Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 icludes: 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
Muscta
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 lcal), 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

City

Shinas

Postal code

324

Phone

+968 26 724056

Fax

+968 26 724043

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
Khadraween road
City
Shinas
Province
North Batinah governorate
Postal code
324
Phone
+968 26 724056
Fax
+968 26 724043
Email
albelushi11@hotmail.com

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
Street address
Khadraween road
City
Shinas
Province
North Batinah governorate
Postal code
324
Phone
+968 26 724056
Fax
+968 26 724043
Email
albelushi11@hotmail.com
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
Specialist
Other areas of specialty/work
Family Physician
Street address
Khadraween road
City
Shinas
Province
North Batinah governorate
Postal code
324
Phone
+968 26 724056
Fax
+968 26 724043
Email
albelushi11@hotmail.com
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 Metaanalysi
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