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, Haghighat 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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Mazandaran
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Phone
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Email
M.Yousofpoor@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnezhad
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Mazandaran University of Medical Sciences, Deputy of research and technology, Moallem Square
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Phone
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Email
pajhooheshi@mazums.ac.ir
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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2nd floor, Arshin Building 6, Haghighat Alley, Roudaki St., Amir Mazandarani Blvd
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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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