

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of high-amplitude intense exercises with the Silverman-voice therapy on the bradykinesia of patients with Parkinson

Protocol summary

Study aim

To determine the effectiveness of high-amplitude intense exercises with the Silverman-voice therapy in improving bradykinesia in Parkinson disease

Design

A randomized, blinded, sham controlled clinical trial with a parallel group design of 30 patients, enrolled between April 2023 and November 2023, and followed for one month

Settings and conduct

Study setting: Physiotherapy Clinic Study duration: The study will conducted over a period of 8 months. Outcome measure: .Cognitive and motor TUG tests , Montreal Cognitive Assessment Procedure: Patients clinically diagnosed as Idiopathic PD by a Neurologist will enroll in the study.patients will assign through purposive sampling method into control and experimental groups.Prior and after 4 weeks each and every subject underwent test using theCognitive and motor TUG tests , Montreal Cognitive Assessment. The Kolmogorov-Smirnov test will be used to check the normality. Repeated measures ANOVA with Bonferroni's post hoc test, independent and paired t-tests for inter- and intra-group comparisons will be used. If necessary and analysis of covariance (ANCOVA) is also used.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Diagnosed as Idiopathic Parkinson and stable medication 4 weeks prior to inclusion Exclusion criteria: severe depression and any medical or musculoskeletal contraindications to exercise

Intervention groups

Control Group: The patients in the control group will receive conventional muscle strengthening and balance training. Experimental Group: In the experimental group the patients will given the standard protocol of LSVT training and conventional muscle strengthening and balance training.

Main outcome variables

Cognitive and motor TUG tests , Montreal Cognitive

Assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190812044516N2**

Registration date: **2023-03-07, 1401/12/16**

Registration timing: **prospective**

Last update: **2023-03-07, 1401/12/16**

Update count: **0**

Registration date

2023-03-07, 1401/12/16

Registrant information

Name

Nahid Tahan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1723

Email address

na_tahan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of high-amplitude intense exercises with the Silverman-voice therapy on the bradykinesia of patients with Parkinson

Public title

Effects of high-amplitude intense exercises in patients with Parkinson

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed as Idiopathic Parkinson stable medication 4 weeks prior to inclusion Being able to walk for 6 m with or without aids

Exclusion criteria:

Severe depression Any medical or musculoskeletal contraindications to exercise

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each sample is a patient

Randomization (investigator's opinion)

Randomized

Randomization description

we use block randomization to allocate participants to the groups with an equal sample size over time. The groups will be labeled (E= experimental, C= control). Then a block size of four will be chosen. So, there were six possible ways to equally assign participants to a block (EECC, ECEC, ECCE, CEEC, CECE, CCEE). Blocks were randomly chosen to determine the assignment of all 32 individuals (16 participants in each group). Allocation concealment is performed using sealed, opaque envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the study do not know which group they are in. The assessment of patients before and after the intervention will be done by another physiotherapist who is not aware of the study procedure.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No.15, Yaman St, Arabi St, Next to Taleghani Hospital, Chamran High way,

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-01-01, 1401/10/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.609

Health conditions studied

1

Description of health condition studied

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Motor TUG test

Timepoint

Before the intervention and one month after the start of the intervention

Method of measurement

Time duration of test in second

2

Description

Cognitive TUG test

Timepoint

Before the intervention and one month after the start of the intervention

Method of measurement

Time duration of test in second

3

Description

Montreal Cognitive Assessment

Timepoint

Before the intervention and one month after the start of the intervention

Method of measurement

The score of test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in the intervention group will perform general physical therapy exercises (including stretching and strengthening exercises) along with the Lee Silverman Standard Method exercise program, which includes high-amplitude, high-intensity exercises. The intervention program will be 4 days a week for 4 weeks and a total of 16 one-hour sessions

Category

Rehabilitation

2

Description

Control group: The participants in the control group will perform general physical therapy exercises (including stretching and strengthening exercises). The intervention program will be 4 days a week for 4 weeks and a total of 16 one-hour sessions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti university of Medical Sciences

Full name of responsible person

Nahid Tahan

Street address

Damavand Ave., Imam Hossein Sq., Tehran, P.O.Box: 1616913111

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nahidta2431@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

No.15, Yaman St, Arabi St, Next to Taleghani Hospital, Chamran High way,

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Mehehsti university of medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nahid Tahan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome is shared

When the data will become available and for how long

Six months after the publication of the results

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

In order to study

From where data/document is obtainable

E-mail address of Nahid Tahan nahidta2431@gmail.com

What processes are involved for a request to access data/document

Request by sending to the respondent's email

Comments