Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the added value of cognitive task training on a multi directional treadmill training program on gait parameters in patients with Parkinson’s disease: An Assessor Blind Randomized Controlled Clinical Trial

Protocol summary

Study aim

Investigating the added value of cognitive task training on a multi directional treadmill training program on gait parameters in Parkinson’s disease.

Design

clinical trial with control group, with parallel groups, an assessor blind, randomized by block randomization, phase 2 on 32 patients is designed. Follow-up will be done two months after the end of the study.

Settings and conduct

The added effect of performing cognitive exercises on multi directional treadmill on gait characteristics in patients with Parkinson's disease is investigated in the Faculty of Rehabilitation Sciences. Blindness is such that the assessor and analyst will not know about each person's therapeutic intervention.

Participants/Inclusion and exclusion criteria

Patients with idiopathic Parkinson's in the moderate stage will be entered, then inclusion criteria (moderate disease level, walk independently at least 6 minutes, MOCA≤24) and exclusion criteria (other neurological problems such as stroke,severe neuropathy, orthopedic problems, severe respiratory, heart diseases, etc.) is appropriate and if they wish to participate, by completing the informed consent form in the study Will participate.

Intervention groups

During 6 weeks, a group of patients will receive the intervention: walking on a treadmill with a dual cognitive task (in the form of subtracting 3 from the announced number and naming words with a choice letter such as "M"). The other group will walk on the treadmill alone for 6 weeks. The intervention will be 3 times a week and each session will last approximately 30 minutes.

Main outcome variables

stride length, walking speed, percentage difference between stride length and walking speed, cognitive and motor function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048753N1**
Registration date: **2020-11-20, 1399/08/30**
Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**
Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

fatemeh fallahzadeh abarghooie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the added value of cognitive task training on a multi directional treadmill training program on gait parameters in patients with Parkinson’s disease: An Assessor Blind Randomized Controlled Clinical Trial

Public title
effectiveness of added cognitive task training to multi directional treadmill training in patients with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with idiopathic Parkinson's disease according to United Kingdom(UK)Bank patients in Hoehn and Yahr scale (H&Y I-III) stages of Parkinson's disease patients should be MED on state patients should be able to independent walking at least for 6 min based on Unified Parkinson's Disease Rating Scale (UPDRS) Montreal Cognitive Assessment (MOCA)≤24 for cognitive system
Exclusion criteria:
other neurological disorders such as CVA, Alzheimer, severe neuropathic impairments A history of any serious orthopedic problems such as surgery or fractures that prevent you from walking on the treadmill Existence of any severe respiratory and pulmonary diseases that prevent the intervention protocol Having a history of heart failure or coronary heart disease and stroke that prevents the intervention protocol Existence of hearing and vision impairment that prevents the correct performance of tests History of head and neck surgery History of Deep Brain Stimulation History of malignant diseases that prevent the intervention protocol Musculoskeletal pain that prevents the intervention protocol Participate in exercise programs such as treadmills for at least the past two months
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of patients in two groups of treadmill and treadmill + cognitive exercise was done by Block Balanced Randomization (BBR) method. The Randomization Sequence is generated with using the free web site at http://www.randomization.com. Non-transparent and sealed envelopes will be used to conceal the assignment of individuals to groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The assessor will not be aware of which intervention will be administered to which subject. The data analyzer also does not know the groups (treadmill or treadmill+cognitive exercise).
Placebo
Not used
Assignment
Parallel
Other design features
All participants are entered to study by neurologists. According to related past studies the sample size estimated 28 subjects (14 subjects per groups) and with considering the 20% attrition with ratio of 1:1 (treadmill group:treadmill+cognitive exercise group) for each of group at least 16 subjects were considered. Assignment of people to groups will be based on the Block Balanced Randomization (BBR) method. After two months from the end of the study, follow up will be performed in both study groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of research in Shiraz University of Medical Science
Street address
Central building of Shiraz University of Medical Science, Zand Ave
City
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Province
Fars
Postal code
7134814336
Approval date
2020-08-19, 1399/05/29
Ethics committee reference number
IR.SUMS.REHAB.REC.1399.030

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
walking speed
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention
Method of measurement
6 min walking test

2

Description
stride length
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention
Method of measurement
meters

3

Description
motor system function
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention
Method of measurement
Unified Parkinson's Disease rating Scale(UPDRS III)

4

Description
cognitive function
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention•
Method of measurement
MOCA test

5

Description
the percentage difference between stride length and walking speed
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention•
Method of measurement
Dual task cost methods(DTcost)

Secondary outcomes

1

Description
quality of life
Timepoint
before intervention, immediately after 6 weeks of intervention, after 2 moths from the end of intervention•
Method of measurement
PDQ39 questionnaire

Intervention groups

1

Description
control group : The people in the control group will be treated with treadmill exercise for 6 weeks. they will walk on treadmill in all four directions. Exercises in the control group will be offered 3 times a week, each training session lasts about 30 minutes(5min warm-up,[7min forward,7min backward,3min right sideway,3min left sideway],5min cooldown).All training sessions will be performed under the supervision of a physiotherapist.
Category
Treatment - Other

2

Description
Intervention group : The people in the intervention group will be treated with treadmill exercise+cognitive exercises for 6 weeks. They will walk on treadmill in all four directions. Exercises in the intervention group will be offered 3 times a week, each training session lasts about 30 minutes(5min warm-up,20min exercising[7min forward,7min backward,3min right sideway,3min left sideway],5min cooldown). Cognitive exercising will be counting backwards from 100 by subtracting 3’s, Naming words starting with a special letter such as M. All training sessions will be performed under the supervision of a physiotherapist.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
shiraz university of medical sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Shiraz 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
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Fatemeh Fallahzadeh
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Person responsible for updating data

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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

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