Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effect of Crocus sativus (saffron) herbal tea on happiness in postmenopausal women: A randomized clinical trial

Protocol summary

Study aim
Determining the effect of saffron herbal tea on the happiness of postmenopausal women

Design
Clinical trial with control group, with parallel groups, one-sided, randomized, phase 3 on 72 postmenopausal women. The randomized blocks method will be used for randomization.

Settings and conduct
Study place: Health centers will be under the supervision of Larestan University of Medical Sciences. The research assistant will select eligible postmenopausal women by referring to the selected health center through available sampling. In the random allocation phase, the researcher will not know about the assignment of individuals to groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Samples are willing to participate in research voluntarily. 2. Volunteers do not suffer from acute psychosis, chronic and debilitating diseases and cognitive diseases such as dementia and They have also not been treated similarly recently. 3. Candidates should be familiar with Persian language. 4. Candidates should not participate in other treatment programs that interfere with the present study. 5. Candidates should be able to swallow and have no oral or digestive problems that interfere with drinking. Exclusion criteria: 1. Occurrence of any social, family crisis during the study 2. Hospitalization or acute and chronic illness that interferes with research. 3. History of allergy to herbal medicines 4. Addiction to drugs and alcohol and painkillers 5. Taking psychiatric drugs

Intervention groups
The intervention group includes postmenopausal women who receive 30 mg of saffron herbal tea with candy in 300 ml of boiling water daily. The control group includes postmenopausal women who receive 300 ml of warm water with candy daily.

Main outcome variables
happiness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210403050818N1**
Registration date: **2021-04-09, 1400/01/20**
Registration timing: **prospective**

Last update: **2021-04-09, 1400/01/20**
Update count: **0**

Registration date
2021-04-09, 1400/01/20

Registrant information

Name
Hamed Delam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5224 7110

Email address
h.delam@larums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-07-01, 1400/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Crocus sativus (saffron) herbal tea on happiness in postmenopausal women: A randomized clinical trial

Public title
The effect of Crocus sativus (saffron) herbal tea on happiness

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Samples are willing to participate in research voluntarily. Volunteers do not suffer from acute psychosis, chronic and debilitating diseases and cognitive diseases such as dementia and They have also not been treated similarly recently. Candidates should be familiar with Persian language. Candidates should not participate in other treatment programs that interfere with the present study. Candidates should be able to swallow and have no oral or digestive problems that interfere with drinking.

Exclusion criteria:
Occurrence of any social, family crisis during the study Hospitalization or acute and chronic illness that interferes with research. History of allergy to herbal medicines Reluctance of the samples to continue participating in the research Addiction to drugs and alcohol and painkillers Taking psychiatric drugs

Age
From **47 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized block methods are used to randomly assign participants to intervention and control groups. The selected samples are placed in each of the intervention groups or the control group according to the randomized blocks according to the inclusion in the study. Thus, according to the sample size of this study, which is estimated at 72 people, 9 blocks of 8 are used. Each block consists of cells A and B. According to the previous agreement, cell A will belong to the intervention group and cell B will belong to the control group. At this stage, the researcher who assigns individuals to the intervention and control group will not know the type of allocation. This means that in each block, 4 people are in the intervention group and 4 people are in the control group. Sampling continues until 9 blocks are completed. Finally, 36 people in each group are selected in randomized blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Larestan University of Medical Sciences

Street address
North Ghadir Boulevard, Karmandan Street, behind Larestan Grand Bazaar

City
Larestan

Province
Fars

Postal code
7431889629

Approval date
2021-03-01, 1399/12/11

Ethics committee reference number
IR.LARUMS.REC.1399.017

Health conditions studied

1

Description of health condition studied
Happiness score in postmenopausal women

ICD-10 code
F32.8

ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Happiness

Timepoint
Measurement of happiness score before intervention and 2 weeks after intervention

Method of measurement
Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will involve the use of 30 mg of dried stigmas of the saffron plant, which are boiled once in the morning (in 300 ml of boiling water for 10-15 minutes).And with candy, it will be consumed daily in the form of 1 cup of saffron herbal tea. Patients will be instructed to use the drug completely and at the same time avoid using other herbs. According to previous research, the duration of this intervention will be 2 weeks. According to the results of previous studies, the maximum safe daily dose of saffron is 1.5 grams, so it is expected that the dose in the present study does not cause side effects. The subjects of the intervention group will receive the number of their drinks (30 mg teabags) for the whole study period (2 weeks) as soon as they enter the study, to monitor the consumption of saffron in the intervention group, according to the previous agreement and maintaining the confidentiality of information. The group will be contacted daily (up to two weeks) and the process of saffron consumption will be evaluated.

Category

Treatment - Drugs

2

Description

Control group: A glass of hot water and candy is provided daily for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers of Larestan University of Medical Sciences

Full name of responsible person
Hamed Delam

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North Ghadir Boulevard, Karmandan Street, behind Larestan Grand Bazaar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Larestan University of Medical Sciences

Full name of responsible person
Meghdad Abdollahpour AliTappeh

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Grant name

Grant code / Reference number

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

Title of funding source
Larestan 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
Larestan University of Medical Sciences

Full name of responsible person
Hamed Delam

Position
عضو هیئت علمی

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Larestan University of Medical Sciences

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Faculty member

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Master

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Epidemiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available