Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of intensive rehabilitation treatment protocol-based occupational therapy on freezing of gait, psychological symptoms, and quality of life in Parkinson's elderly

Protocol summary

Study aim

the effectiveness of therapy based on occupational therapy based on occupational therapy in improving the gait of the elderly with parkinson 's disease .

Design

a blind , randomized controlled clinical trial .The control group . Parallel group . Over 64 people

Settings and conduct

The intensive rehabilitation protocol based on occupational therapy in the clinic will be performed one hour a day and 5 days a week for a month. The correction is a blind and only the initial outcome assessor is unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

acquiring a higher score from 4 in the freezing questionnaire of راه and 5 , having a minimum literacy rate for the company in research (part of کاردرمانی cognitive exercises and follow - up) and obtain -21 and higher scores on the مختصر (MMSE)؛ severe mental disorders , heart disease and blood pressure , vision problems and the history of deep stimulation stimulation. (from the medical case of elderly people with Parkinson 's , and asking for their professional doctor)

Intervention groups

The intervention group receives occupational therapy exercises for 4 weeks and 5 days per week for one hour, and its effect on gait problems in Parkinson's patients will be investigated.The control group continues their previous treatment.

Main outcome variables

Evaluation of improvement in gait freezing, psychological symptoms and quality of life with occupational therapy exercises

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170725035278N3**
Registration date: **2021-03-07, 1399/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-07, 1399/12/17**
Update count: **0**

Registration date

2021-03-07, 1399/12/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-18, 1400/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intensive rehabilitation treatment protocol-based occupational therapy on freezing of gait, psychological symptoms, and quality of life in Parkinson's elderly

Public title

The effect of intensive rehabilitation treatment protocol-based occupational therapy on freezing of gait, psychological symptoms, and quality of life in Parkinson's elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Achieving a score higher than 4 in the Freezing Walking Questionnaire,, being in stage 2 to 5 of the severity of Parkinson's disease and Yar having the minimum literacy to participate in research (part of cognitive occupational therapy exercises and following instructions) obtaining a score 21 and above In the Mini-Mental State Examination. age over 60 years

Exclusion criteria:

severe mental disorders. (from the medical case of elderly people with Parkinson 's , and asking for their professional doctor) heart disease and blood pressure vision problems the history of deep stimulation stimulation

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

the method of allocation of subjects after applying the entry and exit criteria is randomly allocated to the block method . the unit of randomization is individual . the size of blocks may be high and each block is repeated twice . then , using the software soft ware " s software , the sequencing is generated . using this list , which is randomly generated , participants are assigned to one of the two groups . in order to hide a random assignment list , a specific code will be assigned to each intervention group , which is only the main host of the project (supervisor) . these codes are written on a paper and sealed inside a sealed envelope . on this paper , as well as the envelope , a unique code for each patient will be written . also , inside each packet is a foil to make the envelope not readable under the light . each packet contains a white paper and a sheet of paper . all packets are arranged in order of random sequence within a box - box and sealed in the seal box . the main researcher , after examining the criteria of entering the study and obtaining informed consent and also registration of the patient " s specifications in special form , is called " " random assignment list " " (this person is an expert who is involved in the process of entry and entry of the sample) . also , before opening the envelope , the person must write the name and name of the family and the person 's age on the envelope in such a way that the manuscript falls on the paper in the envelope .

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the type of intervention, only the primary outcome evaluator is unaware of the type of intervention and also the data is provided to the statistical expert for statistical analysis in a blind and randomized code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganj Afrooz St., Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2020-11-14, 1399/08/24

Ethics committee reference number

IR.MUBABOL.REC.1399.367

Health conditions studied

1

Description of health condition studied

Parkinson's patients

ICD-10 code

G20

ICD-10 code description

Parkinson disease

Primary outcomes

1

Description

Freezing Of Gait

Timepoint
Before and after the intervention
Method of measurement
Freezing Of Gait Questionnaire (FOG)

Secondary outcomes

1

Description
Psychological symptoms
Timepoint
Before and after the intervention
Method of measurement
Brief Symptome Inventory (BSI-18)

Intervention groups

1

Description
Intervention group: Occupational therapy exercises are performed in a clinic using simple sports equipment such as steps, large balls, as well as stationary bicycles or treadmills. The duration of the exercises is 4 weeks and 6 days a week for one hour. They do 5 days in the clinic and one day they have to do exercises at home.
Category
Rehabilitation

2

Description
Control group: There is no specific treatment for these people.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid specialized and sub-specialized clinic
Full name of responsible person
Dr. Payam Saadat
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Ganj Afrooz Street. West side of Ayatollah Rouhani Hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable