Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the efficacy of Saffron on happiness and quality of life in healthy adults

Protocol summary

Study aim
Assessment of the efficacy of Saffron on happiness and quality of life in healthy adults
Design
Randomized triple blinded placebo-controlled clinical trial
Settings and conduct
Participants in the study are selected from the male and female dormitory students of Shahed University who volunteered to participate in the project, after mental evaluation by GHQ questionnaire and having inclusion criteria. Taking medication and placebo for 2 weeks and twice a day after a meal. Also, the checklist for using the medication reminder and the registration form of drug side effects will be filled in by the mentioned people. In order to control the complete use of the drug combination, follow-up is done by phone every week. At the end of the treatment period, individuals are re-examined and questionnaires are filled out.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Indivisual's mental health (indivisuals with scores lower than 7 in the depression section of GHQ mental health questionnaire , who will be referred to as "healthy indivisuals" in his study. Obtaining informed consent Exclusion criteria: Mental disease according to GHQ mental health questionnaire; Pregnancy or lactation
Intervention groups
Medication group and placebo group In the drug group, people in the saffron capsule group are given 500 mg capsules containing 75 mg of saffron powder and 425 mg of bread powder, which are packed in 42-digit cans. In the placebo group, people are given exactly the same capsule containing bread powder and food coloring (500 mg) packed in 42-digit cans.
Main outcome variables
Happiness; quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200813048396N1**
Registration date: **2021-01-10, 1399/10/21**
Registration timing: **prospective**

Last update: **2021-01-10, 1399/10/21**
Update count: **0**
Registration date
2021-01-10, 1399/10/21

Registrant information
Name
Mohsen Keyhan Soltani Hosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2258 9176
Email address
mksoltani47@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-19, 1399/10/30
Expected recruitment end date
2021-04-19, 1400/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assessment of the efficacy of Saffron on happiness and quality of life in healthy adults

Public title
Assessment of the efficacy of Saffron on happiness and quality of life in healthy adults
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Indivisual's mental health (indivisuals with scores lower than 7 in the depression section of GHQ mental health questionnaire , who will be referred to as "healthy indivisuals" in his study Obtaining informed consent
Exclusion criteria:
History of mental disease according to GHQ mental health questionnaire Pregnancy or lactation
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will take advantage of the random allocation method through the table of random numbers to develop subjects to the two intervention and placebo groups
Blinding (investigator's opinion)
Triple blinded
Blinding description
Initially, 500 mg capsules of the drug containing 75 mg of saffron and 425 mg of bread powder are prepared and for the control group, using capsules similar to the main drug , with the same weight containing bread powder , which is similar to the intervention sample, is prepared . After preparation of drugs and placebos, the pharmacist researchers will assign a code to the medicine researchers will not know if each participant is in the medication group or the placebo group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahed University
Street address
Persian Gulf freeway, in front of the Holy Shrine
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.SHAHED.REC.1399.051

Health conditions studied

1

Description of health condition studied
Healthy people
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Change in happiness questionnaire score
Timepoint
Before intervention, Two weeks after starting the study
Method of measurement
Oxford questionnaire

2

Description
Change in quality of life questionnaire score
Timepoint
Before intervention, Two weeks after starting the study
Method of measurement
SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Saffron in the form of 500 mg capsules containing 75 mg of saffron powder and 425 mg of bread powder, which is packed in 42 cans in the Clinical Research Center of Traditional Medicine of

Shahed University. 28 capsules for 14 days, twice a day, one capsule each time and two hours after a meal. Saffron product is also determined based on the amount of crocin, determined and standardized.

Category

Treatment - Drugs

2

Description

Control group: The capsules are prepared in exactly the same way as bread powder and food coloring (500 mg) and are packed in 42 cans in the Clinical Research Center of Traditional Medicine of Shahed University. 28 capsules for 14 days, twice a day, one capsule each time and two hours after a meal.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed University dormitory

Full name of responsible person

Mohsen-Keyhan Soltani Hosseini

Street address

Persian Golf freeway, in front of the Holy Shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5522 8800

Email

mksoltani47@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Street address

Persian Golf freeway, in front of Holy Shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5522 8800

Email

naseri@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

10

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

Shahed University

Full name of responsible person

Mohsen Keyhan Soltani Hosseini

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.37 , Boostan 8th , Pasdaran Avenue

City

Tehran

Province

Tehran

Postal code

1666677311

Phone

+98 21 2258 9176

Email

mksoltani47@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Persian Golf freeway, in front of Holy Shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5522 8800

Email

naseri@shahed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Keyhan Soltani Hosseini

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No 37 , Boostan 8th . Avenue Pasdaran

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Phone

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Email

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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

All data can be shared after identifying individuals

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers in academic centers

Under which criteria data/document could be used

After receiving the request, the amount of access will be announced

From where data/document is obtainable

Dr Mohsen Naseri

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

One month after receiving the written request, the result will be announced

Comments