Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Study of the effectiveness of happiness training on quality of life and negative and positive affection in women with premenstrual syndrome: a randomized controlled clinical trial

Protocol summary

Study aim

To determine the effectiveness of happiness training on quality of life and negative and positive affection in women with premenstrual syndrome

Design

Two-armed randomized controlled trial

Settings and conduct

This study will be conducted on women referring to Shahid Babaie Health Center of Tabriz. The researcher will refer to health center and will select women with age of 15 to 49 years according to their records, then will call them and they will be invited to participate in the study. In face to face session, the women who obtain a premenstrual syndrome score of over 28 (average and high score) will be included in study and written consent will be obtained. Then questionnaires of socio-demographic information, quality of life and positive and negative affection will be completed by the participants. Participants will be randomly assigned into two groups of counseling and control through block randomization. For the intervention group, educational counseling will be provided using the Fordyce method in eight 120-minute sessions. At the last session, the questionnaires will be completed again by the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who have symptoms of premenstrual syndrome with a normal menstrual cycle
Exclusion criteria: History of physical illness; Personality or mood disorders

Intervention groups

For the intervention group, educational counseling will be provided using the Fordyce method in eight 120-minute sessions.The control group will receive routine cares.

Main outcome variables

Quality of life and negative and positive affection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N47**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-08, 1397/09/17**
Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-31, 1397/08/09

Expected recruitment end date

2018-12-30, 1397/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the effectiveness of happiness training on quality of life and negative and positive affection in women with premenstrual syndrome: a randomized controlled clinical trial

Public title
The effectiveness of happiness training on quality of life and negative and positive affection in women with premenstrual syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Women who have symptoms of premenstrual syndrome Having age between 15 to 48 Having at least secondary education Having a normal menstrual cycle (21-35 days).

Exclusion criteria:
History of physical illness Taking psychoactive drugs Suffering from personality disorder and mood disorders

Age
From **15 years** old to **48 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be conducted using the website www.random.org and through blocking with block sizes of four and six and an allocation ratio of 1: 1 to the two groups of education and control.

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 Tabriz University of Medical Sciences

Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2018-09-24, 1397/07/02

Ethics committee reference number
IR.TBZMED.REC.1397.540

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Negative and positive affection

Timepoint
Before intervention, eight weeks after the intervention

Method of measurement
Negative and positive affection questionnaire

2

Description
Quality of life

Timepoint
Before intervention, eight weeks after the intervention

Method of measurement
Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, eight 120-minute sessions of group counseling once a week will be provided.

Category
Treatment - Other

2

Description
The control group will receive routine cares.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Babaei Health Center
Full name of responsible person
Khadije Hajizadeh
Street address
South Shariati
City
Tabriz
Province
East Azarbaijan
Postal code
56541-51338
Phone
+98 41 3479 6770
Email
hajizade_k@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6969
Email
mirghafourvandm@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hajizadeh Khadije
Position
Ph.D student of Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
56541-51338
Phone
+98 41 3479 6770
Email
hajizade_k@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mojgan Mirghafourvand
Position
PhD of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
56541-51338
Phone
+98 41 3479 6770
Email
mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hajizadeh Khadije

Position

Ph.D student of Midwifery

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Street address

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

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Province

East Azarbaijan

Postal code

56541-51338

Phone

+98 41 3479 6770

Email

hajizade_k@yahoo.com

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

Data of participants are privacy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available