

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of curcumin on mental health and sleep quality in elderly

Protocol summary

Study aim

The aim of this study is to determine the effects of curcuminoids supplementation on mental health and sleep quality in elderly.

Design

Clinical trial with control group, parallel groups, double-blind (both patients and researchers), randomized, 70 patients, phase 3

Settings and conduct

70 elderly referring to health centers affiliated with Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. In this study, investigators and study participants will not know the type of supplement prescribed for the patient until the end of the data analysis. Supplements and placebos are similar in shape and size. Time of intervention: 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the intervention and Ability to communicate verbally
Exclusion criteria: History of allergy to curcumin plant products and complaints of known psychological illness and Alzheimer.

Intervention groups

Intervention group: capsule contains 40 mg curcuminoids (Nano Sina Elixir Company, Iran), four curcuminoid capsules daily, for 4 weeks orally. Control group: curcuminoids placebos capsule (Nano Sina Elixir Company, Iran), four capsules daily, for 4 weeks orally.

Main outcome variables

Sleep Quality and mental health (Primary outcome) will be measured at the beginning of the study; at the end of the fourth week and one month after the last day of intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220330054370N1**

Registration date: **2022-04-07, 1401/01/18**

Registration timing: **prospective**

Last update: **2022-04-07, 1401/01/18**

Update count: **0**

Registration date

2022-04-07, 1401/01/18

Registrant information

Name

samira abbaszadeh-mashkani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5544 3022

Email address

abbaszadeh_sa@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-03, 1401/02/13

Expected recruitment end date

2022-07-04, 1401/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin on mental health and sleep quality in elderly

Public title

Effect of curcumin supplementation in elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the intervention Ability to communicate verbally Get a score of 22 or higher on the mental health questionnaire Score 3 and above on the sleep quality questionnaire Age of 60 to 70 years old

Exclusion criteria:

History of allergy to curcumin plant products Complaints of known psychological illness and Alzheimer's Taking curcumin and antioxidant supplements during the last 3 months before the intervention

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Dentistry- Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.KAUMS.REC.1400.060

Health conditions studied

1

Description of health condition studied

Mental health

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Quality of sleep

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of sleep

Timepoint

At the beginning of the study, 4 and 8 weeks after intervention

Method of measurement

The Pittsburgh Sleep Quality Index

2

Description

Mental health

Timepoint

At the beginning of the study, 4 and 8 weeks after intervention

Method of measurement

Goldberg Mental Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of patients (n=35) will be requested to take four curcuminoid capsules daily for 4 weeks (each capsules contain 40 mg curcumin). The curcuminoid capsules will be produced in the Nano Sina Elixir Company from curcuma.

Category

Treatment - Drugs

2

Description

Control group: In this group of patients (n=35) will be requested to take four placebo capsules daily for 4 weeks. The placebo capsules (Contain Starch) will be produced in the Nano Sina Elixir Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Health Center

Full name of responsible person

Mohammad Afshar

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

City

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Postal code

8814187159

Phone

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Email

afshar_m_1344@yahoo.com

Web page address

<http://www.kaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafshe

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

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Email

banafshe57@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Afshar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Afshar

Position

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Person responsible for updating data

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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

At the end of the intervention, unidentified data will be disseminated.

When the data will become available and for how long

The data access period will start after the intervention.

To whom data/document is available

The data of this study will be made available to academic researchers and industry professionals.

Under which criteria data/document could be used

Unidentifiable study data for use in industry and meta-analytical studies will be made available to academic researchers and industry professionals.

From where data/document is obtainable

To access the study data, send a message to afshar_m_1344@yahoo.com or refer to Kashan University of Medical Sciences.

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

After sending a written request to the main person in charge of this project (Dr Mohammad Afshar) and explaining the purpose of obtaining the study data, unidentified data will be provided to her.

Comments