Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Fordyce happiness training on marital satisfaction and mental health in women with premenstrual syndrome

Protocol summary

Study aim
The effect of Fordyce happiness training on marital satisfaction and mental health in women with premenstrual syndrome

Design
This study is a not blinded clinical trial. The study population will be included all women with the premenstrual syndrome who will refer to private clinics in Kermanshah city.40 eligible patients will be selected conveniently and randomly assigned to intervention and control groups.

Settings and conduct
This study, which will be conducted at Kermanshah private clinics of obstetrics and gynecology and not blinded. Patients with the premenstrual syndrome will be in two intervention and control groups and the intervention group will receive cognitive-behavioral counseling based on the principles of happiness.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The menstrual period between 35-21 in the six recent periods; At least 5 years have passed since marriage Exclusion criteria: No-participation in two or more sessions of training sessions; Acute or chronic physical and mental illnesses

Intervention groups
The intervention group will receive a cognitive-behavioral counseling based on the principles of Fordey's Happiness in six sessions of 60-90 minutes, with a 7-day interval. The control group will not receive any training

Main outcome variables
Marital satisfaction; Mental health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N94**
Registration date: **2018-06-12, 1397/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-12, 1397/03/22**
Update count: **0**

Registration date
2018-06-12, 1397/03/22

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 1821 4653

Email address
fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2018-09-06, 1397/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Fordyce happiness training on marital satisfaction and mental health in women with premenstrual syndrome

Public title
Effect of happiness training on marital satisfaction and

mental health in women with premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Score 20 and above of the premenstrual syndrome screening questionnaire Score lower than 142 of the shortened questionnaire (47 questions) Enrich marital satisfaction Score 22 to 42 of the Goldberg Mental Health Questionnaire The menstrual period is between 35-21 in the six recent periods At least 5 years have passed since marriage

Exclusion criteria:

Non-participation in two or more sessions of training sessions Acute or chronic physical and mental illnesses

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation (Individually) using random numbers table through of receiving code

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-05-08, 1397/02/18

Ethics committee reference number

ir.kums.rec.1397.047

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

Marital Satisfaction

Timepoint

The beginning of the study, the end of the study, and 45 days after the end of the study

Method of measurement

Using Enrich Marital Satisfaction Questionnaire

2

Description

Mental Health

Timepoint

The beginning of the study, the end of the study, and 45 days after the end of the study

Method of measurement

Using Mental Health Questionnaire (GHQ-28)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive a cognitive-behavioral counseling based on the principles of Fordey's Happiness in six sessions of 90-60 minutes, with a 7-day interval.

Category

Behavior

2

Description

The control group will not receive any training

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Personal office

Full name of responsible person
Fereshteh Abdolrahmi

Street address
Municipal Parking

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3835 6774

Email
A.fereshteh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Farid Najafi

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Fereshteh Abdolrahmi

Position
Master of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3826 6429

Email
A.Fereshteh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Marzieh Kaboudi

Position
Faculty Member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Reproductive Health

Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3826 6429

Email
fkoboudim@kums.as.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person

Fereshteh Abdolrahmi

Position
Master of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3826 6429

Email
A.Fereshteh@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared

When the data will become available and for how long
3 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable
To receive the documentation, email send for update manager

What processes are involved for a request to access data/document
In a 25-day period, the documents will be sent e-mail

Comments