Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of guided imagery on pain and need to Pain reliever in women with uterine fibroids

Protocol summary

Study aim
Determining the effect of guided visualization on pain intensity and need for pain relief in women with uterine fibroids

Design
A randomized controlled clinical trial with parallel groups

Settings and conduct
Sampling will be done in health centers in Zanjan.First, 72 eligible women are randomly selected and then randomly assigned to the intervention and control groups.The intervention group will receive eight counseling sessions in person.The participants will complete self-report questionnaires before the intervention، immediately after the sessions and two months after the last counseling session

Participants/Inclusion and exclusion criteria
Women aged 24 to 45 years with minimum third grade of junior high school education and diagnosis of uterine fibroid confirmed by ultrasound and complain of fibroid complications such as heavy menstrual bleeding, pain caused by fibroid and have not received medical treatment before.

Intervention groups
The intervention group includes guided visualization with the content of some principles of relaxation. Guided visualization group sessions will be held during eight face-to-face, weekly and consecutive sessions. The maximum time of each session will be 90 minutes. Participants in the control group will not receive any intervention.

Main outcome variables
Pain ، the need for painkillers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160608028352N10**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date
2022-12-11, 1401/09/20

Registrant information

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Roghieh Kharaghani

Name of organization / entity
Zanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-31, 1401/10/10

Expected recruitment end date
2023-03-30, 1402/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of guided imagery on pain and need to Pain reliever in women with uterine fibroids

Public title
The effect of guided visualization on fibroid symptoms

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Age 24 to 45 years Having at least third grade of junior high school education Uterine fibroid diagnosis confirmed by ultrasound Having complications of fibroids, such as heavy menstrual bleeding and fibroid pain (that have been confirmed by a gynecologist and have not received medical treatment before). Not having any underlying diseases or major psychiatric disorders.
Exclusion criteria:
Menopause Lack of cooperation in treatment Unwillingness to continue participating in the study The need for surgical interventions during the study
Age
From **24 years** old to **45 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
The sampling method will be convenient and allocation will be blocked randomization. For this purpose, four-person blocks have been created to determine the two groups of intervention and control. The sample size in the two groups is 72 participants, so the allocation of participants in the intervention and control groups by random selection of 18 four-person blocks (72 people) will be done from the following blocks. The selection of each block will be done using random table numbers. 1- AABB 2- BBAA 3- ABAB 4- BABA 5- ABBA 6- BAAB
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
The ethics Committee of Zanjan University of Medical Sciences
Street address
The ethics committee of Zanjan University of Medical Sciences north side of Azadi Blvdedical Sciences،first floor
City
zanjan
Province
Zanjan
Postal code
4525613113
Approval date
2022-11-22, 1401/09/01
Ethics committee reference number
IR.ZUMS.REC.1401.262

Health conditions studied

1

Description of health condition studied
Uterine fibroid
ICD-10 code
D25
ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
pain
Timepoint
Before the intervention, immediately after the intervention and two months after the last counseling
Method of measurement
McGill pain questionnaire

2

Description
need to Pain reliever
Timepoint
Before the intervention, immediately after the intervention and three months after the last counseling
Method of measurement
self reporting

Secondary outcomes

1

Description
Bleeding
Timepoint
Before the intervention, immediately after the intervention and two months after the last counseling
Method of measurement
Higham chart

Intervention groups

1

Description
There will be 36 people in the intervention group who will participate in 8 group counseling sessions in groups of 9 people. Guided visualization counseling using relaxation and cognitive techniques in the form of group activities to reduce disturbing thoughts. A 90-minute meeting will be held every week. The number of sessions was determined according to the studies that intervened with a counseling approach similar to the researcher's approach. The content of the sessions will be based on the suggestions of the book "Mental Imagery" written by Rossman and translated by Mehdi Karacheh Daghi (2013) and the book "The Constructive Power of Mental Imagery" written by Tommy Ronen and translated by Akram Khamse (2013).

Category
Behavior

2

Description
Control group: Participants in this group will not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Somayeh Karimi
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Somayeh Karimi
Position
Zanjan University of Medical Sciences
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Title and more details about the data/document
After completion of the study, information on the main outcome will be shared.
When the data will become available and for how long
Starting the access period from 2023
To whom data/document is available
Data and documentation will be available to medical researchers.
Under which criteria data/document could be used
The data can be used to study, give a citation, create new ideas, and practically apply in medical centers.
From where data/document is obtainable
Email to somayehkarimi892@yahoo.com
What processes are involved for a request to access data/document
The data will be provided to the applicant within one month after reviewing and confirming the request.
Comments