Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of three cueing devices (visual, auditory, and vibration) for people with Parkinson’s disease with freezing of gait difficulties

Protocol summary

Study aim
Investigating the effectiveness of visual, auditory and vibrational feedbacks in improving movement disorders in patients with Parkinson's disease
Design
Clinical trial without control group, blinding and randomization did not take place. On 25 patients.
Settings and conduct
in the neurology clinic of Ghaem Hospital and the personal neurology office
Participants/Inclusion and exclusion criteria
patients with an age range of 40 to 80 years has idiopathic Parkinson's diagnosed by a neurologist and has Freezing of gait movement dry movement disorder Grade 2 (occasional dry movement when walking) or grade 3 (frequently walking dry movement and occasionally falling after it) and has acceptable hearing and vision ; Patients with acute movement disorders or other neurological and physical disorders, vision, hearing and heart problems
Intervention groups
Parkinsonian patients Interventions include the use of visual, auditory, and vibrational feedbacks
Main outcome variables
1- Walking speed (meters per second) 2-The average step length in a certain interval (cm) 3-the number of steps per minute

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240104060608N1**
Registration date: **2024-05-04, 1403/02/15**
Registration timing: **prospective**

Last update: **2024-05-04, 1403/02/15**
Update count: **0**
Registration date
2024-05-04, 1403/02/15

Registrant information
Name
Amir Ata Mashreghi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 51 3768 3564
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-06-21, 1403/04/01
Expected recruitment end date
2024-09-22, 1403/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of three cueing devices (visual, auditory, and vibration) for people with Parkinson’s disease with freezing of gait difficulties

Public title
Effect of three cueing devices (visual, auditory, and vibration) for people with Parkinson’s disease with freezing of gait difficulties
Purpose
Supportive
Inclusion/Exclusion criteria

Inclusion criteria:
patients with an age range of 40 to 80 years with idiopathic Parkinson's diagnosed by a neurologist Has dry movement disorder-Freezing of gait-movements Grade 2 (occasional dry movement when walking) or grade 3 (frequently walking dry movement and occasionally falling after it) Acceptable vision and hearing
Exclusion criteria:
Patients with acute movement disorders or other neurological and physical disorders, vision, hearing and heart problems

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
No. 63, 3rd Yas Ave.,Sajjad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9186645745

Approval date
2023-11-18, 1402/08/27

Ethics committee reference number
IR.MUMS.REC.1402.235

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 (velocity)

Timepoint
day 1 and 8

Method of measurement
meters per seconds

2

Description
stride length

Timepoint
day1 and 8

Method of measurement
steps per distance

3

Description
cadence

Timepoint
day1 and day8

Method of measurement
steps per min

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, each patient will be examined by a neurologist before starting the test and the degree of their movement disorder will be determined, then the degree of improvement of the patient's movement disorder will be examined separately or together after using visual, auditory and vibrational feedbacks .In order to evaluate these feedbacks, we have created a device in this field that provides all three required outputs.In this device, a rhythmic auditory pulse based on the number of pulses per minute is used for the auditory indicator.In the visual part, two linear lasers (step-by-step lighting) are used, which are connected to the patient's knee .It should be mentioned that the length of the step can be adjusted based on the patient's ability. Such activation of each laser is done by two sensors that are connected to the heel of the patients.In the following, the functional

improvement of patients is measured with the help of sensory and vibrational feedback .Sensory-vibration feedbacks can be evaluated in a dependent or separate manner in such a way that a rhythmic vibrational pulse that can be dependent on the auditory marker is created or based on the patient's steps used by the sensors in the heels, to be activated.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurological clinic of Ghaem hospital
Full name of responsible person
Khashayar Atiaee
Street address
Mahhad, Ahmadabad Blvd, Ghaem hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3840 0001
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ali Shoeibi
Street address
in the end of Shahid fakouri Blvd, in front of Fakouri 94, knowledge and health city, Mashhad, Iran
City
Mashhad
Province
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Postal code
91778-99191
Phone
+98 51 3843 6727
Email
p.relations@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Islamic Azad University
Full name of responsible person
Amir Ata Mashreghi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Psychiatrics
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

data on the results of trial and about the answers to questionnaires and also demographic data would be publishable

When the data will become available and for how long

after finishing the trial

To whom data/document is available

publisher of this trial

Under which criteria data/document could be used

all the researchers that are interested in the results of this trial could request and get access to the data

From where data/document is obtainable

from emailing to corresponding author

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

after emailing to the corresponding author, data without mentioning the personal information of the patients, would be sent to the researcher

Comments