# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Evaluation of the effect of crocus sativus tea on anxiety level of nurses working in intensive care units

## Protocol summary

**Study aim**
Evaluation of the effect of crocus sativus tea on anxiety level of nurses working in intensive care units

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized on 100 patients. For randomization, software for generating random numbers using a block method called Sealed Envelope has been used.

**Settings and conduct**
This research is a randomized controlled clinical trial that will be performed in intensive care units of Amirkabir Arak hospital on nurses who have continuous shifts. Block randomization method with 6 blocks of 4 is used to allocate the samples. People are assigned to two groups of 34. Every day for 40 days, the researcher gives tea containing saffron and water to the intervention group and placebo containing water and two drops of saffron essential oil to the control group. At the beginning and end of the study, the nurses of both groups completed the demographic questionnaire and the Spiel Berger questionnaire. Based on this, the anxiety level of nurses is determined. Then, in the end, the average of obvious anxiety between the two intervention and control groups is compared. The data analyzer and participants will not know how the samples are placed in the intervention and control groups.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Nurses who attend the ward only for 175 hours per month, Not taking any sedative and anti-anxiety drugs؛ Exclusion criteria: Unwillingness to participate in the study, Allergic to saffron

**Intervention groups**
Intervention group: At the beginning of the shift, nurses consume herbal tea containing 100 mg of saffron and 100 ml of water daily for 40 days. Control group: Nurses in the control group take a placebo containing 100 ml of water and two drops of saffron essential oil daily at the beginning of their shift for 40 days.

**Main outcome variables**
Anxiety level

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210501051142N4**
Registration date: **2022-10-26, 1401/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-26, 1401/08/04**
Update count: **0**

**Registration date**
2022-10-26, 1401/08/04

**Registrant information**
**Name**
Aida Arjloo
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 86 3402 0115
**Email address**
golmehrsherafati@gmail.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-10-02, 1401/07/10
**Expected recruitment end date**
2022-11-11, 1401/08/20
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of crocus sativus tea on anxiety level of nurses working in intensive care units

**Public title**
Evaluation of the effect of crocus sativus tea on anxiety level

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Nurses who attend the ward only for 175 hours per month (mandatory hours). Not taking any sedative and anti-anxiety drugs

**Exclusion criteria:**
Unwillingness to participate in the study Allergic to saffron Complications caused by the consumption of saffron The presence of any underlying disease Pregnancy

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**
Target sample size: **68**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Nurses are divided into an intervention group and a control group based on the order of entry and the randomization sequence that is established in advance. The sequence is unpredictable and the arrangement is completely random. To allocate the samples, the block randomization method with the size of 6 blocks of 4 blocks will be used, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for two groups. At first, the sequence ABAB, ABBA, BBAA, BABA, BAAB, AABB is produced, then randomly and by placing among the blocks, a block is selected and the arrangement pattern in that block will be used to allocate nurses, then this block is placed in the main container and Another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The data analyzer and participants will not know how the samples are placed in the intervention and control groups.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Arak university of medical sciences

**Street address**
Arak university of medical sciences, Basij Sq., Sardasht region

**City**
Arak

**Province**
Markazi

**Postal code**
3848176593

**Approval date**
2022-05-15, 1401/02/25

**Ethics committee reference number**
IR.ARAKMU.REC.1401.064

## Health conditions studied

### 1

**Description of health condition studied**
Anxiety level

**ICD-10 code**
F41.9

**ICD-10 code description**
Anxiety disorder, unspecified

## Primary outcomes

### 1

**Description**
Anxiety rate

**Timepoint**
Before the intervention and 40 days after the start of the first intervention, the anxiety level of each patient is measured.

**Method of measurement**
At the beginning and end of the study, the demographic questionnaire and the Spiel Berger questionnaire were completed by the nurses of both groups and based on this, the anxiety level of nurses is determined.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The intervention group is given tea containing 100 mg of saffron and 100 ml of water for 40 days. At the beginning of the study, demographic questionnaire and Spiel Berger questionnaire are completed by nurses. Based on the response to the Spiel Berger questionnaire, the level of primary anxiety of nurses is determined. Then, at the end of 40 days, the Spiel Berger questionnaire is completed again by the nurses, and all the dependent variables of the research are checked at the beginning and the end of the study, and according to the articles that have measured the level of anxiety with the Spiel Berger questionnaire, in this study, the level Overt anxiety is checked.

**Category**
Other

### 2

**Description**
Control group: The control group was given a placebo containing 100 ml of water and two drops of saffron essential oil to flavor the water in such a way that it cannot be identified with the tea containing saffron for 40 days. The essential oil used was prepared by Magnolia Company, which is the largest company in the production of flavorings and essential oils in Iran, which started its activity in 2013. At the beginning of the study, demographic questionnaire and Spiel Berger questionnaire are completed by nurses. Based on the response to the Spiel Berger questionnaire, the level of primary anxiety of nurses is determined. Then, at the end of 40 days, the Spiel Berger questionnaire is completed again by the nurses, and all the dependent variables of the research are checked at the beginning and the end of the study, and according to the articles that have measured the level of anxiety with the Spiel Berger questionnaire, in this study, the level Overt anxiety is checked.

**Category**
Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Amir Kabir Hospital

**Full name of responsible person**
Mahbobeh Sajadi

**Street address**
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province

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Arak

**Province**
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**Email**
golmehrsherafati@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
DR Alireza Kamali

**Street address**
University complex of the Great prophet, Basij square, Sardasht.

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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**
Arak University of Medical Sciences

**Proportion provided by this source**
80

**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**
Arak University of Medical Sciences

**Full name of responsible person**
Mahbobeh Sajadi

**Position**
Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**
Nursery

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University complex of the Great prophet, Basij square, Sardasht.

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## Person responsible for scientific inquiries

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**Position**
Associate professor

**Latest degree**
Ph.D.

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Arak University of Medical Sciences

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Mahbobeh Sajadi

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Associate professor

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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**
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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
Only the part of the data related to the original outcome will be able to be shared.

**When the data will become available and for how long**
since the winter of 2023

**To whom data/document is available**
Researchers and students in this field

**Under which criteria data/document could be used**
In order to reduce the level of anxiety of the medical staff

**From where data/document is obtainable**
Vice chancellor for education and research, Arak university of medical sciences

**What processes are involved for a request to access data/document**
These documents will be available on the website of Arak university of medical sciences.

**Comments**