

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of *Matricaria chamomilla* extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Protocol summary

Summary

Sleep is one of the basic human needs. Research suggests that sleep quality is diminished with increasing age and the elderly are susceptible to damage caused by poor quality of sleep. Pharmacotherapy for the treatment of sleep disorders, which in many cases may cause adverse effects in the elderly. Research has shown that chamomile extract may be effective on sleep quality. Therefore, in this quasi-experimental clinical trial to determine the effect of MC extract on sleep quality in elderly people admitted to nursing homes takes place, aged 80, after informed consent, are divided into two groups. Intervention group twice daily after lunch and after dinner, chamomile extract 400 mg capsules and the control group received no intervention will be. Sleep quality in elderly people by participating in both pre- and post-intervention questionnaires Pittsburgh Sleep Quality Standard will be measured and will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102015080N1**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Mehrdad Abdullahzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Khorasgan (Isfahan) Branch , Islamic Azad University

Expected recruitment start date

2014-05-14, 1393/02/24

Expected recruitment end date

2014-06-14, 1393/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Matricaria chamomilla* extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Public title

The effect of chamomile on sleep in elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: tend to participate in the study and give consent to do so; having more than 60 years of age; having mental health; the non- occurrence of whatever specific diseases of liver, kidney, asthma, cancer and mental disorders are diagnosed; stay in one of the nursing homes studied; ability to answer questions; lack of sensitivity to chamomile or any of its ingredients; lack of continuous consumption of tea or chamomile extract during the last six months; capability than chamomile

capsules orally; lack of sleep-related illnesses, such as obstructive sleep apnea or restless legs syndrome; the lack of dependence on any drug, analgesics, anti-depressants, sleeping, alcohol and the lack of heparin, warfarin, and aspirin (due to drug interactions with chamomile extract). Exclusion criteria: stopping chamomile by subject, for whatever reason before the end of the intervention period; drug against the patient dose; catching whatever disease during the study period , which led to a ban by the oral administration of MC; indicate any allergic reaction to the MC during the research; lack of willingness to cooperate in the investigation; withdrawal from the study for reasons such as death, illness, or transferred to other centers.

Age

From **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2014-05-14, 1393/02/24

Ethics committee reference number

23810403922004

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description

Quality of sleep

Timepoint

Pre-intervention and post-intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Chamomile extract of 400 mg twice daily

Category

Treatment - Drugs

2

Description

No action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nursing homes related to IsfahanWelfare

Full name of responsible person

Street address

City

Isfshsn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

Full name of responsible person

Dr. payam najafi

Street address

Khorasgan (Isfahan) Branch , Islamic Azad University ,
Isfahan , Iran

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Isfahan

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

Yes

Title of funding source

Khorasgan (Isfahan) Branch , Islamic Azad University ,
Isfahan , Iran

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**

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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