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
Befor 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 befor 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 Aveniue, Gheytarieh, 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
Univercity of Social Walfare and Rehabilitation Science
Full name of responsible person
Mahdieh Sedighi Pashaki
Position
Master Student of Rehabilitation Nursing
Other areas of specialty/work
Street address
N.44, Secend NIkoo Aleey, Shahid Alami Street, Qods City, Tehran, Iran
City
Tehran
Postal code
3751137865
Phone
+98 21 4684 0377
Fax
Email
mahdieh.sedighi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Social Welfare and Rehabilitation Science
Full name of responsible person
Dr. Farahnaz Mohammadi Shahbaghaghi
Position
Ph.D. Nursing
Other areas of specialty/work
Street address
Kodakyar avenue, Daneshjoo blvd, Evin street, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2218 0036
Fax
Email
F-mohammadi- 2000@yahoo.com
Web page address

Person responsible for updating data

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

N.44, Secend Nikoo Alley, Shahid Alami Street, Qods City, Tehran, Iran

City

Tehran

Postal code

Phone

00

Fax

Email

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