

# 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

##### Email address

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

BOULEVARDTOOS-toos 35

###### City

mashhad

###### Province

Razavi Khorasan

###### Postal code

36910552

###### Phone

+98 51 3691 0364

###### Fax

###### Email

feizianAR@mums.ac.ir

###### Web page address

<http://www.iranpronet.com>

#### 2

##### Recruitment center

###### Name of recruitment center

center of rehabilitation and Keeping Ashiyan mehr

###### Full name of responsible person

maryam zarif

###### Street address

Mashhad - BOULEVARD Fakouri - Fakori 17 and 19

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

38943498\_051

###### Phone

+98 51 5252 6858

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###### Email

feizianAR941@mums.ac.ir

###### Web page address

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Full name of responsible person

Sayyed reza Mazloom

###### Street address

Doctora cross road, Daneshgah St.

###### City

Mashhad

###### Province

Razavi Khorasan

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91778-99191

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+98 51 3859 1511

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+98 51 3871 3638

###### Email

p-relation@mums.ac.ir

###### Web page address

##### 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  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No.30, Eesteghlal St.  
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torbate jam  
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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Raouf feizian  
**Position**  
Senior of nursing elderly  
**Latest degree**  
Bachelor  
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Nursery  
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Nursing & Mid Wiferry Faculty, Daneshgah St.,  
**City**  
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**Province**  
Razavi Khorasan

**Postal code**  
9573114415  
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**Email**  
feizianAR941@mums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Abdolraouf feizian  
**Position**  
Nurse  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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**Email**  
feizianAR941@mums.ac.ir  
**Web page address**

## 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