

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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

##### Phone

+968 26 724056

##### Email address

drzulikha.albalushi@moh.gov.om

##### 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

**Street address**

Khadraween road

**City**

Shinas

**Postal code**

324

**Phone**

+968 26 724056

**Fax**

+968 26 724043

**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**

Khadraween road

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324

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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

**Street address**

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North Batinah governorate

**Postal code**

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

Ministry of health,Oman

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

Specialist

**Latest degree**

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**Email**

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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 Code**Undecided - 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/document**All 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/document**Authorized researchers from academic institutions only  
can get in touch with Dr Zaleikha Al belushi at her above  
email address.**Comments**