Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of adding Otago exercises to trunk exercises on motor assessment, freezing of gait, balance, position sense, lower extremity muscle quality index in middle-aged women with Parkinson's disease

Protocol summary

Study aim
The effect of adding Otago exercises to trunk exercises on motor assessment, freezing of gait, balance, position sense, lower extremity muscle quality index in middle-aged women with Parkinson's disease

Design
A randomized controlled clinical trial with four parallel groups and a single-blinded outcome assessor will be conducted involving 60 middle-aged women with Parkinson’s disease. Participants will be allocated to the study groups using stratified randomization with a random number generator.

Settings and conduct
This study will involve 60 middle-aged women with Parkinson’s disease at a neurology clinic in Shiraz, Iran. Following baseline assessment, participants will be randomly allocated to four groups: Otago exercises, trunk exercises, combined exercises, and control. The control group will receive no exercise intervention, and the outcome assessor will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Female sex , Age between 40 and 60 years ,Confirmed diagnosis of Parkinson’s disease by a neurologist , Regular use of prescribed medications for Parkinson’s disease , Hoehn and Yahr stages 1–3 , No other neurological disorders Exclusion Criteria: History of surgery or bone/joint fractures causing functional limitations, Participation in other physical rehabilitation programs during the study, Failure to attend five non-consecutive or three consecutive exercise sessions , Unstable cardiovascular diseases , Medical contraindications to exercise, History of deep brain stimulation (DBS) surgery for symptom management

Intervention groups
Group 1: Otago Exercise Program Group 2: Trunk Exercises Group 3: Combined Otago and Trunk Exercises Group 4: Control Group

Main outcome variables
Motor assessment; Freezing of gait; Balance; Joint position sense; Lower limb muscle quality index

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20261011071394N1**
Registration date: **2026-11-05, 1405/08/14**
Registration timing: **prospective**

Last update: **2026-11-05, 1405/08/14**
Update count: **0**

Registration date
2026-11-05, 1405/08/14

Registrant information

Name
Mansore Golbou
Name of organization / entity
The University of Sistan and Baluchestan
Country
Iran (Islamic Republic of)
Phone
+98 71 5383 7266
Email address
mansore.golbou@pgs.usb.ac.ir

Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-12-11, 1405/09/20
Expected recruitment end date
2027-01-10, 1405/10/20
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Otago exercises to trunk exercises on motor assessment, freezing of gait, balance, position sense, lower extremity muscle quality index in middle-aged women with Parkinson's disease

Public title

Adding Otago exercises to trunk exercises in women with Parkinson’s disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female sex Age range of 40 to 60 years. Definite diagnosis of Parkinson’s disease made by a neurologist Regular and stable use of prescribed Parkinson’s disease medications Being in Hoehn and Yahr stages 1 to 3 of Parkinson’s disease Absence of other neurological or musculoskeletal diseases

Exclusion criteria:

History of surgery or fractures involving bones or joints that limit physical function Participation in physical rehabilitation programs during the study Failure to attend training sessions (five non-consecutive sessions or three consecutive sessions) Voluntary withdrawal from the study Unstable cardiovascular diseases Medical contraindications to exercise History of deep brain stimulation (DBS) surgery for symptom management

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 60 eligible patients will be recruited using convenience and purposive sampling. To control for the potential effect of disease severity and ensure a balanced distribution across the study groups, participants will be stratified into three categories according to disease stage, based on the Hoehn and Yahr scale (stages 1, 2, and 3), after enrollment and before group allocation. Subsequently, participants will be allocated to four study groups using stratified permuted block randomization, with an allocation ratio of 1:1:1:1. Separate random allocation sequences will be generated for each of the three strata using blocks of four, such that within each block, one participant will be assigned to each of the four study groups. The random allocation sequences will be generated using the Randomization.com website by an independent researcher who will not be involved in participant recruitment or assessment. This method will be used to promote balance in the number of participants across the study groups and to control for the distribution of disease severity.

Blinding (investigator's opinion)

Single blinded

Blinding description

All outcome assessments will be performed by a single assessor who will remain blinded to the group allocation of each participant throughout the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Sistan and Balochestan

Street address

University Street, University of Sistan and Baluchestan,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745845

Approval date

2026-06-16, 1405/03/26

Ethics committee reference number

IR.USB.REC.1405.015

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Motor Assessment

Timepoint

At the beginning of the study (before the intervention began) and 12 weeks after the exercises

Method of measurement

Unified Parkinson's Disease Rating Scale, Part III (Motor Examination)

2

Description

Freezing of Gait

Timepoint

At the beginning of the study (before the intervention began) and 12 weeks after the exercises

Method of measurement

New Freezing of Gait Questionnaire

3

Description

Balance

Timepoint

At the beginning of the study (before the intervention began) and 12 weeks after the exercises

Method of measurement

Mini-Balance Evaluation Systems Test

Secondary outcomes

1

Description

Position Sense

Timepoint

At the beginning of the study (before the intervention began) and 12 weeks after the exercises

Method of measurement

Knee Joint Position Sense Assessment Using the Measure App on an iPhone

2

Description

Lower Extremity Muscle Quality Index

Timepoint

At the beginning of the study (before the intervention began) and 12 weeks after the exercises

Method of measurement

The Lower Extremity Muscle Quality Index , will be calculated using the specific MQI formula based on performance in the Ten-Times Sit-to-Stand Test.

Intervention groups

1

Description

Intervention group: Otago Exercises , Participants in this group will perform the Otago exercise program three times per week during the intervention period.

Category

Rehabilitation

2

Description

Intervention group: Trunk Exercises , Participants in this group will perform trunk exercises three times per week during the intervention period.

Category

Rehabilitation

3

Description

Intervention group: Combined Otago and Trunk Exercises ,Participants in this group will perform a combined exercise program consisting of Otago exercises and trunk exercises three times per week during the intervention period.

Category

Rehabilitation

4

Description

Control group: Participants in the control group will not receive any exercise intervention during the study period and will continue their usual daily activities and prescribed medical treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Razieh Rezaei Neurology Clinic

Full name of responsible person

Mansore Golbou

Street address

Unit 8, 2nd Floor, Sib Medical Building, Ababian Alley, Zand Street

City

Shiraz

Province

Fars

Postal code

7134835167

Phone

+98 921 790 9813

Email

mansore.golbou@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Sistan and Baluchestan

Full name of responsible person

Mansore Golbou

Street address

Daneshgah Street, University of Sistan and Baluchestan98

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816745845

Phone
+98 936 073 8829

Email
mansore.golbou@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
University of Sistan and Baluchestan

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
University of Sistan and Baluchestan

Full name of responsible person
Mansore Golbou

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
Pathology and Corrective Exercises

Street address
Alley No. 3, Sardaran Street

City
Neyriz

Province
Fars

Postal code
7491647963

Phone
007153837266

Email
mansore.golbou@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Sistan and Baluchestan

Full name of responsible person
Mansore Golbou

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
Pathology and Corrective Exercises

Street address
Alley No. 3, Sardaran Street

City
Neyriz

Province
Fars

Postal code
7491647963

Phone
+98 71 5383 7266

Email
mansore.golbou@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of Sistan and Baluchestan

Full name of responsible person
Mansore Golbou

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
Pathology and Corrective Exercises

Street address
Alley No. 3, Sardaran Street

City
Neyriz

Province
Fars

Postal code
7491647963

Phone
+98 71 5383 7266

Email
mansore.golbou@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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

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

Data Dictionary

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