

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The Effect of sour cherry Juice consumption on the elderlies Sleep Quality

Protocol summary

Study aim

Determine the effect of cherry juice on elderly sleep quality

Design

This randomized clinical trial was conducted on 102 elderlies residing in Mashhad's elderly homes the first with using Pittsburgh sleep quality questionnaire, their sleep status were checked and recorded then, in the sour cherry juice group, for 15 days at 9-10 PM, as much as 200 cc of natural sour cherry choice is given. In the placebo group, 200 cc of placebo is given to them in the same way. No action is taken for the control group. The quality of sleep will be determined and compared immediately after the intervention (on the 15th day) and two weeks after the intervention and on the 30th day before such as the pre- intervention way.

Settings and conduct

Mashhad's elderly homes (Toos and Ashianmehr), selected randomly and divided into three intervention groups (sour cherry juice), placebo and control

Participants/Inclusion and exclusion criteria

willingness to participate in the study; age over 60 years old; obtaining a score of at least 7 from the short-term cognitive questionnaire; having at least one of the seven disturbing items in sleep quality based on the Pittsburgh's questionnaire; written consent to participate in the research; having the ability to communicate with the researcher. refusal to continue to participate in the study and collaborate with the researcher; having acute illness or hospitalization during the study which prevents keep working; not using cherry juice or placebo for any reason more than 20% of the recommended or recommended dose.

Intervention groups

in the sour cherry juice group, for 15 days at 9-10 PM, as much as 200 cc of natural sour cherry choice is given. In the placebo group, 200 cc of placebo is given to them in the same way.

Main outcome variables

duration of sleep; number of waking up during the night;

useful sleep duration; sleep disturbances; sleep quality; daily function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036673N2**

Registration date: **2018-04-13, 1397/01/24**

Registration timing: **retrospective**

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

Registration date

2018-04-13, 1397/01/24

Registrant information

Name

Raouf Feizian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5252 6858

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feizianar941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-09, 1396/09/18

Expected recruitment end date

2018-01-15, 1396/10/25

Actual recruitment start date

2017-12-09, 1396/09/18

Actual recruitment end date

2018-01-15, 1396/10/25

Trial completion date

empty

Scientific title

The Effect of sour cherry Juice consumption on the elderlies Sleep Quality

Public title

The Effect of sour cherry Juice consumption on the elderlies Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

willingness to participate in the study age over 60 obtaining a score of at least 7 from the short-term cognitive questionnaire, having at least one of the seven disturbing items in sleep quality based on the Pittsburgh's questionnaire having written consent to participate in the research having the ability to communicate with the researcher

Exclusion criteria:

Refusal to continue to participate in the study and collaborate with the researcher having acute illness or hospitalization during the study which prevents keep working not using cherry juice or placebo for any reason more than 20% of the recommended or recommended dose,

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of individuals will be made available on the basis of the criteria for entering the research. The elderly at this stage are randomly assigned (using spss software) in one of the three intervention, placebo or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, two drops A and B (containing 200 cc of cherry juice or 200 cc of placebo) are prepared that only the pharmacist's consultant knows about its content

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Committee for Medical Research Ethics in Mashhad on20/08/1396

Street address

NO.17university streetMashhad univercity medical science building medical of science

City

Mashhad

Province

Razavi Khorasan

Postal code

91778 -99191

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.MUMS.REC.1396.275

Health conditions studied

1

Description of health condition studied

quality of sleep in elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep duration

Timepoint

Before intervention - after intervention (day 15) -different after intervention - the thirtieth day

Method of measurement

Using Pittsburgh Sleep Quality Questionnaire

2

Description

waking up during sleepuseful sleep duration

Timepoint

Before intervention - after intervention (day 15) -different after intervention - the thirtieth day

Method of measurement

Using Pittsburgh Sleep Quality Questionnaire

3

Description

daily function

Timepoint

Before intervention - after intervention (day 15) -different
after intervention - the thirtieth day

Method of measurement

Using Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 200 cc of natural sour milk from the specified species of cerasus PERONEUS, which has been standardized according to its phenolic compounds in the traditional medicine laboratory of Mashhad, for 15 days at 10-9 nights in the intervention group Will give

Category

Treatment - Other

2

Description

Intervention group 2: providing 200 cc of ordinary water with artificial sugar (its amount will be normal with lemon juice) and a small amount of cherry essential oil at the same time in the placebo group

Category

Placebo

3

Description

Control group: routin care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

center of rehabilitation and keeping toos elderly

Full name of responsible person

enginer sharifniya

Street address

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2

Recruitment center

Name of recruitment center

center of rehabilitation and Keeping Ashiyan mehr

Full name of responsible person

maryam zarif

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sayyed reza Mazloom

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Doctora cross road, Daneshgah St.

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Grant name

reaserch of univercity

Grant code / Reference number

960752

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Abdolraouf feizian
Position
Nurse
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available