

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of group counseling on depression, stress and anxiety of premenstrual syndrome

Protocol summary

Study aim

This study aims to determine the effect of group counseling on depression, stress and anxiety of premenstrual syndrome referred to health centers of Qazvin city.

Design

Participants of study are 100 women with premenstrual syndrome selected by a convenience sampling method. They were randomly (by 2 blocks method) selected and divided in 2 groups, trial(50) and control(50). The instruments were used to measure the study variables: Demographic, index of measurement of premenstrual syndrome and DASS-21 questionnaires. The trial group received three sessions of group -counseling aimed at reducing depression, stress and anxiety of premenstrual syndrome. At the end both of index of measurement of premenstrual syndrome and DASS-21 questionnaires will be completed by two groups, in order to determine the effect of group counseling on depression, stress and anxiety of premenstrual syndrome.

Settings and conduct

10 centers selected among all health centers of Qazvin city. Participants of study are 100 women with premenstrual syndrome selected by a convenience sampling method. They were randomly (by 2block method) selected and divided in 2 groups, trial(50) and control(50). The instruments were used to measure the study variables: Demographic, index of measurement of premenstrual syndrome and DASS-21 questionnaires. The trial group received three sessions of group -counseling aimed at reducing depression, stress and anxiety of premenstrual syndrome. At the end both of index of measurement of premenstrual syndrome and DASS-21 questionnaires will be completed by two groups, in order to determine the effect of group counseling on depression, stress and anxiety of premenstrual syndrome.

Participants/Inclusion and exclusion criteria

Women inclusion criteria: women with premenstrual

syndrome based on index of measurement of premenstrual syndrome, with normal menstruation, aged 15 to 49 according to WHO, married, Qazvin resident. Women exclusion criteria: women who did not like to participate for any reasons, any known psychiatric diseases based on the patient manifestation, use of psychological drugs, have specific diet.

Intervention groups

100 married women with premenstrual syndrome referred to health centers in Qazvin city.

Main outcome variables

The main outcome variables: the depression, stress and anxiety of premenstrual syndrome will be assessed before and after the intervention.

General information

Reason for update

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT20171216037897N1**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **retrospective**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

farnaz fooladiha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3367 6336

Email address

f.fuladiha@qums.ac.ir

Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2017-11-09, 1396/08/18

Expected recruitment end date

2018-01-08, 1396/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling on depression, stress and anxiety of premenstrual syndrome

Public title

The effect of counseling on premenstrual syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women inclusion criteria: women with premenstrual syndrome based on index of measurement of premenstrual syndrome .with normal menstruation. married. aged 15 to 49 years old. Qazvin resident.

Exclusion criteria:

women who did not like to participate for any reasons. any known psychiatric diseases based on the patient manifestation. use of psychological drugs. have specific diet.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants of study are 100 women with premenstrual syndrome selected by a convenience sampling method. They were randomly (by 2 blocks method) selected and divided in 2 groups, trial(50) and control(50)

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**

دانشگاه علوم پزشکی قزوین

Street address

Qazvin university of medical science, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.QUMS.REC.1396.298

Health conditions studied**1****Description of health condition studied**

premenstrual syndrom

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Depression of premenstrual syndrome

Timepoint

Before and after intervention

Method of measurement

Questionnaire

2**Description**

stress of premenstrual syndrome

Timepoint

Before and after intervention

Method of measurement

Questionnaire

3**Description**

Anxiety of premenstrual syndrome

Timepoint

Before and after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the trial group received three sessions of group -counseling

Category

Behavior

2

Description

Control group: No interventions

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

health centers of Qazvin city

Full name of responsible person

Dr. Zinat Jourabchi

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Email

f.fuladiha@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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nursingpublicaffairs@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Jourabchi

Position

M.S. student

Latest degree

Bachelor

Other areas of specialty/work

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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

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

Not applicable

Title and more details about the data/document

All the data have code to identify.

When the data will become available and for how long

2020

To whom data/document is available

Qazvin University of Medical Science.

Under which criteria data/document could be used

By confirmation of Qazvin University of Medical Science.

From where data/document is obtainable

Qazvin University of Medical Science.

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

refer to Qazvin University of Medical Science or sending email to f.fuladiha@qums.ac.ir

Comments