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A Multifactorial Exercise Program to Reduce Falls in People With Parkinson Disease

This study has been completed.

Sponsor:
Boston University

Information provided by (Responsible Party):
Theresa D Ellis, Boston University

ClinicalTrials.gov Identifier:
NCT02302144

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Purpose

The primary objective of this study is to investigate the effects of a theoretically driven, highly challenging exercise program (balance and strengthening exercises) in reducing fall rate, improving balance and reducing fear of falling in persons with Parkinson's disease.

In this pilot, randomized, cross-over study, 32 participants with Parkinson disease will be randomly assigned to either an early start (immediately following enrollment) or late start (3 months after enrollment) multifactorial exercise program which will meet 2 times per week for 1.5 hours over 3 months. The exercise program will consist of balance and strengthening exercises which will be individualized depending on the ability of each participant. Fall rate, balance, walking ability, fear of falling, mood, anxiety, and quality of life will be measured prior to the start, at 3 months and 6 months after enrollment. Subjects will be enrolled for 6-7 months.

Condition	Intervention
Parkinson Disease	Behavioral: Balance & Strengthening Exercises

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Crossover Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multifactorial Exercise Program to Reduce Falls in People With Parkinson Disease

Resource links provided by NLM:

Genetics Home Reference related topics: Parkinson disease Perry syndrome

MedlinePlus related topics: Anxiety Exercise and Physical Fitness Parkinson's Disease

U.S. FDA Resources

Further study details as provided by Boston University:

Primary Outcome Measures:

- Falls Diary [Time Frame: 6-7 Months] [Designated as safety issue: Yes]

  Subjects will be asked to record each falling episode in the falls diary at the time of the fall or as soon as possible in relation to the actual time that the fall occurred. Subjects will be interviewed regarding fall episodes at each treatment session.

Secondary Outcome Measures:

- Change in Activities-specific Balance Confidence [Time Frame: 6-7 Months] [Designated as safety issue: No]

  Activities-specific Balance Confidence (ABC) Scale is a self-administered questionnaire in which subjects rate their level of confidence in performing a series of 16 activities.

- Change in Falls Self-Efficacy [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Falls Self-Efficacy Scale is a self-administered questionnaire in which subjects rate their level of concern about falling when performing designated activities.

- Change in Balance Evaluation Systems Test (BESTest) [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Balance Evaluation Systems Test (BESTest) is a 36 item test which is used to assess postural control / balance. Subjects are asked to perform a series of tasks such as sitting and leaning, standing on compliant and noncompliant surfaces, stepping forward, backward and to the side and walking on level and unlevel surfaces, while turning the head and while negotiating obstacles.

- Change in Six-Minute Walk Test [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The six-minute walk test (6MWT) is a measure of the distance a participant walks in a 6 minute time period. The 6-minute walk test is a safe, simple and useful measure of walking ability in patients with Parkinson's disease. The test will be carried out on level, obstacle-free enclosed corridors.

- Change in Freezing of Gait Questionnaire [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Freezing of Gait Questionnaire (FOG) is a 6-item test in which the patient is interviewed and asked questions about their walking ability.

- Change in Unified Parkinson's Disease Rating Scale [Time Frame: 6-7 Months] [Designated as safety issue: No]

  Section I, II, III and IV of the Unified Parkinson's Disease Rating Scale (UPDRS) will be utilized to assess nonmotor and motor signs.

- Change in Scales for Outcomes in Parkinson Disease [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Scales for Outcomes in Parkinson Disease (SCOPA-AUT) consists of 26 items assessing autonomic function including gastrointestinal, urinary, cardiovascular, thermoregulatory, pupillomotor and sexual function.

- Change in Parkinson's Disease Questionnaire-39 [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Parkinson's Disease Questionnaire-39 (PDQ-39) is a quality of life instrument that contains 39-self-report items and was specifically developed for people with Parkinson's disease. The PDQ-39 measures the degree of healthy, competent, and satisfying participation in daily life activities.

- Change in Beck Anxiety Inventory [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Beck Anxiety Inventory (BAI) is a measure of the severity of anxiety in adolescents and adults. The items assess typical features of anxiety, and the measure.

- Changes in Beck Depression Inventory Second Edition [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Beck Depression Inventory Second Edition (BDI-II) is a measure of the severity of depression in adolescents and adults. The items target common symptoms of depression.

- Changes in Penn State Worry Questionnaire [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Penn State Worry Questionnaire (PSWQ) is a measure of the worry characteristic of generalized anxiety disorder (GAD). Specifically, this measure of pathological worry assesses three areas of worry (generality, excessiveness, and uncontrollability).

- Change in Panic Disorder Severity Scale [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Panic Disorder Severity Scale (PDSS) is a questionnaire designed to measure the overall severity of panic disorder. The items assess the severity of seven dimensions of panic disorder and associated symptoms: frequency of panic attacks, distress during panic attacks, panic-focused anticipatory anxiety, phobic avoidance of situations, phobic avoidance of physical sensations, and impairment and interference in work and social functioning.

- Changes in Anxiety Sensitivity Index [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Anxiety Sensitivity Index (ASI) is an instrument on which respondents rate the degree to which they fear negative consequences resulting from anxiety symptoms. It yields a total score, representing the global-order anxiety sensitivity factor, as well as three lower-order factor scores, representing physical, psychological, and social concerns.

- Changes in Social Phobia Inventor [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Social Phobia Inventory (SPIN) is a self-report questionnaire used to measure symptoms of social phobia (or social anxiety disorder). The SPIN specifically evaluates the spectrum of fear (e.g. fear of being embarrassed), avoidance (e.g. avoidance of parties), and physiological (e.g. blushing) symptoms associated with social phobia.

- Changes in Social Interaction Anxiety Scale [Time Frame: 6-7 Months] [Designated as safety issue: No]

  The Social Interaction Anxiety Scale (SIAS) is a self-report questionnaire used to measure general fears of social interaction and fears of being scrutinized during activities and performance tasks. The scale is intended to measure affective, behavioral, and cognitive reactions in 20 social interaction situations.

Enrollment:	32
Study Start Date:	December 2011
Study Completion Date:	June 2013
Primary Completion Date:	June 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Early Multi-Ex-PD Immediately following enrollment, subjects will participate in a group balance and strengthening program (Multi-Ex-PD) 2x/week for 90 minutes over 3 months within the Center for Neurorehabilitation at Sargent College. Each of the exercises consists of a progression which ranges from less challenging to more challenging. The program will be individualized to the subject to appropriately match their abilities. Each subject will be progressed to a more challenging exercise once specific criteria are met. Resistance for the strengthening exercises will be applied using weighted vests.	Behavioral: Balance & Strengthening Exercises Progressive balance and strengthening exercises conducted in a group format yet tailored to each individual
Experimental: Late Multi-Ex-PD Three months after enrollment, subjects will participate in a group balance and strengthening program (Multi-Ex-PD) 2x/week for 90 minutes over 3 months within the Center for Neurorehabilitation at Sargent College. Each of the exercises consists of a progression which ranges from less challenging to more challenging. The program will be individualized to the subject to appropriately match their abilities. Each subject will be progressed to a more challenging exercise once specific criteria are met. Resistance for the strengthening exercises will be applied using weighted vests.	Behavioral: Balance & Strengthening Exercises Progressive balance and strengthening exercises conducted in a group format yet tailored to each individual

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- have a diagnosis of idiopathic Parkinson's disease (using UK Brain Bank Criteria)
- have a Hoehn & Yahr stage of 2-4 during the "ON" state
- Mini mental status score > 26
- be 40 years of age or older, so as to represent the typical age range of PD
- be on a stable dose of Parkinson's medications for at least 2 weeks prior to study onset and during the 3 month study period.
- have experienced at least one fall in the past 3 months and greater or equal to 2 falls in the past one-year (A fall was defined as an unexpected event where the person inadvertently came to rest on the ground or other lower level not due to a major intrinsic or extrinsic event)
- able to walk without physical assistance or an assistive device for at least 5 continuous minutes
- able to understand, communicate with and be understood by recruitment personnel
- able to attend the exercise program twice per week at Sargent College
- be interested in participating and provide informed consent

Exclusion Criteria:

- have a diagnosis of atypical Parkinsonism
- have a Hoehn & Yahr stage of 1 or 5
- have had previous surgical management of PD (i.e., deep brain stimulation surgery; pallidotomy)
- serious co-morbidities that may interfere with ability to participate in an exercise program (i.e., musculoskeletal, cardiovascular, and neurological (other than Parkinson's))
- be pregnant

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02302144

Locations

United States, Massachusetts

Center for Neurorehabilitation, College of Health & Rehabilitation Sciences, Sargent College, Boston University
Boston, Massachusetts, United States, 02215

Sponsors and Collaborators

Boston University

Investigators

Principal Investigator: Terry Ellis, PhD, PT, NCS Boston University

More Information

Additional Information:

Center for Neurorehabilitation at Boston University EXIT

Publications:

Gillespie LD, Robertson MC, Gillespie WJ, Lamb SE, Gates S, Cumming RG, Rowe BH. Interventions for preventing falls in older people living in the community. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD007146. doi: 10.1002/14651858.CD007146.pub2. Review. Update in: Cochrane Database Syst Rev. 2012;9:CD007146.

Wood BH, Bilclough JA, Bowron A, Walker RW. Incidence and prediction of falls in Parkinson's disease: a prospective multidisciplinary study. J Neurol Neurosurg Psychiatry. 2002 Jun;72(6):721-5.

Genever RW, Downes TW, Medcalf P. Fracture rates in Parkinson's disease compared with age- and gender-matched controls: a retrospective cohort study. Age Ageing. 2005 Jan;34(1):21-4.

Melton LJ 3rd, Leibson CL, Achenbach SJ, Bower JH, Maraganore DM, Oberg AL, Rocca WA. Fracture risk after the diagnosis of Parkinson's disease: Influence of concomitant dementia. Mov Disord. 2006 Sep;21(9):1361-7.

Johnell O, Melton LJ 3rd, Atkinson EJ, O'Fallon WM, Kurland LT. Fracture risk in patients with parkinsonism: a population-based study in Olmsted County, Minnesota. Age Ageing. 1992 Jan;21(1):32-8.

Temlett JA, Thompson PD. Reasons for admission to hospital for Parkinson's disease. Intern Med J. 2006 Aug;36(8):524-6.

Hely MA, Morris JG, Traficante R, Reid WG, O'Sullivan DJ, Williamson PM. The sydney multicentre study of Parkinson's disease: progression and mortality at 10 years. J Neurol Neurosurg Psychiatry. 1999 Sep;67(3):300-7.

Spottke AE, Reuter M, Machat O, Bornschein B, von Campenhausen S, Berger K, Koehne-Volland R, Rieke J, Simonow A, Brandstaedter D, Siebert U, Oertel WH, Ulm G, Dodel R. Cost of illness and its predictors for Parkinson's disease in Germany. Pharmacoeconomics. 2005;23(8):817-36.

Jacobs JV, Horak FB. Cortical control of postural responses. J Neural Transm (Vienna). 2007;114(10):1339-48. Epub 2007 Mar 29. Review.

Bloem BR, Beckley DJ, van Dijk JG, Zwinderman AH, Remler MP, Roos RA. Influence of dopaminergic medication on automatic postural responses and balance impairment in Parkinson's disease. Mov Disord. 1996 Sep;11(5):509-21.

Chang JT, Morton SC, Rubenstein LZ, Mojica WA, Maglione M, Suttorp MJ, Roth EA, Shekelle PG. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomised clinical trials. BMJ. 2004 Mar 20;328(7441):680. Review.

Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, Koch ML, Trainor K, Horwitz RI. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. N Engl J Med. 1994 Sep 29;331(13):821-7.

Rose DJ. Preventing falls among older adults: no "one size suits all" intervention strategy. J Rehabil Res Dev. 2008;45(8):1153-66.

Ashburn A, Fazakarley L, Ballinger C, Pickering R, McLellan LD, Fitton C. A randomised controlled trial of a home based exercise programme to reduce the risk of falling among people with Parkinson's disease. J Neurol Neurosurg Psychiatry. 2007 Jul;78(7):678-84. Epub 2006 Nov 21.

Pickering RM, Grimbergen YA, Rigney U, Ashburn A, Mazibrada G, Wood B, Gray P, Kerr G, Bloem BR. A meta-analysis of six prospective studies of falling in Parkinson's disease. Mov Disord. 2007 Oct 15;22(13):1892-900.

Ebersbach G, Edler D, Kaufhold O, Wissel J. Whole body vibration versus conventional physiotherapy to improve balance and gait in Parkinson's disease. Arch Phys Med Rehabil. 2008 Mar;89(3):399-403. doi: 10.1016/j.apmr.2007.09.031.

Horak FB. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? Age Ageing. 2006 Sep;35 Suppl 2:ii7-ii11. Review.

Cakit BD, Saracoglu M, Genc H, Erdem HR, Inan L. The effects of incremental speed-dependent treadmill training on postural instability and fear of falling in Parkinson's disease. Clin Rehabil. 2007 Aug;21(8):698-705.

Allen NE, Canning CG, Sherrington C, Lord SR, Latt MD, Close JC, O'Rourke SD, Murray SM, Fung VS. The effects of an exercise program on fall risk factors in people with Parkinson's disease: a randomized controlled trial. Mov Disord. 2010 Jul 15;25(9):1217-25. doi: 10.1002/mds.23082.

Protas EJ, Mitchell K, Williams A, Qureshy H, Caroline K, Lai EC. Gait and step training to reduce falls in Parkinson's disease.

NeuroRehabilitation. 2005;20(3):183-90.

Dorsey ER, Constantinescu R, Thompson JP, Biglan KM, Holloway RG, Kieburtz K, Marshall FJ, Ravina BM, Schifitto G, Siderowf A, Tanner CM. Projected number of people with Parkinson disease in the most populous nations, 2005 through 2030. Neurology. 2007 Jan 30;68(5):384-6. Epub 2006 Nov 2.

Responsible Party:	Theresa D Ellis, Assistant Professor and Director of Center for Neurorehabilitation, Boston University
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Other Study ID Numbers:	BU-SAR-BAL
Study First Received:	November 24, 2014
Last Updated:	November 24, 2014
Health Authority:	United States: Institutional Review Board

Keywords provided by Boston University:
Postural Instability (falling)
Gait Disturbances (e.g., freezing)
Bradykinesia (slowness of movement), rigidity

Additional relevant MeSH terms:

Parkinson Disease	Movement Disorders
Basal Ganglia Diseases	Nervous System Diseases
Brain Diseases	Neurodegenerative Diseases
Central Nervous System Diseases	Parkinsonian Disorders

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