

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Assessment of Lippia Citriodora effect on Sleep Disorder versus Oil ineffective: A double blind study

#### Protocol summary

##### Summary

Main goal: Assessment of Lippia Citriodora Oil effect on Sleep Disorder versus ineffective Oil Design and Method: The statistical population of this study is all people over 60 years old with sleep disorder in elders of care centers of Tehran. This study is a randomized, double-blind clinical trial. Before randomization, the eligibility criteria will be checked by gathering the information about the disease and drugs of elders, recorded and examined according to their medical records and then questions asked from elders who have used drugs affecting on sleep disorders about having sleep-related problems. Then the study and details of intervention will be explained by the interviewer, and the patients will enter to the study after signing the informed consent. Patients will be assigned to the intervention and control groups based on Balanced Block Randomization. In the control group two drops ineffective oil and in the intervention group two drops Lemon verbena Oil will be administered in the nose morning and night. Basic information, including Pittsburgh Sleep Quality, and Demographic questionnaire will be asked in the beginning, 2 and 4 weeks after starting the medications. Patients will be asked for probable complications. Main outcomes: improving subjective quality of sleep and increasing sleep efficiency. Since the Lemon verbena medicine has scent and Placebo is scentless, for blinding intervention and control patients, the drugs are put near each other in order to take Lemon verbena smell and also a little amount of Lemon verbena oil will be sprayed on the medicine container.

#### General information

##### Acronym

insomnia

##### IRCT registration information

IRCT registration number: **IRCT2016061528485N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-23, 1395/10/03

##### Registrant information

###### Name

seyran mohamadi bolban abad

###### Name of organization / entity

University of Rehabilitation Sciences and Social Welfare

###### Country

Iran (Islamic Republic of)

###### Phone

+98 918 667 5708

###### Email address

se.mohamadi@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Aging Research Center, University of Social Welfare and Rehabilitation

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### 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

Assessment of Lippia Citriodora effect on Sleep Disorder versus Oil ineffective: A double blind study

**Public title**

Assessment of Lippia Citriodora effect on Sleep Disorders versus Oil ineffective: A double blind study

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria (inclusion): Tendency to participate in the study! Having over 60 years old! Having sleep disorders, in self-reported, or clinical level, and according to the Pittsburgh questionnaire: Ability of respond to the questionnaire: No history of any allergy, to lemon verbena, or mangroves plants! No continuous using from (twice or more in per week) from lemon Herbal Tea, or lemon extract over 1 month ago: No problems with the airway and nasal obstruction Exclusion criteria (exclusion): Having dependence or addiction to alcohol , drugs and medicines! Having disease, like that heart failure, respiratory disorders, and diseases of sleep, and wake-up cycle such as, respiratory apnea, and restless leg syndrome! Using from Effective drugs, on the sleep and wake up cycle (except previous prescribed drugs )

**Age**

From **60 years** old to **90 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **82**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

University of Rehabilitation Sciences and Social Welfare

**Street address**

koodakyar deadlock Boulevard student Evin field  
Tehran

**City**

Tehran

**Postal code**

1985713834

**Approval date**

2016-05-23, 1395/03/03

**Ethics committee reference number**

IR.USWR.REC.1395.50

**Health conditions studied****1****Description of health condition studied**

sleep disorder

**ICD-10 code**

G47.0

**ICD-10 code description**

Disorders of initiating and maintaining sleep [insomnias]

**Primary outcomes****1****Description**

Improve sleep quality

**Timepoint**

Intervention. Two weeks after starting treatment and after the treatment (4 weeks after the intervention)

**Method of measurement**

questionnaire

**Secondary outcomes****1****Description**

Improve sleep Subjective quality

**Timepoint**

Early intervention. 2 weeks after starting intervention and 4week after intervention

**Method of measurement**

questionnaire

**Intervention groups****1****Description**

In the control group using vegetable oils in lemon and control groups using inert oil (liquid paraffin)

**Category**

Placebo

**2****Description**

dropping two drops of inert oil in the nose morning and night

**Category**

Placebo

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Kahrizak Charity Foundation in tehran

**Full name of responsible person****Street address**

Kahrizak, the end of the boulevard Doctor Hakim zadeh. Qom old road after Bhsht zahra, Tehran,Iran

**City**

Tehran

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

University of Welfare and Rehabilitation Research Center

**Full name of responsible person**

Robab Sahaf

**Street address**

Kodakyar deadlock Boulevard student Evin field . Welfare and Rehabilitation Sciences University / Center for Aging Research. Tehran

**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 Welfare and Rehabilitation Research Center

**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**

University of Welfare and Rehabilitation Research Center

**Full name of responsible person**

Seyran mohamadi bolban abad

**Position**

MSc Student of Gerontology, University of Social Welfare and Rehabilitation Sciences

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

Tehran

**City**

Tehran

**Postal code****Phone**

+98 21 2218 0154

**Fax****Email**

mohammadi162@yahoo.com

se.mohamadi@uswr.ac.ir

**Web page address**

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

University of Welfare and Rehabilitation Research Center

**Full name of responsible person**

Robab Sahaf

**Position**

PHD Gerontology

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

Welfare and Rehabilitation Sciences University / Center for Aging Research. Koodakyar street. Boulevard student . Evin. Tehran

**City**

Tehran

**Postal code****Phone**

+98 21 2218 0154

**Fax****Email**

robabsahaf@gmail.com

**Web page address**

### Person responsible for updating data

#### Contact

**Name of organization / entity**

University of Rehabilitation Sciences and Social Welfare

**Full name of responsible person**

Şeyran mohamadi bolban abad

**Position**

MSc Student of Gerontology, University of Social Welfare and Rehabilitation Sciences

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

Department of Aging. koodakyar street. Boulevard student. Evin. Tehran.

**City**

Tehran

**Postal code****Phone**

00

**Fax****Email**

mohammadi162@yahoo.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*