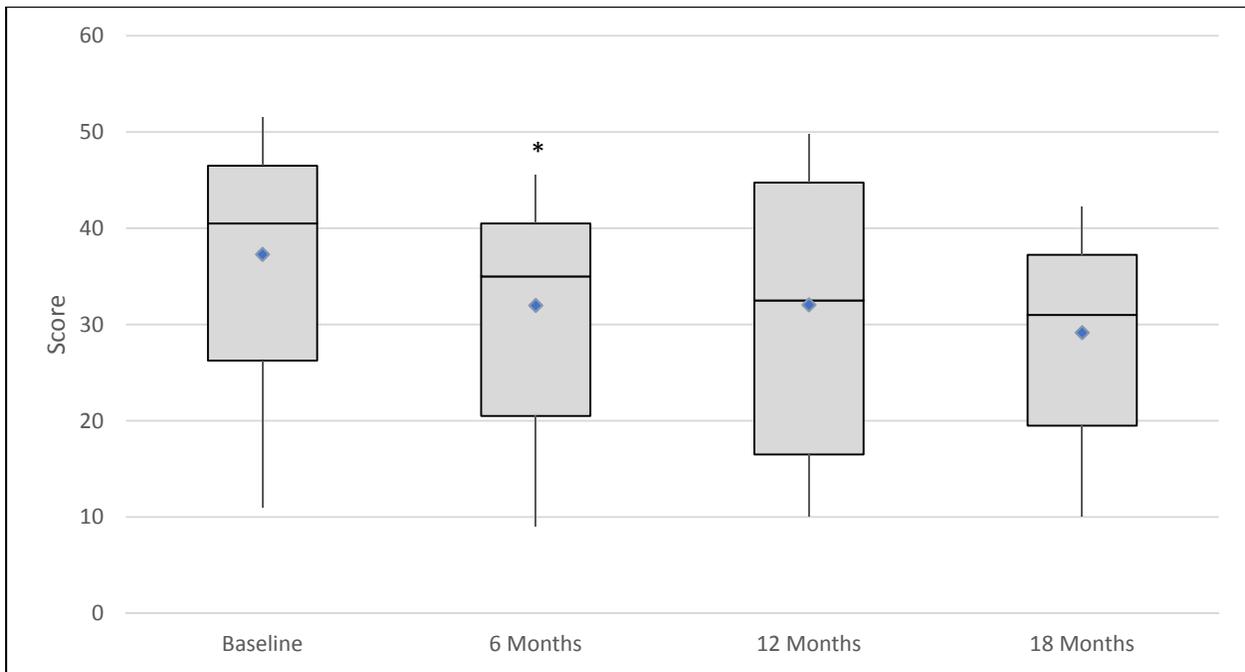
Fatigue was significantly improved ($p < 0.05$) from baseline to 6 months with median Fatigue Severity Scale (FSS) scores decreasing by 5.5 points (based on a 9 to 63-point scale with higher scores indicating worse fatigue) over that time period. Median FSS scores remained lower than baseline at 12 and 18 months, although not statistically significant. Median FSS scores at baseline, 6, 12 and 18 months were 40.5 (IQR 25.5, 48), 35 (IQR 20, 41), 32.5 (IQR 16, 45.5) and 31 (IQR 18, 37.5), respectively. Global fatigue, as measured by the Visual Analogue Fatigue Scale, remained stable across the duration of the study with no significant changes at any of the study intervals. Self-efficacy and subject reported physical activity, as measured by the Physical Activity Scale for the Elderly (PASE), remained stable across the duration of the study. Depression, as measured by the Geriatric Depression Scale-Short Form (GDS-15), was unchanged across the duration of the study. Median GDS-15 scores at baseline, 6, 12 and 18 months were 3 (IQR 1.5,6), 2.5 (IQR 2, 4.5), 2 (IQR 1,3) and 3 (IQR 2,4), respectively. Refer to Table 3 for fatigue and other secondary outcomes data.

Table 3: Other Secondary Outcomes

Outcomes	Baseline Median (IQR)	6 months Median (IQR)	12 Months Median (IQR)	18 Months Median (IQR)
<i>Self-Efficacy</i>	30 (29, 33.5)	31.5 (28, 35)	31 (29, 35)	31.5 (28, 34)
<i>PASE</i>	146 (72.5, 191)	174 (89, 209)	162 (72, 196)	117 (79.5, 188)
<i>Fatigue Severity Scale</i>	40.5 (25.5, 48)	35 (20, 41)	32.5 (16, 45.5) ²	31 (18, 37.5)
<i>Global Fatigue Score (VAFS)</i>	6 (4, 8)	7 (5, 9) ^{1*}	7.5 (5, 8)	7 (5, 9)
<i>Geriatric Depression Scale-Short Form</i>	3 (1.5, 6)	2.5 (2, 4.5)	2 (1, 3)	3 (2, 4)

Pairwise comparison: 1= Baseline vs. 6 months, 2= baseline vs. 12 months, 3= baseline vs. 18 months, 4= 6 months vs. 12 months, 5= 6 months vs. 18 months, 6= 12 months vs. 18 months. If there is a number, then the pairwise comparison was statistically significant using the Wilcoxon Sign Rank (p<0.05). An (*) indicates the p-value was between 0.05 and 0.10 thus a marginal difference. PASE = Physical Activity Scale for the Elderly; VAFS = Visual Analogue Fatigue Scale.

Figure 4: Fatigue Severity Scale Scores



* indicates significant difference ($p < 0.05$) from baseline

Healthcare Utilization and Falls

Physician visits over the prior 6 months were significantly less when compared from baseline to 18 months (4 visits at baseline vs. 3 visits at 18 months; $p < 0.05$). Total healthcare contacts decreased from 4 at baseline to 3 at 18 months which was trending towards significance (p -value between 0.05 and 0.10). Overall, there were few hospital admissions across the duration of the study. The number of subjects who reported a single hospital admission over the prior 6 months was 4 at baseline, 3 at 6 months, 1 at 12 months and 3 at 18 months. Total nights spent in the hospital, when summed for all subjects, were 22 at baseline (one subject reported 10 nights), 5 at 6 months, 2 at 12 months and 5 at 18 months. This equated to an average number of nights spent in the hospital per study participant of 1.1 nights at baseline, 0.25 at 6 months, 0.12 at 12 months and 0.42 at 18 months. Refer to Table 4 for healthcare utilization data. There were few falls across the duration of the study. A total of 5 falls were reported by 3 subjects during the initial 6-month interventional period. At 12 months 8 total subjects (40%) had experienced at least one fall. Of the fallers, 6 out of 8 (75%) had at least one repeat fall. None of the falls resulted in injury requiring medical evaluation or further care. Falls are reported in Table 5.

Table 4: Healthcare Utilization

Outcomes	Baseline Median (IQR)	6 months Median (IQR)	12 Months Median (IQR)	18 Months Median (IQR)
<i>Total Healthcare Contacts</i>	4 (2, 6)	3 (2, 5)	3 (2, 4)	3 (2, 5) ^{3*}
<i>Physician Visits</i>	4 (2, 6)	3 (2, 5)	3 (2, 4)	3 (2, 3.5) ³
<i>Hospital ER Visits</i>	0 (0, .5)	0 (0, 0)	0 (0, 0)	0 (0, .5)
<i>Different Hospital Admissions</i>	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, .5)
<i>Total Nights in Hospital</i>	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)

Pairwise comparison: 1= Baseline vs. 6 months, 2= baseline vs. 12 months, 3= baseline vs. 18 months, 4= 6 months vs. 12 months, 5= 6 months vs. 18 months, 6= 12 months vs. 18 months. If there is a number, then the pairwise comparison was statistically significant using the Wilcoxon Sign Rank ($p < 0.05$). An (*) indicates the p-value was between 0.05 and 0.10 thus a marginal difference.

Table 5: Subject Reported Falls

Study Month	Total Number of Falls (N)
1	0 (20)
2	3 (20)
3	0 (20)
4	0 (20)
5	1 (20)
6	1 (20)
7	3 (17)
8	0 (17)
9	1 (16)
10	5 (16)
11	1 (16)
12	2 (14)
13	2 (13)
14	2 (12)
15	2 (12)
16	2 (12)
17	0 (12)
18	0 (12)

Objective Assessments

Overall, objective assessment measures were improved across the duration of the study. The 30 Second Chair Stand significantly improved from a baseline of 12 repetitions (IQR 9, 15) to 14 repetitions (IQR 9, 15) at 6 months ($p < 0.05$) and continued to trend toward improvement at 12 months with a median of 15 repetitions (IQR 12, 17). The 2-Minute Step Test significantly improved from a median of 82 steps (IQR 75, 85) at baseline to 102 steps (IQR 84, 105) at 6 months ($p < 0.05$). Further significant improvement in the 2-Minute Step Test was seen at 12 months with median steps increasing to 108 (IQR 88, 112) ($p < 0.05$). Improvement in the 6-Minute Walk Test was also significantly improved ($p < 0.05$) when median baseline distance (1180 feet) was compared to 6-month (1327 feet) and 12-month (1485 feet) distance. Specifically, the 6-Minute Walk Test showed participants gained an average of 147 additional feet at 6 months and 305 additional feet at 12 months when compared to baseline distance. Timed Up and Go was also significantly improved from 8.0 seconds (IQR 6.8, 10.2) at baseline to 6.7 (IQR 5.9, 10.7) at 6 months ($p < 0.05$) and further improved to 6.3 (IQR 5.3, 8.2) at 12 months ($p < 0.05$). Objective assessment data is reported in Table 6.

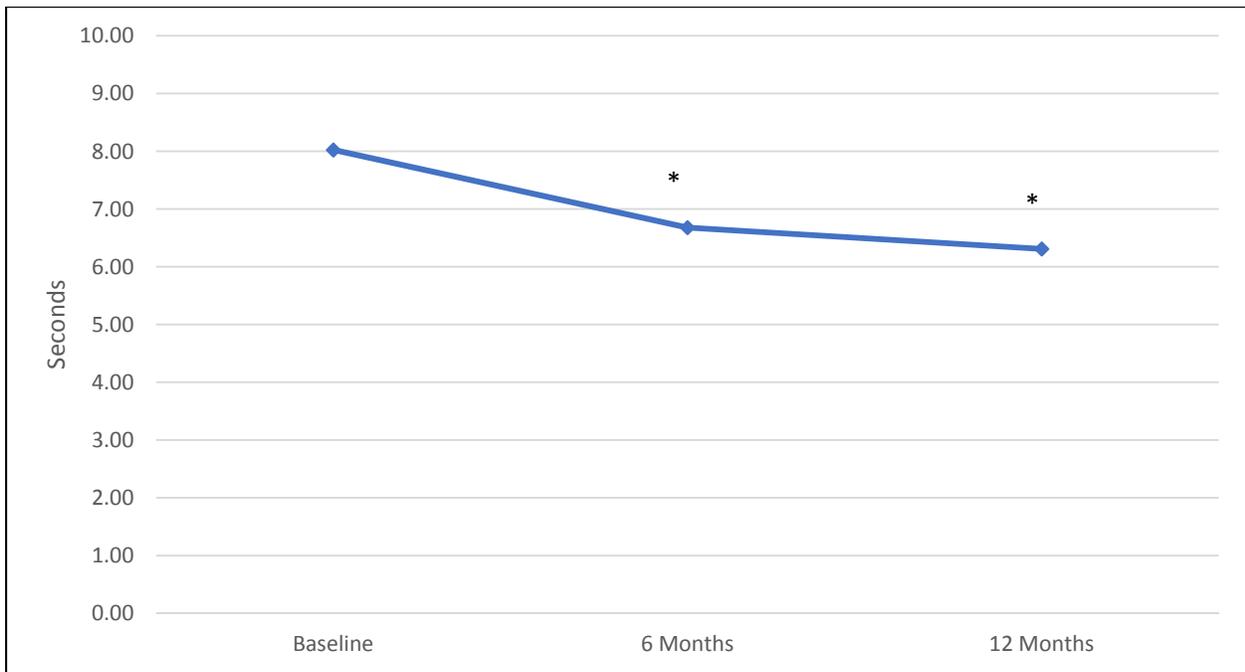
Adverse Events

No serious adverse events associated with the intervention were reported or observed during the 18-month study period. None of the subject reported falls occurring during the intervention resulted in serious injury, such as hip fracture.

Table 6: Objective Assessments

Outcomes	Baseline Median (IQR)	6 months Median (IQR)	12 Months Median (IQR)
<i>Timed Up and Go (seconds)</i>	8.0 (6.8, 10.2)	6.7 (5.9, 10.7) ¹	6.3 (5.3, 8.2) ²
<i>30 Second Chair Stand (repetitions)</i>	12 (9, 15)	14 (9, 15) ¹	15 (12, 17) ²
<i>Two-Minute Step Test (steps)</i>	82 (75, 85)	102 (84, 105) ¹	108 (88, 112) ^{2,3}
<i>Six-Minute Walk Test (feet)</i>	1180 (971, 1350)	1327 (1049, 1465) ¹	1485 (1170, 1810) ^{2,3}
Pairwise comparison: 1= Baseline vs. 6 months, 2= baseline vs. 12 months, 3= 6 months vs. 12 months. If there is a number, then the pairwise comparison was statistically significant using the Wilcoxon Sign Rank (p<0.05).			

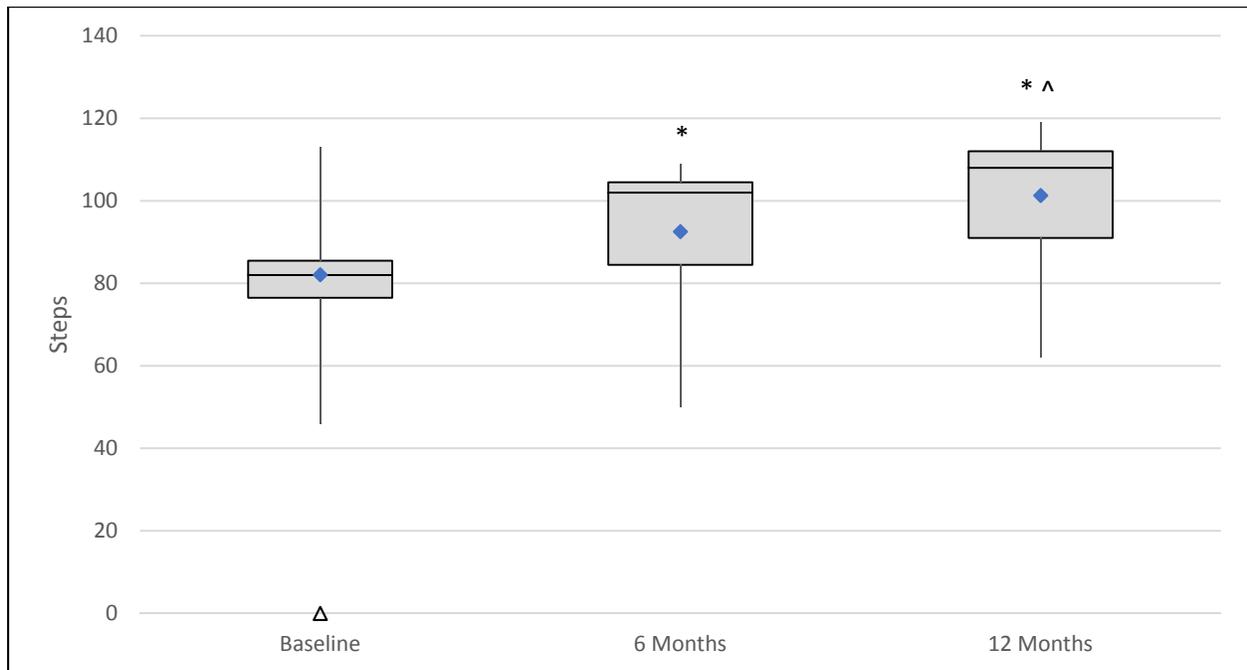
Figure 5: Timed Up and Go



Median values reported.

* indicates significant difference ($p < 0.05$) from baseline.

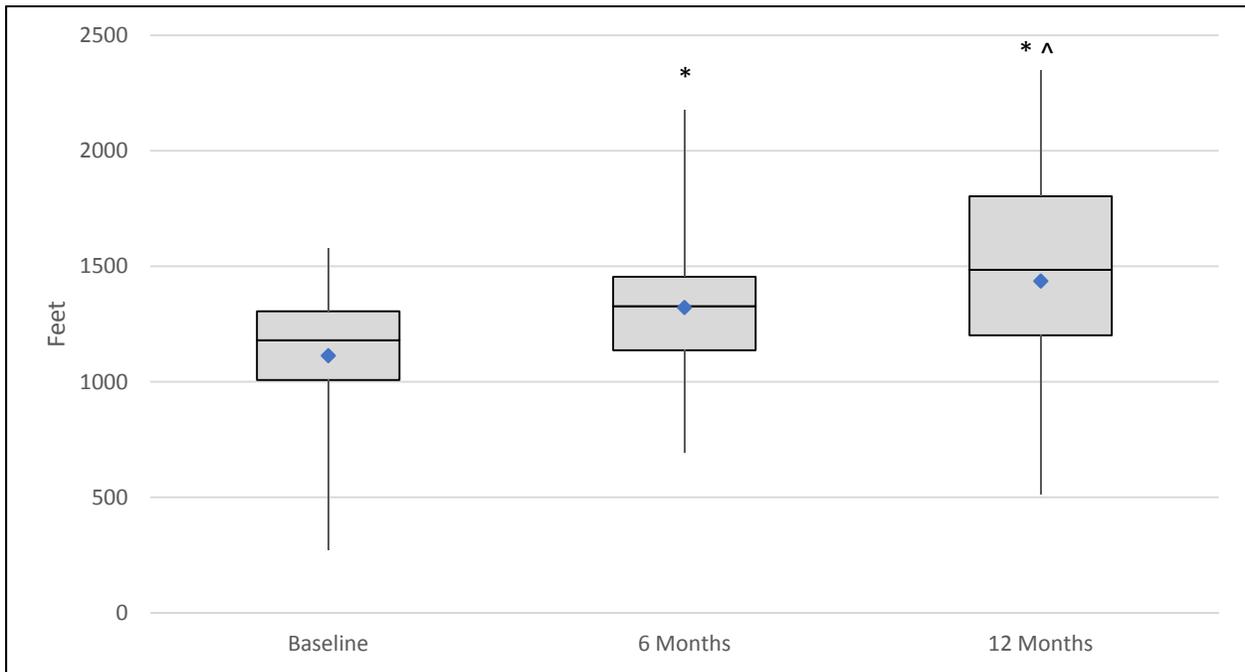
Figure 6: Two-Minute Step Test



* indicates significant difference ($p < 0.05$) from baseline; ^ indicates significant difference ($p < 0.05$) from 6 months.

Δ indicates one outlier who was unable to complete the assessment.

Figure 7: Six-Minute Walk Test



* indicates significant difference ($p < 0.05$) from baseline; ^ indicates significant difference ($p < 0.05$) from 6 months.

Discussion

The purpose of this study was to determine if intervening early in PD with a comprehensive Wellness Program is feasible and to evaluate the program's impact on quality of life, mood, fatigue, number of falls and healthcare utilization within the study group. We found that a comprehensive wellness program involving disease specific group exercise, disease specific education and the promotion of group socialization was feasible and served to maintain overall quality of life across the 18-month study. All but one of the enrolled subjects successfully completed the required 6-month intervention. Most subjects attended more than the minimum of two required fitness classes per week. Additionally, the majority of subjects continued to regularly attend Wellness Program fitness classes, offered at the study site, following the required 6-month interventional period. A total of 14 subjects (70%) continued to participate at 12 months and 12 subjects (60%) continued to participate at 18 months. The high continued long-term participation seen in this study is significant as consistent, long-term exercise is associated with a protective effect on quality of life and functional mobility in PD.²⁶ Therefore, we feel this type of comprehensive PD wellness intervention, aimed at improving quality of life in early PD, is practical for implementation on a larger scale. Furthermore, no serious adverse events were reported or observed during the interventional period. We feel this demonstrates the relative safety of this type of intervention.

Stable PDQ39-SI scores across the 18-month duration of this study were seen and are significant as PD is a notably progressive disease, invariably leading to declining HRQoL over time.²⁷ Patient reported mobility and emotion specific HRQoL, as indicated by PDQ-39 sub-area scoring, were significantly improved following 12 months of the Wellness Program intervention. The improvement in PDQ-39 mobility sub-area scoring is consistent with previous studies which utilized similarly structured group fitness class programs.^{8,19} However, our analysis only noted a trend towards improved mobility specific HRQoL at 6 months while other similar studies have shown significant improvement sooner, most within 6 weeks to 6 months. This may be attributed to our subjects, who were early in their disease course, reporting overall good mobility specific HRQoL at baseline. This may have made improvement more difficult to detect.

At baseline the median PDQ-39 mobility score was 21.25 (IQR 15, 43.8), which reflects relatively good patient reported mobility when compared to other studies of similar PD populations.²⁸

The PDQ-39 sub-areas of activities of daily living and social support trended towards significantly improved at 6 and 12 months, respectively, indicating that this type of intervention could potentially be tailored to further address and improve these specific sub-areas. The maintenance and potential improvement of social support across time is important as PD often leads to social isolation as the disease progresses. Although our Wellness Program offered various optional opportunities for social interaction beyond the group format fitness classes, such as PD support group meetings, a more structured support group format may have promoted further improvement in this patient reported quality of life sub-area.

All PDQ-39 sub-areas were either maintained or improved across the duration of this study except for patient reported communication. The communication sub-area trended towards worsened at 6 months, was significantly worsened from baseline to 12 months, and continued to trend towards worsened from baseline at 18 months. One potential explanation for this finding is that the group format of the Wellness Program may have brought attention to PD voice issue earlier in the disease progression for some of the study participants than if they were not regularly socializing in a diverse PD community. Furthermore, while all of the Wellness Program participants were diagnosed with PD within the last 5 years, there were a variety of PD disease stages, some advanced, represented at the study site. The clinic associated with the study site serves a diverse PD community and study participants likely had regular social interaction with this community while visiting the study site during the Wellness intervention. This could have potentially brought light to issues involving voice and communication for our group of study participants. This finding underscores the importance of addressing voice symptoms and patient communication concerns early in the disease course. Additionally, we feel PD wellness programs designed to facilitate early, open communication between participants can be utilized to generate productive discussion regarding voice issues in PD.

We found fatigue was significantly decreased at 6 months while overall activity levels, as measured by the PASE survey, remained stable. Fatigue scores, based on the FSS, improved by 5.5 points from baseline to 6 months. This is significant as increased fatigue in PD is recognized

as an important variable associated with lower overall life satisfaction.²⁹ In general, our subjects reported above average levels of physical activity when compared with community norms. The mean PASE score at baseline for all study participants was 142.8 which is higher than similarly aged non-PD community norms of 102.4 for men and 89.1 for women.³⁰ High levels of physical activity continued to be reported throughout the study. We hypothesize that consenting study participants may be more likely to pursue an active role in their health, which could account for higher than average baseline physical activity. Regardless, Wellness Program participation did not facilitate or impede overall physical activity as PASE scores remained stable throughout the study.

Our study group had an overall low rate of depression with GDS-15 median scores of 3 points at baseline, 2.5 at 6 months, 2 at 12 months and 3 at 18 months. A GDS-15 score of at least 5 points is needed to be suggestive of mild depression.²⁴ Self-efficacy remained stable in our study group which is an important determinant of overall life satisfaction.²⁹

Objective results from our study were very encouraging. Study participants significantly improved in all of the objective measures from baseline to 6 months and continued to realize significant improvement at 12 months. These measures included: Timed Up and Go, 30-second chair stand, two-minute step test and six-minute walk test. Again, the improvement in objective measures is consistent with previous studies which utilized group format exercise in PD.^{17,18, 19} These results show that a group format PD wellness program focused on improving HRQoL can also serve to significantly improve functional outcomes such as gait speed, stepping and sit-to-stand endurance, and Timed Up and Go. This is significant as these measures are all practically important to patients in their daily lives.

Wellness Program participant healthcare utilization was stable from baseline out to 12 months and was decreased by 18 months. Total healthcare contact was trending towards significantly decreased and physician visits were significantly decreased at 18 months, when compared to baseline. Overall, 5 out of 20 subjects had a hospital encounter, defined as emergency room visit or hospital admission, during the first 12 months of the study. This is consistent with a previous study reporting 25.6% of PD patients (average disease duration of 8.9 years \pm 6.4) had a hospital encounter within the prior one year.³²

There were few falls across the duration of the study. Those who fell were much more likely to experience a second fall. However, experiencing a fall did not deter participation in the Wellness Program as all of the fallers continued to participate in ad lib fitness classes following the required 6-month interventional period. This is encouraging as fear of falling can severely limit physical activity and further promote isolation in PD. Notably, several prior studies have shown that the fear of falling has an even greater impact on HRQoL than does actually falling.^{33,}
³⁴ We feel the social nature of our Wellness Program and PD specific design of the group fitness classes created an optimal environment to promote self-confidence and potentially overcome fear of falling, at least to some degree. This, in combination with significant improvement in functional mobility, likely contributed to the overall stable HRQoL reported in this study.

This study has some limitations. First with such a small sample size a marginal statistical difference or statistical trend may represent an actual significant difference. Second, our Wellness Program intervention did not specifically address voice issues in early PD which may be reflected in the worsening of patient reported communication seen in our study. Third, while this study was interested in investigating feasibility and HRQoL as well as various objective and healthcare utilization measures in this specific PD community we do not have PD control group data for comparison which somewhat limited the depth of our analysis regarding impact of the Wellness Program.

Now that this type of intervention has been proven to be feasible likely next steps should include a randomized controlled study utilizing the described Wellness Program. This would address the lack of PD control group data cited as a limitation to our data analysis.

Future Direction

Few studies have investigated the individual needs of a specific PD community and the impact of a PD wellness program over time. This single site pilot study, of 20 participants involved in a comprehensive PD Wellness Program intervention, has begun to elucidate where clinicians may make the greatest impact on PD HRQoL while achieving overall improved patient care and reducing healthcare associated costs. Future studies could aim to establish how HRQoL changes over time in this specific PD population absent any Wellness Program intervention. This work would establish control data, ideally long-term over the course of disease progression, which would aid in more accurately evaluating future wellness interventions in this PD community.

Additionally, future studies may aim to further explore how PD wellness interventions affect healthcare utilization. Although this study showed that a comprehensive wellness intervention significantly decreased physician visits it would be worthwhile to further investigate the specific reasons for healthcare utilization within this study population. This type of investigation may lead to further insights into how to best care for PD patients while decreasing healthcare utilization and associated costs. Also, performing a cost analysis between standard PD management and standard management plus the incorporation of a wellness intervention would be useful as this study did not seek to determine the actual or estimated healthcare dollars potentially saved as a result of this Wellness Program.

Future studies should also seek to further investigate the early worsening of communication specific HRQoL, as seen in our study population. Determining potential reasons for worsening of communication specific HRQoL would allow for refinement of future wellness interventions to further improve efficacy. Finally, additional insights may be gained through enrolling and analyzing a larger number of patients in a similar intervention as to increase the power of statistical analyses, more accurately characterize data trends and further improve the guidance of future PD wellness interventions.

Conclusions

Parkinson's disease is a chronic, progressive neurodegenerative disease that substantially impacts patients' health-related quality of life. This study appears to show that comprehensive wellness intervention in early PD is feasible, effective and safe. Wellness Program participants achieved significant improvements regarding a variety of commonly affected disease complications including mobility, emotions and fatigue while maintaining a stable overall quality of life across the 18-month study. Additionally, our data indicates that early comprehensive wellness intervention can promote long-term, lasting habits as the majority of study participants continued to participate following the required 6-month interventional period. We feel that early establishment of these habits, such as regular exercise and supportive socialization, will continue to provide significant benefits to PD patients as their disease progresses.

Furthermore, this study shows that a PD specific comprehensive wellness intervention can effectively reduce PD patients' healthcare utilization through a reduction in physician visits and potential reduction in total healthcare contacts. Ultimately, the results from this study will allow for better design and implementation of future PD wellness interventions. These future programs may further improve quality of life for PD patients while also improving care and reducing costs to patients and to the healthcare system.

References

1. Cheng KY, Lin WC, Chang WN, et al. Factors associated with fall-related fractures in parkinson's disease. *Parkinsonism Relat Disord*. 2014;20(1):88-92.
2. Kowal SL, Dall TM, Chakrabarti R, Storm MV, Jain A. The current and projected economic burden of parkinson's disease in the united states. *Mov Disord*. 2013;28(3):311-318.
3. Martinez-Martin P, Rodriguez-Blazquez C, Kurtis MM, Chaudhuri KR, NMSS Validation Group. The impact of non-motor symptoms on health-related quality of life of patients with parkinson's disease. *Mov Disord*. 2011;26(3):399-406.
4. Damiano AM, Snyder C, Strausser B, Willian MK. A review of health-related quality-of-life concepts and measures for parkinson's disease. *Qual Life Res*. 1999;8(3):235-243.
5. Schrag A, Jahansahi M, Quinn NP. What contributes to quality of life in patients with Parkinson's disease? *J Neurol Neurosurg Psychiatry* 2000; 69: 308–312.
6. Chapuis S, Ouchchane L, Metz O, Gerbaud L, Durif F. Impact of the motor complications of Parkison's disease on the quality of life. *Mov Disord* 2005; 20: 224–230.
7. Centers for Disease Control and Prevention. Measuring healthy days: Population assessment of health-related quality of life. Centers for Disease Control and Prevention, Atlanta, Georgia 2000.
8. Hackney ME, Earhart GM. Health-related quality of life and alternative forms of exercise in parkinson disease. *Parkinsonism Relat Disord*. 2009;15(9):644-648.
9. Adkin AL, Frank JS, Jog MS. Fear of falling and postural control in Parkinson's disease. *Mov Disord*. 2003;18:496–502.
10. Kerr GK, Worringham CJ, Cole MH, Lacherez PF, Wood JM, Silburn PA. Predictors of future falls in Parkinson disease. *Neurology*. 2010;75:116–124.
11. Melton 3rd LJ, Leibson CL, Achenbach SJ, Bower JH, Maraganore DM, Oberg AL, et al. Fracture risk after the diagnosis of Parkinson's disease: influence of concomitant dementia. *Mov Disord* 2006;21:1361e7.
12. Veazey C, Aki SO, Cook KF et al. Prevalence and Treatment of Depression in Parkinson's Disease. *J Neuropsychiatry Clin Neurosci*. 2005; 17(3):310-323.

13. Ehrt U, Brønnick K, Leentjens AF, Larsen JP, Aarsland D. Depressive symptom profile in Parkinson's disease: a comparison with depression in elderly patients without Parkinson's disease. *Int J Geriatr Psychiatry* 2006;21:252-258.
14. Nutt JG, Siderowf A, Guttman M, Nelson EC, Schmidt P, Zamudio J, et al. Correlates of health related quality of life (HRQL) in Parkinson's disease (PD) [abstract]. *Mov Disord*. 2012; 27(Suppl 1):546.
15. Wielinski C, Erickson-Davis C, Wichmann R, Walde-Douglas M, Parashos SA. Falls and injuries resulting from falls among patients with Parkinson's disease and other Parkinsonian syndromes. *Move Dis*. 2005;20:410–415.
16. Woodford H, Walker R. Emergency hospital admissions in idiopathic parkinson's disease. *Movement Disorders*. 2005;20(9):1104-1108.
17. Goodwin VA, Richards SH, Taylor AH, Campbell JL. The effectiveness of exercise interventions for people with Parkinson's disease: a systematic review and meta-analysis. *Mov Disord* 2008; 23:631-640.
18. Hirsch MA, Toole T, Maitland OG, Rider RA. The effects of balance training and high-intensity resistance training on persons with idiopathic Parkinson's disease. *Arch Phys Med Rehabil* 2003;84: 1109-1117.
19. T. Ellis, C.J. de Goede, R.G. Feldman, E.C. Wolters, G. Kwakkel, R.C. Wagenaar. Efficacy of a physical therapy program in patients with Parkinson's disease: a randomized controlled trial. *Arch Phys Med Rehabil*, 86 (2005), pp. 626–632.
20. Suzukamo Y, Ohbu S, Kondo T, Kohmoto J, Fukuhara S. Psychological adjustment has a greater effect on health-related quality of life than on severity of disease in parkinson's disease. *Movement Disorders*. 2006;21(6):761-766.
21. Farley BG, Koshland GF. Training BIG to move faster: The application of the speed-amplitude relation as a rehabilitation strategy for people with parkinson's disease. *Exp Brain Res*. 2005;167(3):462-467.
22. Bushnell DM, Martin ML. Quality of life and parkinson's disease: translation and validation of the US Parkinson's disease questionnaire (PDQ-39). *Qual Life Res*1999;8:345–50.

23. Marinus J., Ramaker C., van-Hilten J.J., Stiggebout A.M.. Health related quality of life in Parkinson's disease: a systematic review of disease specific instruments. *J Neurology Neurosurgery Psychiatry*, 2002; 72: 241-148.
24. Weintraub D, Saboe K, Stern MB. Effect of age on geriatric depression scale performance in parkinson's disease. *Mov Disord*. 2007;22(9):1331-1335.
25. Friedman JH, Alves G, Hagell P, et al. Fatigue rating scales critique and recommendations by the movement disorders society task force on rating scales for Parkinson's disease. *Movement Disorders*. 2010;25(7):805-822.
26. Rafferty MR, Schmidt PN, Luo ST, et al. Regular exercise, quality of life, and mobility in parkinson's disease: A longitudinal analysis of national parkinson foundation quality improvement initiative data. *J Parkinsons Dis*. 2016.
27. Soh S, Morris ME, McGinley JL. Determinants of health-related quality of life in Parkinson's disease: A systematic review. *Parkinsonism Relat Disord*. 2011;17(1):1-9.
28. Fitzpatrick R, Peto V, Jenkinson C, Greenhall R, Hyman N. Health-related quality of life in Parkinson's disease: a study of outpatient clinic attenders. *Mov Disord* 12: 916-922, 1997.
29. Rosqvist K, Hagell P, Odin P, Ekström H, Iwarsson S, Nilsson MH. Factors associated with life satisfaction in parkinson's disease. *Acta Neurol Scand*. 2016.
30. Washburn RA, Smith KW, Jette AM, Janney CA. The physical activity scale for the elderly (PASE): development and evaluation. *J Clin Epidemiol*. 1993;46:153-162.
31. Willis AW, Schootman M, Tran R, et al. Neurologist-associated reduction in PD-related hospitalizations and health care expenditures. *Neurology*. 2012;79(17):1774-1780.
32. Shahgholi L, De Jesus S, Wu S, et al. The profile of the hospitalized and re-hospitalized parkinson disease patient: 5 year data from the national parkinson foundation (S48.006). *Neurology*. 2015;84(14 Supplement).
33. Brozova H, Stochl J, Roth J, Ruzicka E. Fear of falling has greater influence than other aspects of gait disorders on quality of life in patients with parkinson's disease. *Neuro Endocrinol Lett*. 2009;30(4):453-457.

34. Grimbergen YA, Schrag A, Mazibrada G, Borm GF, Bloem BR. Impact of falls and fear of falling on health-related quality of life in patients with parkinson's disease. *J Parkinsons Dis.* 2013;3(3):409-413.

Appendix A – Survey Components

Parkinson's Disease Quality of Life Questionnaire (39 – question)

Geriatric Depression Scale (short form)

Healthcare Utilization

Falls Survey

Self-efficacy Scale

Fatigue Severity Scale/ Visual Analogue Fatigue Scale

Physical Activity Scale for the Elderly (PASE)

Parkinson's Disease Quality of Life Questionnaire (PDQ-39)

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

*Please **check one box** for each question*

		Never	Occasionally	Sometimes	Often	Always or cannot do at all
1.	had difficulty doing the leisure activities you would like to do?	<input type="checkbox"/>				
2.	had difficulty looking after your home, for example, housework, cooking or yardwork?	<input type="checkbox"/>				
3.	had difficulty carrying grocery bags?	<input type="checkbox"/>				
4.	had problems walking half a mile?	<input type="checkbox"/>				
5.	had problems walking 100 yards (approximately 1 block)?	<input type="checkbox"/>				
6.	had problems getting around the house as easily as you would like?	<input type="checkbox"/>				
7.	had difficulty getting around in public places?	<input type="checkbox"/>				
8.	needed someone else to accompany you when you went out?	<input type="checkbox"/>				

Please verify that you have **checked one box for each question**
before going on to the next page.

Final English (US) PDQ-39 1996
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Due to having Parkinson's disease,
how often during the last month have you...

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
9. felt frightened or worried about falling in public?	<input type="checkbox"/>				
10. been confined to the house more than you would like?	<input type="checkbox"/>				
11. had difficulty showering and bathing?	<input type="checkbox"/>				
12. had difficulty dressing?	<input type="checkbox"/>				
13. had difficulty with buttons or shoelaces?	<input type="checkbox"/>				
14. had problems writing clearly?	<input type="checkbox"/>				
15. had difficulty cutting up your food?	<input type="checkbox"/>				
16. had difficulty holding a drink without spilling it?	<input type="checkbox"/>				
17. felt depressed?	<input type="checkbox"/>				
18. felt isolated and lonely?	<input type="checkbox"/>				

Please verify that you have **checked one box for each question**
before going on to the next page.

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

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
19. felt weepy or tearful?	<input type="checkbox"/>				
20. felt angry or bitter?	<input type="checkbox"/>				
21. felt anxious?	<input type="checkbox"/>				
22. felt worried about your future?	<input type="checkbox"/>				
23. felt you had to hide your Parkinson's from people?	<input type="checkbox"/>				
24. avoided situations which involve eating or drinking in public?	<input type="checkbox"/>				
25. felt embarrassed in public due to having Parkinson's disease?	<input type="checkbox"/>				
26. felt worried about other people's reaction to you?	<input type="checkbox"/>				
27. had problems with your close personal relationships?	<input type="checkbox"/>				

Please verify that you have **checked one box for each question**
before going on to the next page.

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

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
28. lacked the support you needed from your spouse or partner? <i>If you do not have a spouse or Partner, please check here</i> <input type="checkbox"/>	<input type="checkbox"/>				
29. lacked the support you needed from your family or close friends?	<input type="checkbox"/>				
30. unexpectedly fallen asleep during the day?	<input type="checkbox"/>				
31. had problems with your concentration, for example when reading or watching TV?	<input type="checkbox"/>				
32. felt your memory was failing?	<input type="checkbox"/>				
33. had distressing dreams or hallucinations?	<input type="checkbox"/>				
34. had difficulty speaking?	<input type="checkbox"/>				
35. felt unable to communicate effectively?	<input type="checkbox"/>				
36. felt ignored by people?	<input type="checkbox"/>				

Please verify that you have **checked one box for each question** before going on to the next page.

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

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
37. had painful muscle cramps or spasms?	<input type="checkbox"/>				
38. had aches and pains in your joints or body?	<input type="checkbox"/>				
39. felt uncomfortably hot or cold?	<input type="checkbox"/>				

Please verify that you have **checked one box for each question.**

Thank you for completing the questionnaire.

Final English (US) PDQ-39 1996

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Geriatric Depression Scale (short form)

Instructions: Circle the answer that best describes how you felt over the past week.

- | | | |
|---|-----|----|
| 1. Are you basically satisfied with your life? | yes | no |
| 2. Have you dropped many of your activities and interests? | yes | no |
| 3. Do you feel that your life is empty? | yes | no |
| 4. Do you often get bored? | yes | no |
| 5. Are you in good spirits most of the time? | yes | no |
| 6. Are you afraid that something bad is going to happen to you? | yes | no |
| 7. Do you feel happy most of the time? | yes | no |
| 8. Do you often feel helpless? | yes | no |
| 9. Do you prefer to stay at home, rather than going out and doing things? | yes | no |
| 10. Do you feel that you have more problems with memory than most? | yes | no |
| 11. Do you think it is wonderful to be alive now? | yes | no |
| 12. Do you feel worthless the way you are now? | yes | no |
| 13. Do you feel full of energy? | yes | no |
| 14. Do you feel that your situation is hopeless? | yes | no |
| 15. Do you think that most people are better off than you are? | yes | no |

Total Score _____

!

Healthcare Utilization!

1. In the past 6 months, how many times did you visit a physician? Do **not** include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number. ____ times
2. In the past 6 months, how much time did you go to a **hospital** emergency room? Fill in with "0" or another number. ____ times
3. How many different **times** did you stay in a hospital **overnight** or longer in the past 6 months? Fill in with "0" or another number. ____ times
4. How many total **nights** did you spend in the hospital in the past 6 months? Fill in with "0" or another number. ____ nights

!

Falls (if you don't know the exact answer, provide your best guess)!

How many falls have you had in the last week? _____!

How many falls have you had in the last month? _____!

How many falls have you had in the last 6 months? _____!

Self-efficacy Scale(5)*

Circle response that best captures how you feel.*

- | | | |
|---------|--|---|
| 1 2 3 4 | I can always manage to solve difficult problems if I try hard enough. | * |
| 1 2 3 4 | If someone opposes me, I can find the means and ways to get what I want. | * |
| 1 2 3 4 | It is easy for me to stick to my aims and accomplish my goals. | * |
| 1 2 3 4 | I am confident that I could deal efficiently with unexpected events.* | |
| 1 2 3 4 | Thanks to my resourcefulness, I know how to handle unforeseen situations.* | |
| 1 2 3 4 | I can solve most problems if I invest the necessary effort.* | |
| 1 2 3 4 | I can remain calm when facing difficulties because I can rely on my coping abilities.* | |
| 1 2 3 4 | When I am confronted with a problem, I can usually find several solutions.* | |
| 1 2 3 4 | If I am in trouble, I can usually think of a solution.* | |
| 1 2 3 4 | I can usually handle whatever comes my way.* | |

1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true

*

*

FATIGUE SEVERITY SCALE (FSS)

Date _____ Name _____

Please circle the number between 1 and 7 which you feel best fits the following statements. This refers to your usual way of life within the last week. 1 indicates “strongly disagree” and 7 indicates “strongly agree.”

Read and circle a number.	Strongly Disagree	→	Strongly Agree
1. My motivation is lower when I am fatigued.	1	2	3 4 5 6 7
2. Exercise brings on my fatigue.	1	2	3 4 5 6 7
3. I am easily fatigued.	1	2	3 4 5 6 7
4. Fatigue interferes with my physical functioning.	1	2	3 4 5 6 7
5. Fatigue causes frequent problems for me.	1	2	3 4 5 6 7
6. My fatigue prevents sustained physical functioning.	1	2	3 4 5 6 7
7. Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3 4 5 6 7
8. Fatigue is among my most disabling symptoms.	1	2	3 4 5 6 7
9. Fatigue interferes with my work, family, or social life.	1	2	3 4 5 6 7

VISUAL ANALOGUE FATIGUE SCALE (VAFS)

Please mark an “X” on the number line which describes your global fatigue with 0 being worst and 10 being normal.

0	1	2	3	4	5	6	7	8	9	10

**PHYSICAL ACTIVITY SCALE
FOR THE ELDERLY
(P A S E)**



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INSTRUCTIONS:

Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:

During the past 7 days, how often have you seen the sun?

[0.] NEVER	[1.] SELDOM (1-2 DAYS)	[2.] SOMETIMES (3-4 DAYS)	[3.] OFTEN (5-7 DAYS)
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Answer all items as accurately as possible. All information is strictly confidential.

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0.] NEVER ↓ GO TO Q.#2	[1.] SELDOM (1-2 DAYS) ↓	[2.] SOMETIMES (3-4 DAYS) ↓	[3.] OFTEN (5-7 DAYS) ↓
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- 1a. What were these activities?

- 1b. On average, how many hours per day did you engage in these sitting activities?
- [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS
- [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER ↓ GO TO Q.#3	[1.] SELDOM (1-2 DAYS) ↓	[2.] SOMETIMES (3-4 DAYS) ↓	[3.] OFTEN (5-7 DAYS) ↓
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- 2a. On average, how many hours per day did you spend walking?
- [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS
- [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#4	↓	↓	↓

3a.	What were these activities? _____
3b.	On average, how many hours per day did you engage in these light sport or recreational activities? [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#5	↓	↓	↓

4a.	What were these activities? _____
4b.	On average, how many hours per day did you engage in these moderate sport and recreational activities? [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#6	↓	↓	↓

5a.	What were these activities? _____
5b.	On average, how many hours per day did you engage in these strenuous sport and recreational activities? [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#7	↓	↓	↓

6a.	What were these activities? _____
6b.	On average, how many hours per day did you engage in exercises to increase muscle strength and endurance? [1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS [3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

[1.] NO [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

[1.] NO [2.] YES

9. During the past 7 days, did you engage in any of the following activities?

Please answer YES or NO for each item.

	<u>NO</u>	<u>YES</u>
a. Home repairs like painting, wallpapering, electrical work, etc.	1	2
b. Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c. Outdoor gardening	1	2
d. Caring for an other person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_____ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

- [1] Mainly sitting with slight arm movements.
[Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.]

- [2] Sitting or standing with some walking.
[Examples: cashier, general office worker, light tool and machinery worker.]

- [3] Walking, with some handling of materials generally weighing less than 50 pounds.
[Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

- [4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds.
[Examples: lumberjack, stone mason, farm or general laborer.]

**THANK YOU FOR TAKING THE TIME AND EFFORT
TO COMPLETE THIS QUESTIONNAIRE!**