

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Valerian on The Quality of Sleep and Anxiety in Patients with MS

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effect of hypochlorite on sleep quality and anxiety in patients with MS. One-blind study was conducted in two intervention and control groups (with placebo). The study population was MS patients referred to Rafideh Rehabilitation Hospital. The number of participants in the study was 46 (two groups of 23). The intervention group received tea bags from Svalbat al-Tayb and the control group receiving wheat flour, which was coated with red currants. The intervention was announced in the winter of 1395.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070531348N2**

Registration date: **2017-09-15, 1396/06/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-15, 1396/06/24

##### Registrant information

###### Name

مهدیه صدیقی پاشاکی

###### Name of organization / entity

دانشگاه علوم بهزیستی و توانبخشی

###### Country

Iran (Islamic Republic of)

###### Phone

+98 919 411 6472

###### Email address

ma.sedighi@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

University of Rehabilitation Sciences and Social Welfare

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Valerian on The Quality of Sleep and Anxiety in Patients with MS

##### Public title

Effect of Valerian on The Quality of Sleep and Anxiety in Patients with MS

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Entry Criteria: Confirmation of MS by the center's neurologist; The absence of other neurological disorders and mental and mental disorders, according to the patient's case and opinion; At least six months of diagnosis; Having reading and writing skills or having a companion to complete; the person questionnaire in the age range of 20-45 years; Failure to have liver disease or deficiency in liver enzymes, lack of pregnancy and lactation; Failure to receive complementary and alternative therapies during the past three months. (To reduce anxiety and improve sleep quality.) Exit criteria: No patient incentive to continue cooperation. During the research; To perform this intervention in the past (because of the decrease in the amount of suppression, the probability of answering the questions based on the information stored in the previous study); Not having enough insight into the disease and not having the ability to collaborate in the study; Drug use New sedative and hypnotic; Alcohol users, Barbiturates and Benzodiazepine

(in iron users between consumption Valerie N and iron should be 1 to 2 hours apart); Hepatitis and pregnancy ;  
If not used for 2 days

### Age

From **75 years** old to **55 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **46**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Univercity of Social Walfare and Rehabilitation  
Science

##### Street address

Kodakyar avenue, Daneshjoo blvd, Evin street,  
Tehran, Iran

##### City

Tehran

##### Postal code

##### Approval date

2016-11-05, 1395/08/15

##### Ethics committee reference number

uswr.REC.1395.321

## Health conditions studied

### 1

#### Description of health condition studied

MS

#### ICD-10 code

G35-G37

#### ICD-10 code description

Demyelinating diseases of the central nervous system

## Primary outcomes

### 1

#### Description

Sleep Quality, Anxiety

#### Timepoint

Before Intervention- After Intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Improve The Quality of Sleep, Reduce Anxiety

#### Timepoint

Before The Intervention - After The End of Intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Patients in the intervention group used tea bags of valerian at a dose of 2 grams per night for 30 to 90 minutes before bedtime and for 21 nights and put one tea in a glass of boiling water after 15 minutes milling it (all patients had the same glasses).

#### Category

Treatment - Drugs

### 2

#### Description

control group: In the same package, the intervention group consisted of wheat flour, tafted with red sugar, at 2 grams per night for 30 to 90 minutes before bed time and for 21 nights and put one it in a glass of boiling water after 15 minutes milling it(all patients had the same glasses).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rofeide Rehabilitation Hospital

##### Full name of responsible person

Mahdieh Sedighi Pashaki

##### Street address

Rofeide Rehabilitation Hospital, Nemati Alley, East  
Brothers Aveniuue, Gheytaarieh, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University Of Social Welfare And Rehabilitation Sciences

**Full name of responsible person**

Dr. Farahnaz Mohammadi Shahbaghaghi

**Street address**

Kodakyar avenue, Daneshjoo blvd, Evin street, Tehran, Iran

**City**

Tehran

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

Yes

**Title of funding source**

University Of Social Welfare And Rehabilitation Sciences

**Proportion provided by this source****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*

### 2

#### Sponsor

**Name of organization / entity**

University of Social Welfare and Rehabilitation

**Full name of responsible person**

Dr. Farahnaz Mohammadi Shahbaghaghi

**Street address**

Kodakyar avenue, Daneshjoo blvd, Evin street, Tehran, Iran

**City**

Tehran

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

Yes

**Title of funding source**

University of Social Welfare and Rehabilitation

**Proportion provided by this source****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**

University of Social Welfare and Rehabilitation Science

**Full name of responsible person**

Mahdieh Sedighi Pashaki

**Position**

Master Student of Rehabilitation Nursing

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

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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ma.sedighi@uswr.ac.ir; mahdieh.sedighi@gmail.com

**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*