Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of circadian rhythms modulation on anticipatory postural adjustments for gait initiation in people with Parkinson’s disease

Protocol summary

Study aim

Determine the impact of circadian rhythms modulation by timed exposure to bright light (TEBL) on improving anticipatory postural adjustment (APA) during self-initiated gait in medicated PD patients. Determine the impact of circadian rhythms modulation by timed exposure to bright light (TEBL) on anticipatory postural adjustment (APA) responses to auditory and visual cues during gait initiation in medicated PD patients.

Design

To carry out this project, the participant will be randomly and double blinded placed in one of the study groups (A or B).

Settings and conduct

the volunteer is invited to participate in the test session at Javad Mofafgian Smart Neurorehabilitation Technologies Research Center. Blinding in this study is done in such a way that the patient receives glasses (intervention or comparison group) in coded packages. Coding is done by one of the colleagues of the project and the doctor, evaluator and patient are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria for patients with Parkinson's disease in this study, idiopathic Parkinson's disease diagnosed by a neurologist, stage 2 or 3 disease according to the Hoehn and Yahr scale, and walking ability. Walking independently without the need for mobility aids (such as canes and walkers) for 30 minutes.

Intervention groups

People in both control and intervention experimental groups will wear glasses for two weeks. Participants receiving the placebo glasses will be asked to wear the red light glasses every night (two hours before bedtime) for one hour.

Main outcome variables

Parkinson's disease; Circadian rhythms; Anticipatory postural adjustment; Gait initiation

General information

Reason for update

Acronym

CPD

IRCT registration information

IRCT registration number: **IRCT20221014056170N1**
Registration date: **2023-01-09, 1401/10/19**
Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**
Update count: **0**

Registration date

2023-01-09, 1401/10/19

Registrant information

Name

Laila Alibiglou

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

laila.alibiglou@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of circadian rhythms modulation on anticipatory postural adjustments for gait initiation in people with Parkinson’s disease

Public title
The effect of circadian rhythms modulation for gait initiation in people with Parkinson’s disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 40 and 75 years. Idiopathic Parkinson's disease diagnosed by a neurologist. Being in stages 2 and 3 of the disease based on the Hoehn and Yahr scale. The ability to walk independently without the need for mobility aids (such as canes and walkers) for 30 minutes.

Exclusion criteria:
Presence of accompanying neurological disorders or history of other neurological disorders or major psychiatric illness. The presence of cognitive disorders affecting the study. Drug and alcohol addiction. The presence of vision and hearing problems, which affect the patient's ability to perform the test correctly. The presence of sensory problems in the legs or musculoskeletal disorders in the lower limbs. Suffering from chronic back pain and the presence of a prosthesis in the lower limb that limits the range of movements. Having severe tremors, a score greater than 2 on any of the items 3.15a to 3.17e on the clinical test (MDS-UPDRS). History of episodes of freezing of gait or dyskinesia History of implant surgery (Deep brain stimulation or DBS)

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description
The use of lottery in this study is chosen for random sampling. The researcher will give each member of the community a special code. Therefore, there will be a numbered paper at the disposal of the researcher as many people as there are in the community. Then he pours them into a bag or container and stirs them. Then he takes out the beads one by one, notes their number and they are placed in the intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients (intervention or comparison group) in code packages are received. Coding by one of the project collaborators It takes place and the doctor, evaluator and patient are blinded.

Placebo
Used

Assignment
Crossover

Other design features
In the cross-over design, each candidate receives all the interventions of the study in consecutive periods, and each participant is his OR her own witness (control). Which participant will receive one of the interventions in the first or second phase is randomly determined based on the random placement of the participant in group A or group B. Thus, each patient should participate in the tests for four sessions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Iran University of Medical Sciences, Hemat highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2022-12-14, 1401/09/23

Ethics committee reference number
IR.IUMS.REC.1401.715

Health conditions studied

1

Description of health condition studied
Parkinson disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Circadian rhythms function

Timepoint

Measurements will be taken before using the glasses and 14 days after using the glasses.

Method of measurement

Examining the daily sleep pattern

2

Description

Anticipatory postural adjustment

Timepoint

Measurements will be taken before using the glasses and 14 days after using the glasses.

Method of measurement

Gait analysis and Electromyography indicators

3

Description

Gait initiation

Timepoint

Measurements will be taken before using the glasses and 14 days after using the glasses.

Method of measurement

Gait analysis and Electromyography indicators

4

Description

Severity of Parkinson's disease

Timepoint

Measurements will be taken before using the glasses and 14 days after using the glasses.

Method of measurement

Unified Parkinson’s Disease Rating Scale or UPDRS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will wear glasses for two weeks. At the time of receiving the intervention (TEBL), the participants will be asked to wear glasses that shine active bright light through a light source consisting of 2 blue-green light emitting diodes (Re-Timer, 500 nm peak wavelength) to each eye. with irradiance of each diode set at the high setting: 506 Lux lm/m² and 230 µW/cm²) every night, two hours before going to sleep for one hour. At the time of receiving the placebo treatment (control), the subjects will wear glasses with the same appearance, except that a modified light source with 2 dim red light-emitting diodes (Re-timer with 2 dim red light-emitting diodes, 625 nm peak wavelength with irradiance of each diode set at the low setting: 135 Lux lm/m², 143 µW/cm²) will shine the light to the eyes.

Category

Rehabilitation

2

Description

Control group: Participants receiving the placebo glasses will be asked to wear the red light glasses every night (two hours before bedtime) for one hour.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز دکتر موفقیان

Full name of responsible person

Javad Movafaghiyan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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
Iran University of Medical Sciences
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Laila Alibiglou
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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
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
Not applicable