Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Benson's relaxation technique on anxiety, pain and physiological indicators of bone marrow biopsy candidates

Protocol summary

Study aim
Assessing the impact of Benson's relaxation technique on anxiety, pain, and physiological indicators in patients undergoing bone marrow sampling

Design
This study is a randomized clinical trial with a before-and-after design and parallel groups. Block design was used for randomization through a website.

Settings and conduct
This study will be conducted with 80 patients at Khansari Hospital in Arak 2024. Patients will be selected using a convenience sampling method and will be randomly divided into two groups, control and intervention, in blocks of four. In the intervention group, patients will be asked to practice Benson's relaxation technique in the morning on the day of the sample collection, one hour before sampling. The control group will only receive usual care. After the intervention, both groups will complete a questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. The patient must be a candidate for a bone marrow biopsy according to the specialist's opinion. 2. Age between 18 and 65 years. 3. Moderate to severe anxiety score based on the Spielberger Anxiety Questionnaire. 4. No use of sedatives or painkillers Exclusion Criteria: 1- Withdrawal from the study 2- Previous experience of bone marrow sampling

Intervention groups
The intervention group receives training on Benson relaxation techniques in addition to the standard services, while the control group only receives the regular services

Main outcome variables
Reducing anxiety; relieving pain; improving physiological indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201104049259N1**
Registration date: **2024-08-11, 1403/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-11, 1403/05/21**
Update count: **0**

Registration date
2024-08-11, 1403/05/21

Registrant information
Name
Mahla Qomi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-27, 1403/05/06

Expected recruitment end date
2024-09-27, 1403/07/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Benson's relaxation technique on anxiety, pain and physiological indicators of bone marrow biopsy candidates

Public title
The effect of Benson's relaxation technique on anxiety, pain and physiological indicators of bone marrow biopsy candidates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient must be a candidate for bone marrow biopsy according to the specialist physician's opinion Age between 18 and 65 years Ability to perform muscle relaxation techniques No physical or mental illnesses that would prevent participation in the study Moderate to severe anxiety score based on the Spielberger Anxiety Questionnaire Willingness to participate in the study must be informed and voluntary No use of sedative or analgesic medications to manage pain and anxiety during the bone marrow biopsy
Exclusion criteria:
Previous experience of bone marrow biopsy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients will be registered based on the determined sample size (80 individuals) and inclusion criteria. They will be assigned to two groups using block randomization By Block Design Website (a 4-block design will be employed, where two letters A and B are placed in different arrangements within the blocks; a total of 20 blocks will be randomly selected, with each block assigned to groups of four individuals)
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
Third Floor, Prophet Muhammad (PBUH) University Complex, University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2024-06-23, 1403/04/03
Ethics committee reference number
IR.ARAKMU.REC.1403.136

Health conditions studied

1

Description of health condition studied
bone marrow biopsy
ICD-10 code
D75.9
ICD-10 code description
Disease of blood and blood-forming organs, unspecified

Primary outcomes

1

Description
anxiety
Timepoint
Before and after relaxation technique
Method of measurement
State Trait Anxiety Inventory

2

Description
Physiological indicators
Timepoint
Before the relaxation technique, after the relaxation technique, and after the biopsy.
Method of measurement
Physiological indicators form

3

Description
pain
Timepoint
after biopsy
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The anxiety questionnaires and physiological index forms were completed before the Benson relaxation technique. Then, in the Benson relaxation intervention group, patients were instructed to perform the Benson relaxation technique as follows: find a comfortable position, slowly close their eyes, and gradually relax all body muscles from their feet to their face. They were advised to maintain their calm, breathe through their nose while being aware of their breath, and exhale slowly through their mouth. As they exhaled, they were to repeat a number or word that evokes a sense of relaxation for them under their breath and breathe normally and comfortably. This process was to be carried out for 20 minutes, with an emphasis on keeping the muscles relaxed. Afterward, they were to open their eyes and remain still for a few minutes. Patients were asked to perform this relaxation technique on the morning of the day of sampling. The levels of anxiety and physiological indicators were measured after the relaxation and before the sampling. Additionally, physiological indicators and pain levels were assessed after the sampling.

Category
Treatment - Other

2

Description
Control group: In the control group, only standard care will be provided.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Khansari Hospital

Full name of responsible person
Mahla Qomi

Street address
End of University Street

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3818649433

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Davood Hekmatpou

Street address
University of Medical Sciences, Prophet Muhammad (PBUH) University Complex, Research and Technology Deputy.

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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
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
Mahla Qomi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information 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
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
Undecided - It is not yet known if there will be a plan to make this available