

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	number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue
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	City Tabriz
	Province East Azarbaijan
Public title The effectiveness of happiness training on quality of life and negative and positive affection in women with premenstrual syndrome	Postal code 5138947977
Purpose Education/Guidance	Approval date 2018-09-24, 1397/07/02
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	Ethics committee reference number IR.TBZMED.REC.1397.540
Age From 15 years old to 48 years old	Health conditions studied
Gender Female	1 Description of health condition studied Premenstrual syndrome
Phase N/A	ICD-10 code N94.3
Groups that have been masked <i>No information</i>	ICD-10 code description Premenstrual tension syndrome
Sample size Target sample size: 50	Primary outcomes
Randomization (investigator's opinion) Randomized	1 Description Negative and positive affection
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.	Timepoint Before intervention, eight weeks after the intervention
Blinding (investigator's opinion) Not blinded	Method of measurement Negative and positive affection questionnaire
Blinding description	2 Description Quality of life
Placebo Not used	Timepoint Before intervention, eight weeks after the intervention
Assignment Parallel	Method of measurement Quality of life questionnaire
Other design features	Secondary outcomes empty
Secondary Ids empty	Intervention groups
Ethics committees	1 Description For the intervention group, eight 120-minute sessions of group counseling once a week will be provided.
1 Ethics committee Name of ethics committee Ethics committee of Tabriz University of Medical Sciences Street address Research department, third floor, central construction	Category Treatment - Other
	2 Description The control group will receive routine cares.

Category

N/A

Recruitment centers1**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 sources1**Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street addressResearch department, third floor, central construction
number 2, Tabriz University of Medical Sciences,
Golgash 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

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, Tabriz University of
Medical Sciences

City

Tabriz

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