Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating The Effect Of Positive Thinking Training On The Happiness Of Women With Endometriosis

Protocol summary

Study aim
Determining the effect of positive thinking training on the happiness of women with endometriosis referring to specialized gynecological clinics affiliated with Shiraz University of Medical Sciences

Design
Unblinded clinical trial, permutation random assignment to intervention and control groups, 82 sample subjects

Settings and conduct
Research setting: In the research settings of Shiraz Medical Sciences, participants are invited to participate in the study according to the entry and exit criteria and are divided into two intervention and control groups through permutation randomization. In the intervention group, after the pre-test, the intervention is carried out in the form of positive thinking training classes. Immediately and 4 weeks after the intervention, the relevant questionnaires are completed in the two groups and the data are analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Low happiness score according to the Oxford Happiness Questionnaire, married women of childbearing age living with their spouse... Exclusion criteria: Incomplete or non-completion of the questionnaire, unwillingness to continue participating in the research after entering the study or during follow-up...

Intervention groups
Intervention group: After the pre-test, the intervention will be conducted in the form of positive thinking training classes by the researcher in seven sessions, each session lasting 45-60 minutes, once a week. Control group: No intervention will be carried out, but at the end of the study, educational content will be provided to the control group in the form of a booklet to maintain educational justice.

Main outcome variables
Happiness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240507061690N4**
Registration date: **2025-08-01, 1404/05/10**
Registration timing: **prospective**

Last update: **2025-08-01, 1404/05/10**
Update count: **0**

Registration date
2025-08-01, 1404/05/10

Registrant information

Name
Zahra Yazdanpanahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4256

Email address
yazdanz@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2025-11-06, 1404/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating The Effect Of Positive Thinking Training On The Happiness Of Women With Endometriosis

Public title

Investigating The Effect Of Positive Thinking Training On Women's Happiness

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Low happiness score according to the Oxford Happiness Questionnaire Married women of childbearing age who live with their husbands A definitive diagnosis of endometriosis confirmed by ultrasound under the supervision of a specialist doctor No surgical indications for the treatment of endometriosis Willingness to participate in the research and complete the informed consent form No diagnosis of other physical and mental illnesses such as diabetes, cardiovascular diseases, multiple sclerosis, and cancer that could affect the research results Not using psychiatric medications, psychoactive substances, narcotics, or alcohol Possessing at least basic literacy skills No experience of bereavement in the past 6 months among first-degree relatives Currently not pregnant or breastfeeding and has not been pregnant in the last two years

Exclusion criteria:

Incomplete or non-completion of the questionnaire Unwillingness to continue participation in the research after entering the study or during follow-up Failure to attend more than two sessions in the educational program Death of a first-degree relative during the study Undergoing surgery during the study

Age

From **10 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize, a method of permuted blocks will be used to allocate samples to two groups (intervention and control). A total of 84 samples will be placed in 14 blocks of 6. Ultimately, 42 individuals (7 blocks of 6) will be assigned to each group. The random allocation list of samples has been prepared using the Random Allocation software.

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 in Research of Nursing and Midwifery Faculties, Management and Medical Information

Street address

Faculty of Nursing and Midwifery, Namazi Square, Shiraz

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Province

Fars

Postal code

7193613119

Approval date

2025-07-27, 1404/05/05

Ethics committee reference number

IR.SUMS.REC.1404.204

Health conditions studied

1

Description of health condition studied

Happiness

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Endometriosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Happiness score: Happiness in this study refers to the total score that women with endometriosis obtain by answering the standard Oxford questionnaire. A higher score indicates higher happiness in the individual and vice versa.

Timepoint

Before, immediately and 4 weeks after the intervention

Method of measurement

Happiness Scale Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, a pre-test is conducted in the intervention group, and demographic questionnaires and the Oxford Happiness Questionnaire are completed before the intervention in the intervention group. In the intervention group, after the pre-test, the intervention is carried out in the form of positive thinking training classes by the researcher in seven face-to-face sessions, each session lasting 45-60 minutes, once a week. The content of the training provided includes: stating the goals of the program, training in positive thinking and discovering positive beliefs (preparing a list of positive statements), discussing strengths and writing down three positive events in life, moderating negative thoughts, positive emotions, and providing supplementary activities, discussing gratitude and writing it down, defining happiness and ways to strengthen it, and giving participants a sense of worth. To complete the content of each session and further learn, participants in the intervention group will be given a booklet and asked to study the material related to each session before the start of the next session. After the intervention in the intervention group is completed, the Oxford Happiness Questionnaire will be reviewed by the participants twice, immediately and after 4 weeks of training.

Category
Other

2

Description
Control group: First, a pre-test is conducted in the control group, and demographic questionnaires and the Oxford Happiness Questionnaire are completed in the control group before the intervention. The control group, which entered the study at the same time as the intervention group, will be examined for happiness immediately and after 4 weeks of the intervention. It should be noted that no intervention will be performed in the control group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahari Clinic

Full name of responsible person
Zahra Yazdanpanahi

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Namazi Square, Shiraz, Fars Provice

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Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center
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Full name of responsible person
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Opposite Shahid Faghihi Street (Suratgar), Karim Khan Zand Boulevard, Shiraz, Fars Provice

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Seyed Vahid Hosseini

Street address
in front of Fars Regional Electric Company,next to Hazrat Fatima Al-Zahra Mosque, Karimkhan 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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Yazdanpanahi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Observance of ethical principles in the publication of the results (when publishing the study results, it will be avoided to provide any information that leads to the disclosure of people's information). • The results were published in such a way that the names of the participants will not be revealed

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The general results of the research will be provided to the research units and university officials

Under which criteria data/document could be used

Any copying of the entire thesis or part of it is allowed only with the supervisor's approval. • All intellectual rights of this work belong to Shiraz University of Medical Sciences and cannot be transferred to a third party without the written permission of the university. • It is not allowed to use the information and results in the thesis without mentioning the reference

From where data/document is obtainable

Study participants can be in contact with the researcher at all hours of the week and raise their questions and doubts. Address: Shiraz, Namazi Square, Faculty of Nursing and Midwifery. 09155650578 -- Firoozeh Abolhasannezhad

What processes are involved for a request to access data/document

Obtaining an official letter of introduction from Hazrat Fatemeh College of Nursing and Midwifery and obtaining permission from the Research Vice-Chancellor to access research documents from the Faculty and Shiraz University of Medical Sciences.

Comments