Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparative investigation between the effectiveness of Achillea wilhelmsii tablet and group counseling based on acceptance and commitment on Pre Menstrual Syndrome (PMS) symptoms in students living in the dormitories

Protocol summary

Study aim
Determining and comparing the effectiveness of yarrow extract and group counseling based on acceptance and commitment on the symptoms of premenstrual syndrome in students living in dormitories

Design
This study is a randomized controlled clinical trial

Settings and conduct
First, after obtaining the code of ethics from the ethics committee of Kerman University of Medical Sciences and obtaining the code of clinical trial and presenting a letter of introduction to the person in charge of the dormitories, the researcher referred to the dormitories affiliated to the University of Medical Sciences and from the list of dormitory students, 264 people who met the inclusion criteria they enter the study in an accessible way

Participants/Inclusion and exclusion criteria
Criteria for entering the research: All samples should have a menstrual cycle duration of 35-24 days، Being single، The age of the samples should be between 18-45 years، Samples with premenstrual syndrome for at least six months and tend to participate in the study، Do not have any mental or physical illness. Exclusion criteria: Occurrence of intermittent changes in menstrual cycles less than 24 days and more than 35 days، Occurrence of changes in the length of the menstrual period less than 3 days and more than 8 days، Participating in a simultaneous counseling program، Existence of severe stress in the last quarter such as: death of relatives, marriage or surgery Pregnant and lactating women

Intervention groups
The counseling group will receive 8 sessions of 90-minute counseling based on acceptance and commitment once a week, and the yarrow group will be given yarrow pills at variable doses that follow the estrogen pattern of the menstrual cycle, and the control group will not receive any treatment.

Main outcome variables
Symptoms of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201027049164N2**
Registration date: **2021-09-16, 1400/06/25**
Registration timing: **prospective**

Last update: **2021-09-16, 1400/06/25**
Update count: **0**

Registration date
2021-09-16, 1400/06/25

Registrant information

Name
Masumeh Ghazanfarpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-24, 1400/07/02

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation between the effectiveness of Achillea wilhelmsii tablet and group counseling based on acceptance and commitment on Pre Menstrual Syndrome (PMS) symptoms in students living in the dormitories

Public title

Comparative investigation between the effectiveness of Achillea wilhelmsii tablet and group counseling based on acceptance and commitment on Pre Menstrual Syndrome (PMS) symptoms

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All samples should have a menstrual cycle duration of 35-24 days. Being single The age of the samples should be between 18-45 years. Samples with premenstrual syndrome for at least six months and tend to participate in the study. Do not have any mental or physical illness. Do not take any chemical and herbal medicines Do not take birth control pills Have at least one symptom of mental and physical symptoms that should begin 16 days after menstruation

Exclusion criteria:

Menstrual period is less than 3 days and more than 8 days Interval of menstrual cycles less than 24 days and more than 35 days Existence of severe stress in the last trimester such as: death of relatives, marriage or surgery Pregnant and lactating women Participating in a simultaneous counseling program

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **264**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple randomization, the numbers 1 to 135 are assigned to the participants, respectively. Then, using online software to generate random sequences (www.randomizer.org), they will be divided into three groups of 45 will be placed in the counseling group and the yarrow and control receiving group.

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 Kerman University of Medical Sciences

Street address

Deputy of Research and Technology;ebne-e-Sina St.,Jahad Blvd., Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.KMU.AH.REC.1400.090

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

Symptoms of premenstrual syndrome

Timepoint

Beginning of the study (before the start of the intervention) and end of the intervention

Method of measurement

Daily Symptom Report Questionnaire (DSR)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: The counseling group will receive 8 sessions of 90-minute counseling based on acceptance and commitment once a week.
Category
Treatment - Other

2

Description
Intervention group2: The yarrow group is given yarrow pills at variable doses that follow the estrogen pattern of the menstrual cycle. Thus, at first, the estrogen menstrual cycle is low, and then, like the normal menstrual cycle, when estrogen levels gradually increase, the dose of yarrow pills increases. The maximum dose of the pill is given on the fourteenth day according to the peak estrogen in the normal cycle. Then, as in the normal cycle, when the amount of estrogen decreases, the dose of yarrow tablets decreases, ie the dose of the drug starts from 70 mg, twice a day, and until the fourteenth day, we add 10 mg every day, and on the fourteenth day the maximum dose is 200 mg. We will have 14 days
Category
Treatment - Drugs

3

Description
Control group: They do not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitories affiliated to Kerman University of Medical Sciences
Full name of responsible person
zahra pakdel
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Pardakhti
Street address
Vice Chancellor for Research and Technology, Kerman University of Medical Sciences,Tahmasbabad Crossroads
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zahrapakdel75@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
zahra pakdel
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Masoumeh Ghazanfarpour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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

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