

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigating the impact of life skills education on students' premenstrual syndrome symptom severity , residing in dormitories of Ferdowsi University of Mashhad in the school year 2012-2013

Protocol summary

Summary

Introduction: Premenstrual syndrome includes a set of unpleasant physical, emotional or behavioral symptoms which can be observed in luteal phase of the menstrual cycle, in repeated form. 90% of women experience some grades of premenstrual syndrome symptoms. Yet, no definitive treatment has been certified for premenstrual syndrome. This paper tends to investigate the impact of life skills education on students premenstrual syndrome symptom severity, residing in dormitories of Ferdowsi University of Mashhad in the school year 2012-2013.

Method: This research is on a clinical trial basis with two groups. The research sample includes 68 first year bachelor's students, placed in two groups of education and control. Inclusion criteria: premenstrual syndrome, first year bachelor's students residing in dormitory Ferdowsi University of Mashhad, regular menstruation, consent to participate in the study, the GHQ score less than 28 and having at least 5 symptoms of DSMIV PMS symptoms questionnaire. Exclusion criteria was history of regular exercise at 3 months before the study; special diet; use of health plans, pharmacologically and non-pharmacologically plant to relieve premenstrual problems than 3 days before start the study; history of chronic diseases; major accident during the 3 months prior start the study; absence more than one session classes training life skills; introduction to life skills , fields of education psychology, sociology, education and culture, failure to complete calendar day state of PMS symptoms. 4 skills self- Awareness, effective communication, stress management, and coping with anger were taught to the education group in 8 sessions. 8 session were held for the control group and each session Were given a sexually transmitted disease form to individuals and their questions were answered. Data collection tools include: menstrual and individual information questionnaire, general health questionnaire, form of temporary

diagnosis of premenstrual syndrome, daily status registration form, knowledge and attitude assessment form about premenstrual syndrome and life skills. Life skills were taught to the education group in 8 sessions. Data were analyzed, using SPSS16 software and statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052813490N1**

Registration date: **2013-08-13, 1392/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-13, 1392/05/22

Registrant information

Name

Roghayeh Dadi Givshad

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 1431 0943

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dadir891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-01-28, 1391/11/09

Expected recruitment end date

2013-06-04, 1392/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of life skills education on students' premenstrual syndrome symptom severity, residing in dormitories of Ferdowsi University of Mashhad in the school year 2012-2013

Public title

The impact of life skills education on premenstrual syndrome symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: premenstrual syndrome; single and Iranian nationality; student residing in dormitories Ferdowsi University of Mashhad; regular monthly period (the interval between two menstrual cycles 33-28 days and 7-10 days); consent to participate in research; the score less than 28 in GHQ; had least 5 mark (must one of the first symptoms of the four symptoms.) of the form DSMIV (PMS questionnaire based on the Diagnostic and Statistical Manual of Mental Disorders criteria). Exclusion criteria: history of regular exercise at 3 months before the study; special diet; use of health plans, pharmacologicall and non-pharmacologicall plant to relieve premenstrual problems than 3 days before start the study; history of chronic diseases; major accident during the 3 months prior start the study; absence more than one session classes training life skills; introduction to life skills (through attending workshops, reading books and other methods); fields of education, psychology, sociology, education and culture; failure to complete calendar day state of PMS symptoms.

AgeFrom **18 years** old to **23 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description**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**

Mashhad University of Medical Sciences

Street address

Doctora Cross, Faculty of Nursing and Midwifery

City

Mashhad

Postal code**Approval date**

2012-05-11, 1391/02/22

Ethics committee reference number

910594

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 symptom severity

Timepoint

Two months before and one month after intervention

Method of measurement

Daily Calendar form of premenstrual syndrome

Secondary outcomes**1****Description**

Psychological and physical premenstrual syndrome symptom severity

Timepoint

Two months before and one month after intervention

Method of measurement

Daily Calendar of PMS symptoms

Intervention groups**1****Description**

4 skills self- Awareness, effective communication, stress

management, and coping with negative emotions (anger) were taught to the education group in 8 sessions (2 sessions each skill, each session lasting for 2 hours). training Were taught by the researcher After passing life skills training and confirmed psychologist .

Category

Behavior

2**Description**

8 sessions were held for the control group and each session were given a sexually transmitted disease form to individuals and their questions were answered training form presented at the session include women genital tract, sexually transmitted diseases, AIDS, vaginitis and chlamydia infection, gonorrhea, syphilis, herpes and genital warts.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pardis dormitories 2 and 4 Ferdowsi University of Mashhad

Full name of responsible person**Street address****City**

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad - Daneshgah Avenue, Building Qureshi. Research Council of Mashhad University of Medical Sciences

City

Mashhad

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

Yes

Title of funding source

Mashhad 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**

Faculty of Nursing and Midwifery

Full name of responsible person

Roghayeh Dadi Givshad

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MSc Student

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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