

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the Effectiveness of the Traditional Persian Medicine Product based on the Apium Graveolens on the Sleep Quality and Quality of Life of the Community-Dwelling Elderly

Protocol summary

Study aim

Determining the Effectiveness of Iranian Medicinal Product based on Celery Plant on the Quality of Sleep and Quality of Life of the Elderly Living in the Community

Design

Randomized Clinical Trial with Intervention and Control Groups, Double-Blind, on 70 Participants, to Allocate the Samples to Two Groups, the Random Block Method and Random Allocation 2 Software will be Used.

Settings and conduct

This study will be Conducted on Seniors 60 Years and Older Referring to Comprehensive Health Service Centers as Available Sampling and Receiving Drug and Placebo Capsules for 4 weeks and Checking the Quality of Sleep and Quality of Life of the People. The Drug and Placebo Capsules will be Prepared Similar to Each other and Coded before the Intervention by a Statistician Colleague, so that the Researcher and the Patient will Not Know the Type of Intervention.

Participants/Inclusion and exclusion criteria

Enter: Desire to Participate in the Study, at least 60 years old, Poor Quality of Sleep No Cognitive, Speech and Mental Disorders, No Dependence on Drugs and Alcohol, No Drugs Affecting Sleep, No Diseases Affecting Sleep, Not having Epilepsy and Low Blood Pressure
Failure to Enter: Not Taking Medicine for 5 Consecutive Nights or 10 Alternating Nights, Allergic Reaction to Medicine

Intervention groups

In the Present Study, in the Intervention Group, the Participants Took One or Two 500 mg Capsules Containing 250 mg of Dry Celery Extract and 250 ml of Corn Starch (based on the Results of the Pilot Phase) One Hour before Going to Bed at Night for 4 Weeks. The Control group will receive 500 mg Capsules Containing Corn Starch at the Same Dose One Hour before Bedtime for 4 Weeks.

Main outcome variables

Sleep Quality based on Pittsburgh Sleep Quality Standard Questionnaire Investigating the Quality of Life of the Elderly based on the Standard Questionnaire of the Quality of Life of the Elderly Lipad

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240217061029N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Hamta Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 9274

Email address

hamta.ghasemi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2025-04-04, 1404/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of the Traditional Persian Medicine Product based on the Apium Graveolens on the Sleep Quality and Quality of Life of the Community-Dwelling Elderly

Public title

Investigating the Effect of Celery Capsules on the Quality of Sleep and Quality of Life of the Elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Desire to Participate in the Study and Give Informed Consent Age 60 Years and Older Low Quality of Sleep based on the Pittsburgh Sleep Quality Standard Questionnaire (Score 5 and above) Not Having Cognitive Impairment and Speech Impairment (Getting a Score of 25 or Higher on the MMSE Test) Not Having Diagnosed Mental Disorders that Interfere with Sleep, such as Restless Leg Syndrome, Obstructive Sleep Apnea, and Severe Depression and Anxiety Disorders, and are Treated with Relevant Drugs Not Having Dependence on any Narcotic Drugs, Sleeping Pills and Alcohol and Not Consuming These Items in the Last Month Not Having any History of Allergy to Celery and Similar Compounds Not Taking Drugs that Affect the Sleep-Wake Cycle and Anticoagulants Not Suffering from Physical Diseases that Affect the Sleep-Wake Cycle, such as Cancer, Liver and Kidney Disorders, Severe Anemia that Requires Treatment, and Coronary Heart Disorders. Not having Epilepsy, History of low Blood Pressure The Ability to Consume the Product Orally

Exclusion criteria:

Not Taking Medicine for 5 Consecutive Nights or 10 Alternating Nights Showing any Allergic Reaction to the Drug Reluctance to Cooperate Leaving the Study due to Reasons such as Death and Illness Unfortunate Events such as the Death of Relatives

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The Random Block Method will be Used to Allocate the Samples to Two Groups. For this Purpose, Patients will Receive Numbers from 1 to 70 According to Their Arrival. The Randomization Unit will be Individually and by Number with Blocks of 4 Persons. The Selection of the Group Type for Each Person will be done Through the Random Allocation 2 Software. In Order to Create a Random Sequence, Codes A and B will be Generated from the Desired Software, where Code A Mean the Application of the Intervention Group and Code B Mean the Application of the Control Group for Each Person. Finally, the Codes will be Placed in the Sealed Envelope and the Number of Each Patient will be Written on the Envelope. As Each Patient Enters, the Doctor will Open the Envelope and Apply the Desired Treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicine and Placebo Capsules will be Prepared Similar to Each Other, Even in Color and Packaging Container, and Coded before the Intervention by a Statistician Colleague, so that the Researcher and the Participant will not Know the Type of Intervention. (It Should be Noted that at First, the Objectives of the Study are Explained to all Patients and Written Consent will be Obtained from the Patients)

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Mazandaran University of Medical Sciences

Street address

2nd Floor, Arshin Building 6, Haghigat Alley, Rudaki St., Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

4815699761

Approval date

2024-02-28, 1402/12/09

Ethics committee reference number

IR.MAZUMS.REC.1402.652

Health conditions studied

1

Description of health condition studied

Sleep Disorders in the Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The Sleep Quality Score of the Elderly based on the Pittsburgh Sleep Quality Standard Questionnaire

Timepoint

The Beginning of the Study (before the Start of the Intervention) and 4 Weeks after the Start of the Intervention

Method of measurement

Pittsburgh Sleep Quality Standard Questionnaire

Secondary outcomes

1

Description

The Score of the Quality of Life of the Elderly based on the Standard Questionnaire of the Quality of Life of the Elderly Lipad

Timepoint

The Beginning of the Study (before the Start of the Intervention) and 4 Weeks after the Start of the Intervention

Method of measurement

Standard Questionnaire of the Quality of Life of the Elderly Lipad

Intervention groups

1

Description

Intervention Group: due to the Lack of a Similar Study to Investigate the Effectiveness of Celery Plant on Sleep Quality, in Order to Determine the Drug Dose, First 10 Patients (Elderly 60 Years and Older with Poor Sleep Quality) were Selected as a Pilot, of which 5 They Received one 500 mg Celery Capsule (each Capsule Contains 250 mg Dry Celery Extract and 250 mg Corn Starch) and 5 other People, Two 500 mg Celery Capsules (each Capsule Contains 250 mg Dry Celery Extract and 250 mg Starch. Corn), they will Receive it Orally One Hour before Going to Sleep, then by Checking the Quality of Sleep at the End of the Fourth Week, the Dose of the Drug will be Determined.

Category

Treatment - Drugs

2

Description

Control Group: After Determining the Drug Dose in the

Intervention Group, the Control Group will also Receive the same Dose, 500 mg Capsules Containing Corn Starch, One Hour before Going to Bed at Night and will be Examined at the End of the Fourth Week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Service Centers Covered by Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Yousofpoor

Street address

Mazandaran University of Medical Sciences, the Beginning of Valiasr Highway, Joibar Junction, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamta Ghasemi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Yousofpoor

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamta Ghasemi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Scores of Questionnaires

When the data will become available and for how long

6 Months after the Results are Published

To whom data/document is available

Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

Researchers Working in Academic and Scientific Institutions

From where data/document is obtainable

hmtgh69@gmail.com hamta.ghasemi@mazums.ac.ir

What processes are involved for a request to access data/document

Email to the Researcher
Comments