

# 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

##### Street address

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

##### Street address

North Ghadir Boulevard, Karmandan Street, behind Larestan Grand Bazaar

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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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Hamed Delam

**Position**

Faculty member

**Latest degree**

Master

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## Person responsible for updating data

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**Latest degree**

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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