Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of virtual reality and aromatherapy with lavender on anxiety caused by bone marrow biopsy

Protocol summary

Study aim
Comparing the effect of virtual reality and aromatherapy with lavender on anxiety caused by bone marrow biopsy

Design
A randomized controlled clinical trial with no blinding, with parallel groups, conducted on 132 patients. Sealed envelope software was used for randomization.

Settings and conduct
Sampling will be available and the names of these people will be recorded based on the order of entry and entry and exit criteria. The present research will be without blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study, age between 18 and 60 years, having the power of sight and hearing and the ability to read and write in Persian language, absence of severe psychiatric disorders, not having a history of allergies to aromatic substances and proven problems in the sense of smell, no prior allergy to lavender. Exclusion criteria: withdrawal and unwillingness to continue participation at any stage, the occurrence of any acute medical condition that contradicts the patient's participation

Intervention groups
In all three groups, a questionnaire related to demographic characteristics and Spielberger anxiety will be completed. People will be subjected to aromatherapy or virtual reality intervention for 12-20 minutes while waiting. Virtual reality will be through a virtual reality device and headset, and the aromatherapy group will also be asked to smell the aromatherapy through natural breathing for 12-20 minutes. People in the control group also spend the same waiting period without intervention and according to the usual conditions, until they are called according to their turn.

Main outcome variables
Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240711062391N1**
Registration date: **2024-08-17, 1403/05/27**
Registration timing: **prospective**

Last update: **2024-08-17, 1403/05/27**
Update count: **0**

Registration date
2024-08-17, 1403/05/27

Registrant information

Name
Erfan Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-03-21, 1404/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of virtual reality and aromatherapy with lavender on anxiety caused by bone marrow biopsy

Public title

Comparing the effect of virtual reality and aromatherapy with lavender on anxiety caused by bone marrow biopsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age between 18 and 60 years Having the necessary eyesight and hearing Having the ability to read and write in Persian Not suffering from severe psychiatric disorders such as psychotic disorders, bipolar mood disorder, panic disorder and depression. Not having a history of allergy to aromatic substances, proven problems in the sense of smell, previous allergy to lavender and an allergy

Exclusion criteria:

Withdrawal and unwillingness to continue participating in any stage of the study according to the patient's choice and decision Occurrence of any special medical condition that is contrary to the continued participation of individuals

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, random blocks will be used in order to hide the randomized allocation (concealment) and establish balance (balance) during and after the study. In this way, based on the sample size, people will be randomly placed in blocks of 3. Random sequence generation will be done by block building method by Sealed envelope software. In the mentioned software, the total sample size and the number of groups are entered into the software. The randomization unit in the mentioned software is a person. The output of the software is a grouped list that randomly distributes the number of samples in three groups. According to the mentioned list, patients are distributed in three groups according to the time of visit so that the sample size reaches the required number in each group. The randomized list in the form of an Excel file will only be available to the researcher (M-H).

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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij St, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3818887174

Approval date

2024-06-23, 1403/04/03

Ethics committee reference number

IR.ARAKMU.REC.1403.133

Health conditions studied

1

Description of health condition studied

Anxiety caused by bone marrow biopsy

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after the intervention

Method of measurement

The State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

first Intervention group: After randomization, a questionnaire related to demographic characteristics and Spielberger anxiety will be completed. Then people will be subjected to aromatherapy intervention during the waiting time and for 12-20 minutes. In the aromatherapy

group, 2 drops of lavender essential oil (Provided by Ellis Pharmaceutical Company, Kazeroon, Iran) will be poured with a dropper on a 10 x 10 cm gas and will be connected to a distance of 20 cm from the subject's nose and on their shirt. They will be asked to inhale the aromatherapy through natural breathing for 12-20 minutes.

Category
Rehabilitation

2

Description
second Intervention group: Intervention group: After randomization, a questionnaire related to demographic characteristics and Spielberger anxiety will be completed. Then people will be subjected to virtual reality intervention during the waiting time and for 12-20 minutes. The equipment used for the virtual reality technique will be a virtual reality device (Remax-RT-V03 audio visual glasses with internal memory) and headset, with the help of which, patients are exposed to the sound and pleasant scenes of nature with high quality. In this way, conditions are provided for them to experience more relaxation by diverting their thoughts and immersing themselves in a pleasant and enjoyable environment instead of focusing on the surgical process.

Category
Rehabilitation

3

Description
Control group: After randomization, a questionnaire related to demographic characteristics and Spielberger's anxiety will be completed. People in the control group spend the same waiting period without intervention and under usual conditions until they are called according to their turn.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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https://research.arakmu.ac.ir/fa
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
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
Arak University of Medical Sciences
Full name of responsible person
Erfan Mohammadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Erfan Mohammadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Not applicable

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

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

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

Data Dictionary
Not applicable