

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effects of healthy diet in reducing symptoms of premenstrual syndrome and improving quality of life among Omani Adolescents; a randomized controlled open label trial

Protocol summary

Study aim

To study the effects of a healthy and well-balanced diet in reducing symptoms of premenstrual syndrome and improving quality of life among Omani Adolescents

Design

a prospective, open-label, randomized controlled trial of two parallel groups

Settings and conduct

The study will be conducted in three randomly selected secondary schools in Al Seeb Willayah, in Muscat region. Subjects in the intervention group will receive an individual face-to-face dietary consultation by a well-experienced dietician. Subjects in the control group will not receive dietary advice at baseline. Notably, both groups will receive similar advice regarding physical exercise at baseline.

Participants/Inclusion and exclusion criteria

Inclusion: Adolescents in grade 10 or 11, aged 16 years to 19 years, and have regular menstrual cycles.
Exclusion: known to have a psychiatric disorder (such as depression, generalized anxiety disorder, post-traumatic stress disorder, psychotic disorders), diabetes, thyroid disease, oral contraceptive use, herbal remedy use for PMS symptoms, or had dietary advice before for PMS symptoms.

Intervention groups

Subjects in the intervention group will receive an individual face-to-face dietary consultation by a well-experienced dietician. Subjects in the control group will not receive dietary advice at baseline. A healthy diet includes: i) carbohydrates (330-450 g), ii) protein (48-60 g), iii) fibers (19-48 g), iv) energy (2400 kcal), v) calcium (600-960 mg), vi) salt (<5 gm/day) (24), limit extra salt, caffeine, and sugar intake.

Main outcome variables

Improvements in the severity of premenstrual symptoms and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049526N1**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **prospective**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Zaleikha Albelushi

Name of organization / entity

Ministry of health, Oman

Country

Oman

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-01, 1399/11/13

Expected recruitment end date

2021-06-30, 1400/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of healthy diet in reducing symptoms of premenstrual syndrome and improving quality of life among Omani Adolescents; a randomized controlled open label trial

Public title

A healthy diet and premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescents who are at grade 10 or 11, aged 16 years to 19 years old, and have regular menstrual cycles will be included in the study

Exclusion criteria:

known to have psychiatric disorders (such as depression, generalized anxiety disorder, post-traumatic stress disorder, psychotic disorders), diabetes, thyroid disease, oral contraceptive use, herbal remedy use for PMS symptoms, and those who have had dietary advice before for PMS symptoms.

Age

From **16 years** old to **19 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Consecutive or random sampling using computer-generated random number table will be used for the recruitment stage, depending on the prevalence rate of PMS (i.e if the prevalence is high, random sampling will be applied, whereas consecutive sampling will be utilized if there is a limited number of adolescents with PMS). Cluster randomization of schools will be carried to minimize contamination anticipated from recruiting subjects from the same school. Therefore, the intervention and control groups will be derived from different schools.

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 Ministry of Health

Street address

P.O.Box:393, Post code:100, Muscat, Oman

City

Muscat

Postal code

100

Approval date

2020-11-23, 1399/09/03

Ethics committee reference number

MoH/CSR/20/23884

Health conditions studied

1

Description of health condition studied

premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

premenstrual syndrome

Primary outcomes

1

Description

The improvements in the severity of premenstrual symptoms

Timepoint

At baseline and 2 months after intervention

Method of measurement

Daily Record of Severity of Problem (Arabic version)

Secondary outcomes

1

Description

Improvements in quality of life

Timepoint

at baseline and at the end of 2 months of starting the intervention

Method of measurement

The medical outcome study short form-36 (SF-36) and Perceived stress scale PSS

Intervention groups

1

Description

Intervention group :Subjects in the intervention group will receive an individual face-to-face dietary

consultation by a well-experienced dietician. She will educate the participants about the importance of healthy diet, evaluate the baseline dietary habits of each participant and give advice on how to modify them. The healthy diet advice is derived from the food-based dietary guidelines (FBDG) that were proposed for Omani adolescents (24). FBDG for Omani adolescents includes a daily intake of the following: i) carbohydrates (330-450 g), ii) protein (48-60 g), iii) fibers (19-48 g), iv) energy (2400 kcal), v) calcium (600-960 mg), vi) salt (<5 gm/day) (24). Subjects will be specifically advised to limit extra salt, caffeine and sugar intake. Special weighted scoops will be provided to each participant in order to estimate the amount of specific food intake at certain meal (e.g. rice, pasta, etc.). Then, all the participants will be instructed to fill in an online application of their type and amount of food intake on a daily basis. The dietician will assess the compliance to healthy diet through the online application and give advice where necessary. A motivational phone consultation for each participant in the intervention group will be carried out by the principal and co-principal investigators once every two weeks throughout the study period. It will basically include motivating the participants to comply with the dietary advice given and find out any challenges that they may have encountered which may impede their adherence. Both groups (intervention and control group) will receive similar advice regarding physical exercise at baseline.

Category

Treatment - Other

2**Description**

Control group: Subjects in the control group will not receive dietary advice at baseline. However, dietary counseling for each subject in the control group will be provided at the end of the study by the same dietician. Notably, both groups (intervention and control group) will receive similar advice regarding physical exercise at baseline.

Category

Other

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

three randomly selected secondary schools in Al Seeb Willayah, in Muscat region

Full name of responsible person

Zaleikha Issa Al belushi

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Khadraween road

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Shinas

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Email

albelushi11@hotmail.com

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

application for fund was done and still awaiting approval

Full name of responsible person

Ethics committee of center of studies and research in Ministry of health

Street address

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Email

albelushi11@hotmail.com

Web page address

<https://www.moh.gov.om/>

Grant name

application for fund was done and still awaiting approval

Grant code / Reference number

application for fund was done and still awaiting approval

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

No

Title of funding source

application for fund was done and still awaiting approval

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**

Ministry of health

Full name of responsible person

Zalekha Issa Ali Al Belushi

Position

Speialist

Latest degree

Specialist

Other areas of specialty/work

Family Physician

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ministry of health,Oman

Full name of responsible personEthics committee of center of studies and research in
Ministry of health**Position**

Specialist

Latest degree

Specialist

Other areas of specialty/work

Family Physician

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Web page address<https://www.moh.gov.om>**Person responsible for updating data****Contact****Name of organization / entity**

Ministry of health,Oman

Full name of responsible personEthics committee of center of studies and research in
Ministry of health**Position**

Specialist

Latest degree

Specialist

Other areas of specialty/work

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Web page address<https://www.moh.gov.om>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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 CodeUndecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**

Yes - There is a plan to make this available

Title and more details about the data/documentAll collected deidentified IPD from the study titled:
Effects of healthy diet in reducing symptoms of
premenstrual syndrome and improving quality of life
among Omani Adolescents; a randomized controlled
open label trial**When the data will become available and for how long**

Starting 6 months after publication

To whom data/document is available

Academic institutions only

Under which criteria data/document could be used

For Systematic Reviews and Metaanalysis

From where data/document is obtainable

Dr.Zaleikha Al Belushi : albelushi11@hotmail.com

What processes are involved for a request to access data/documentAuthorized researchers from academic institutions only
can get in touch with Dr Zaleikha Al belushi at her above
email address.**Comments**