

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of physical and psychological intervention on quality of sleep and quality of life in people with Parkinson

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of physical and psychological intervention on quality of sleep and quality of life in people with Parkinson aged 45 to 70 years old. Design: Participants are selected from people with parkinson in hospitals and occupational Therapy clinics in Tehran. 40 participants are randomly assigned into control or intervention group by coded envelop. Setting and conduct: Evaluations are done two times before and after the intervention by a trained Occupational Therapist who is blind to type of group. Participants: Subjects must be in level 1 to 4 from Hoehn and Yahr Scale. Intervention: After the baseline assessments, treatment sessions are given for 6 weeks. Each session of Treatment includes: physical and psychological interventions. Main outcome measures: Parkinson's disease sleep scale (PDSS), Parkinson's Disease Questionnaire (PDQ), Depression and Anxiety and Stress (DASS) and Goniometry for shoulder, hip, knee, and ankle joints.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710083551N7**
Registration date: **2017-10-09, 1396/07/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-09, 1396/07/17

Registrant information

Name

Parvin Raji

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 8798

Email address

praji@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for education, Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of physical and psychological intervention on quality of sleep and quality of life in people with Parkinson

Public title

The effect of physical and psychological intervention on quality of sleep and quality of life in people with Parkinson

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: The age range is 45-70 years; Having Level 1-4 by Hoehn and Yahr Scale; Having a sleep disorder using the PDSS score test (score less than 71); not having severe depression (score less than 29) based on Beck depression inventory; Having a cognitive level

above 24 in MMSE exam; Do not take sleep medications; absence of other diseases (cardiovascular disorders, other orthopedic and neurological disorders, etc.).
Exclusion criteria: Lack of patient collaboration; Failure to go on time for tests.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina St, Ghods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3390

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson disease

Primary outcomes

1

Description

Sleep disorders and quality of life

Timepoint

before and after intervention

Method of measurement

Parkinson's disease sleep scale (PDSS), Parkinson's Disease Questionnaire (PDQ)

Secondary outcomes

1

Description

Depression and range of motion

Timepoint

before and after intervention

Method of measurement

Depression and Anxiety and Stress (DASS) and Goniometer

Intervention groups

1

Description

Control group: Balance Exercises

Category

Rehabilitation

2

Description

Intervention Group: Balance exercises+ Jacobson Progressive Muscle Relaxation , stimulus control therapy, muscle stretch, sleep health education, aerobic exercise, teaching daily living activities

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals and occupational Therapy clinics in Tehran

Full name of responsible person

Razieh Zeinali

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for education, Tehran University of
Medical Sciences

Full name of responsible person

Dr Mohammad Jalili

Street address

Vice chancellor for education, 7th floor, Tehran
University of Medical Sciences, Ghods St., Keshavarz
Blvd, Tehran

City

Tehran

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

Yes

Title of funding source

Vice chancellor for education, Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical
Sciences, Picheshemiran, Enghelab Ave, Tehran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email**

praji@tums.ac.ir

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical
Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email**

praji@tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical
Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty