

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Name

Roghieh Kharaghani

Name of organization / entity

Zanjan University of Medical Sciences

Country

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

AgeFrom **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 Blvd medical 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

Street address

Ayatollah Mousavi Hospital, Gavazang Road

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4515613191

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2

Recruitment center

Name of recruitment center

Shafia Specialized Clinic

Full name of responsible person

Somayeh Karimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nadri

Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, Northside Boulevard Azadi, zanjan

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nadri_s@zums.ac.ir

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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Msc student of counseling in midwifery

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Bachelor

Other areas of specialty/work

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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