

# 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  
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Tehran

**Postal code****Phone**

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**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*