

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

□ The effect of motivational interview focused on some principles of Hefz - Alsehe in Iranian medicine on the physical and psychological symptoms of premenstrual syndrome

Protocol summary

Study aim

Determining the effect of the motivational interview focused on some principles of Hefz - Alsehe of Iranian medicine on physical and psychological symptoms of premenstrual syndrome

Design

Randomized controlled clinical trial with parallel groups

Settings and conduct

Sampling will be carried out in Zanjan health centers. First, 52 eligible women will be selected using the simple method and then they will be randomly assigned into the intervention and control groups. The intervention group will receive five counseling sessions online. Participants will complete the questionnaires in a self-reported manner prior to the intervention, immediately after the sessions, and three months after the last session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willing to participate in the study, aged 18-42 years, regular menstruation with an interval of 21-35 days and duration of 3-10 days, Experience of premenstrual syndrome according to premenstrual symptoms screening tool, body mass index of 18.5 to 29.9 kg / m², and access and ability to use social network
Exclusion criteria: Presence of stressors within the last three months, medication or taking hormones to treat or relieve symptoms, Previous history of illness and depression under treatment

Intervention groups

The intervention group will receive motivational interview focused on some principles of Hefz - Alsehe in Iranian medicine, including proper physical activity, eating & drinking, and sleep management. Individual motivational interviewing sessions will be held online in five weekly and consecutive sessions. The maximum time of each session will be 45 min. Participants in the control group will receive no intervention

Main outcome variables

Physical and psychological symptoms of premenstrual syndrome, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210704051787N1**

Registration date: **2022-01-21, 1400/11/01**

Registration timing: **prospective**

Last update: **2022-01-21, 1400/11/01**

Update count: **0**

Registration date

2022-01-21, 1400/11/01

Registrant information

Name

Robab Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3354 9370

Email address

naseri.robab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-27, 1400/11/07

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
□ The effect of motivational interview focused on some principles of Hefz – Alsehe in Iranian medicine on the physical and psychological symptoms of premenstrual syndrome

Public title
The effect of Iranian principles of Hefz - Alsehe on the symptoms of premenstrual syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Willing to participate in the study Aged 18-42 years
 Regular menstruation with an interval of 21-35 days and duration of 3-10 days Experience of premenstrual syndrome according to the premenstrual symptoms screening tool Body Mass Index of 18.5 to 29.9 kg / m2
 Access and ability to use social network
Exclusion criteria:
 Presence of stressors (e.g. the death of a loved person within the last three months) Medication or taking hormones to treat or relieve symptoms Previous history of illness depression under treatment

Age
From **18 years** old to **42 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
The sampling will be performed by the simple and allocation will be blocked randomization. For this purpose, four-person blocks will be defined to determine the two groups of intervention and control. The sample size in the two groups is 50 people, so the allocation of people in both groups by random selection of 13 four-person blocks (52 people) will be from the following blocks. Each block will be selected using a random number table. 1- AAB2 2- BBAA 3- ABAB 4- BABA 5- ABBA 6- BAAB

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

The ethics committee of Zanjan University of Medical Sciences

Street address

The ethics committee of Zanjan University of Medical Sciences, First floor, Northside Azadi, Zanjan

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Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.ZUMS.REC.1400.213

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

2

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Physical and psychological symptoms of premenstrual syndrome

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Premenstrual Symptoms Screening Tool PSST

2

Description

Quality of life

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Short form of quality of life questionnaire SF- 12

Secondary outcomes

1

Description

Physical activity

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Sharkey Physical Activity Index

2

Description

Lifestyle related to eating behavior

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Weight Efficacy Lifestyle Questionnaire

3

Description

Sleep hygiene

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Sleep Hygiene Index

4

Description

Dysmenorrhea

Timepoint

Before the intervention, immediately after the intervention and three months after the last counseling

Method of measurement

Numerical analog scale

Intervention groups

1

Description

Intervention group: General instructions of Iranian medicine on the three principles of physical activity, eating & drinking, and sleep management will be given to the participants in a written form, one week before starting the motivational interview sessions. Participants will be encouraged to assess their own positive/negative behaviors on the basis of these principles before starting motivational interview sessions. Motivational interview sessions will be held individually and virtually in five consecutive weekly sessions. The topics are as follows:

Determining the rules; defining the change stages; describing a typical day and discussing it; evaluating the positive & negative dimensions of behaviors; identifying personal values; discovering conflict between values and behaviors; identifying, reinforcing, and invoking transformational dialogue; improvement the sense of self-efficacy; setting the goal and plan of change in behaviors of physical activity, eating & drinking, and sleep management. The maximum time of each session will be 45 minutes.

Category

Lifestyle

2

Description

Control group: Participants in this group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Robab Naseri

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

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Roozbeh Clinic

Full name of responsible person

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Roozbeh Clinic, Next to Payame Noor University,
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Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Robab Naseri

Position

Msc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity

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Dr Roghieh Kharaghani

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Ph.D of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

Msc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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