

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of group counseling on resiliency to premenstrual syndrome in high school girls

Protocol summary

Summary

Objective: Assessing the effect of group counseling on resiliency to premenstrual syndrome in high school girls. This study is a randomized clinical trial. 120 girls with premenstrual syndrome who are eligible will be recruited to this study. Inclusion criteria: 15-17 year-old high school girls; Resident of Hamedan; Having moderate to severe premenstrual syndrome scores (scores of 19 and more); No response to treatment; The lack of history of physical and mental diseases. Exclusion criteria: Effective drug treatment. 120 girls with moderate to severe premenstrual syndrome will randomly be divided into intervention and control groups. The intervention group will be consulted for 8 sessions, 60 minutes, 2 sessions per week for 4 weeks. The control group will not receive counseling. One month after the intervention, in both groups, questionnaires will be completed. The instruments of collecting data are questionnaires on demographic information, PSST questionnaire and Connor-Davidson Resilience questionnaire. The primary outcome measure is Premenstrual syndrome and secondary outcome measure is Resiliency

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052615341N6**

Registration date: **2017-05-20, 1396/02/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Batul Khodakarami

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0447

Email address

khodakaramy@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling on resiliency to premenstrual syndrome in high school girls

Public title

The effect of resiliency on premenstrual syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 15-17 year-old high school girls; Resident of Hamedan; Having moderate to severe premenstrual syndrome scores (scores of 19 and up); The lack of effective drug treatment for the syndrome such as Sedatives, hypnotics, hormones and anti prostaglandins; The lack of a history of physical and mental diseases; Passing at least 6 menstrual cycles and

exclusion criteria: Effective drug treatment on the syndrome such as Sedatives, hypnotics, hormones and anti prostaglandins; The occurrence of events such as the death or illness of relatives; Failure to attend two consecutive meetings

Age

From **15 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The use of group counseling

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hamedan University of Medical Sciences

Street address

Vice Chancellor of Research and Technology,
Hamedan University of Medical Sciences, Shahid Fahmideh St

City

Hamedan

Postal code

6516845977

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.UMSHA.REC.1395.220

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

Premenstrual syndrome

Timepoint

Before and after the intervention.

Method of measurement

Standard questionnaire PSST(Premenstrual Symptoms Screening Tool)

Secondary outcomes

1

Description

Resiliency

Timepoint

Before and after intervention

Method of measurement

Connor-Davidson Resilience questionnaire

Intervention groups

1

Description

Intervention group: Eight group counseling sessions on the resiliency for 60 minutes for twice a week for 4 weeks

Category

Behavior

2

Description

control group: Counseling sessions are not held

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

High School Girls of Hamedan city

Full name of responsible person

Narges Babakhani(MSc Student of Counseling in Midwifery)

Street address

Taleghani Avenue. Hamedan of Department of Education

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research the Technology,
Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

Hamedan University of Medical Science, Shahid
Fahmide St

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor of Research the Technology, Hamedan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Batul Khodakarami

Position

Master of Sciences, Faculty of Nursing and Midwifery
College

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty