Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 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
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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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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

Street address
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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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