

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the training effects of Coping Strategies and Relaxation on Stress intensity of women who had Uterine Leiomyoma referred to Shiraz Gynecology Clinics-2015

Protocol summary

Summary

The aim of this study is to compare the effects of coping strategies and relaxation techniques on stress, Leiomyoma size and Leiomyoma symptoms. It is a randomized controlled clinical trial (not blinded) on 126 patients with uterine Leiomyoma : Inclusion criteria (Leiomyoma 1-7 cm; mild or moderate stress; age 20-45 years; body mass index less than 25; not taking drugs influential the Leiomyoma and stress; and not participating in yoga classes or other programs affecting stress). We will put qualified individuals randomly in three groups, each group consisting of 42 Patient. In the intervention group 1, will be held 6 sessions of coping strategies, within three weeks (two 90-minute sessions per week) . Class content includes: accepting the position; define the problem; brain storming solutions; make decisions; plan to implement the best solution; implementing the selected solution; evaluation of the results of the implementation of the solution; what are emotions; need of emotional management skills; obstacles of emotions management; cognitive sadness management). In groups 2, will be held a relaxation training session, and then they will be asked to do relaxation (once a day) at home for a month. The control group will not receive any treatments. Stress will be measured before intervention, 1 and 2 months after starting intervention in all three groups. The Leiomyoma size and Leiomyoma symptoms (bleeding, pelvic pain, urinary frequency and urgency of urination) will be measured before intervention and 2 months after the starting intervention in all three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121331387N1**

Registration date: **2017-01-13, 1395/10/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-13, 1395/10/24

Registrant information

Name

Seyedeh Soheila Mohsenipoor

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 4252 3636

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the training effects of Coping Strategies and Relaxation on Stress intensity of women who had Uterine

Leiomyoma referred to Shiraz Gynecology Clinics-2015

Public title

The training effect of coping strategies and relaxation on stress treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 45 years; evidence of vaginal ultrasound of Uterine Leiomyoma (size 1-7 cm); have mild or moderate stress based on the DASS questionnaires; body mass index below 25; not taking any hormones affecting the size of the leiomyoma from start up to a month after the intervention; not taking any effective drug on stress and depression from start up to a month after the intervention; lack of medical conditions including hypertension, thyroid and diabetes; signing a consent form a conscious; non-participation in any classes or programs affecting stress such as relaxation, yoga and meditation. Exclusion criteria: use of any drug affecting the leiomyoma and stress during the intervention and one month after its completion; the patient's unwillingness to continue to work; absence in more than one session.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Ethics Committee

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Postal code

71345-1978

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SUMS.REC.1394.41

Health conditions studied

1

Description of health condition studied

Leiomyoma of uterus

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus, unspecified

Primary outcomes

1

Description

Stress

Timepoint

Before the intervention, one and two months after starting intervention

Method of measurement

DASS standard questionnaire

2

Description

Leiomyoma size

Timepoint

Before and two months after starting intervention

Method of measurement

Vaginal ultrasound

3

Description

The Volume of Menstrual Bleeding

Timepoint

Before and two months after starting intervention

Method of measurement

Number of daily pad

4

Description

Pelvic Pain

Timepoint

Before and two months after starting intervention

Method of measurement

VAS

5

Description

Urinary Frequency

Timepoint

Before and two months after starting intervention

Method of measurement

Patient reports

6**Description**

Urgency of Urination

Timepoint

Before and two months after starting intervention

Method of measurement

Patient reports

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group 1, will be held 6 sessions of coping strategies, within three weeks (two 90-minute sessions per week). Class content includes: the reception of Position; Problem Definition; brain storming solutions; Decision making; planning to implement the best solution; implementing the selected solution; evaluating the results of the implementation of the solution; what are emotions; need of emotional management skills; Barriers to manage emotions; Cognitive manage of emotions; Negative emotional management strategies (management of Anger, anxiety and sadness).

Category

Behavior

2**Description**

In groups 2, will be held beginning a training session relaxation, then will be asked the people to do relaxation once a day for a month at home.

Category

Behavior

3**Description**

There is no intervention for control group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz Hafez Hospital

Full name of responsible person

Seyedeh Soheila Mohsenipoor(Masters Student)

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Chamran Blvd

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2**Recruitment center****Name of recruitment center**

Hazrat Zeinab Hospital

Full name of responsible person

Seyedeh Soheila Mohsenipoor(Masters Student)

Street address

Zeinabiyeh Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

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Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd, Shiraz

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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

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Shiraz University of Medical Sciences

Full name of responsible person

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Master of Midwifery, Faculty Member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty