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Exercise to improve motor and non-motor symptoms in Parkinson’s disease

Submission date
02/10/2024

Recruitment status
Recruiting

Registration date
04/10/2024

Overall study status
Ongoing

Last Edited
04/10/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People living with Parkinson's disease (PD) may experience both motor and non-motor symptoms. Ample evidence indicates the benefits of exercise interventions in improving symptoms in patients with PD. This research aims to examine the effect of an exercise intervention on decreasing those symptoms to improve the quality of life of PD patients by using both objective measures and exploring patients' perspectives and inputs.

Who can participate?
Patients with a diagnosis of early to mid-stage PD who are aged between 40 to 80 years old

What does the study involve?
Participants in this study will be randomly assigned to either an LSVT BIG intervention group or a control group (without receiving the LSVT BIG during this study). The measures to be taken include both movement-related (such as mobility, and balance) and non-movement-related (e.g., fatigue) assessments. All participants will undergo the same measurements.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. However, the findings of this research are expected to contribute to evidence used to guide clinical management of this disease. Possible risks may be associated with falls in the performance of outcome measures such as mobility and balance evaluation. However, the risk level is lower than minimal as the tests will be administered by a licensed therapist, and a gait belt will be used to prevent any risk of falls.

Where is the study run from?
Impact Physical Therapy and Franklin Pierce University Arizona Doctor of Physical Therapy manage this study.

When is the study starting and how long is it expected to run for?
January 2024 to December 2025

Who is funding the study?
LSVT Global Inc.

Who is the main contact?
Dr Ruiping Xia, xiar@franklinpierce.edu

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr RuiPing Xia

Contact details
14455 W Van Buren Street
A-100
Goodyear
United States of America
85338
+1 6235182386
xiar@franklinpierce.edu

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Tamara Hefferon

Contact details
7727 W Deer Valley RD; STE 210
Peoria
United States of America
85382
+1 4802980212
thefferon@impactptaz.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
LSVT-BIG: improving motor and non-motor symptoms in Parkinson’s disease: a mixed-method study

Acronym
LSVT-BIG

Study objectives
LSVT-BIG treatment will improve motor and non-motor symptoms in patients with Parkinson’s disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/07/2024, Franklin Pierce University Institutional Review Board (IRB) (40 University Drive, Ridge, 03461, United States of America; +1 6038994294; Buddingtonl@franklinpierce.edu), ref: RX07182024

Study design
Mixed-methods study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Other therapist office

Study type(s)
Treatment, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Lee Silverman Voice Training (LSVT) BIG therapy is the intervention to be studied.
LSVT BIG is an intensive, effective, one-on-one treatment delivered by an LSVT-BIG certified physical therapist created to help people with Parkinson's disease (PD) address walking, balance and other activities of daily living or even job-related tasks. LSVT-BIG includes one-hour session daily, four sessions per week, for four weeks in a row. Daily homework and carryover exercises are also provided. Participants with PD will be randomly assigned by a computer-generated program to either LSVT-BIG group or control group.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures will be performed at baseline, immediate, 3, and 6 months post-intervention:
1. Non-motor symptoms will be measured by Movement Disorder Society (MDS) - Non-motor symptoms
2. Fatigue is measured by the Parkinson's Fatigue Scale
3. Motor symptoms will be measured by the MDS-Unified PD Rating Scale - Parts 2 and 3.
4. Motor function is measured by Mini-Balance Evaluation Systems Test (MiniBEST) and 5x Sit-To-Stand.

Secondary outcome measures
Quality of Life is measured by the Parkinson's Disease Questionnaire - 39 at baseline, immediate, 3, and 6 months post-intervention

Overall study start date
01/01/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Ages at least 40 years old
2. Have a medical diagnosis of Parkinson’s disease (PD) at an early to mid-stage

Participant type(s)
Patient

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Those who had participated in an LSVT-BIG program in the last year
2. Those who are currently enrolled in another exercise intervention

Date of first enrolment
01/11/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
United States of America

Study participating centre
Impact Physical Therapy
7727 W Deer Valley Rd Ste 210
Peoria
United States of America
85382

Sponsor information

Organisation
Impact Physical Therapy

Sponsor details
7727 W Deer Valley Rd Ste 210
Peoria
United States of America
85382
+1 (623) 208-7575
irb@franklinpierce.edu

Sponsor type
Hospital/treatment centre

Website
https://impactptaz.com/peoria/

Funder(s)

Funder type
Industry

Funder Name
LSVT Global Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed topic-relevant journal (e.g., Journal of Neurologic Physical Therapy)

Intention to publish date
01/05/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Tamara Hefferon at hefferont@franklinpierce.edu. De-identified data on the the primary outcomes as outlined previously at the different time points of interest outlined will be shared with the investigators of the study for statistical analysis. Participant consent will be obtained at the time of study enrollment.

IPD sharing plan summary
Available on request