Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of exercises program versus no exercise on duration and severity of dysmenorrhea among students with primary dysmenorrhea: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of exercises program versus no exercise on duration and severity of dysmenorrhea among students with primary dysmenorrhea. Design: A randomized clinical trial. Setting and conduct: The eligible students with primary dysmenorrhea who are educating at the School of Nursing and Midwifery during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 25 years; single; mild or moderate dysmenorrhea; regular cycles with 21 to 35 days interval. Exclusion criteria: chronic diseases; genital organ diseases; physical disability; educated in midwifery; regular physical activity in control group; resident of dormitory. Intervention group: Routine care plus physical activity one hour per day 3 times a week for 12 weeks. Control group: Just routine care. Primary outcome: (a) assessing the severity of dysmenorrhea before intervention and 12 weeks after that using McGill pain ruler; (b) assessing duration of dysmenorrhea before intervention and 12 weeks after that by history taking. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708309014N179**
Registration date: **2017-09-30, 1396/07/08**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2017-09-30, 1396/07/08

Registrant information

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Name of organization / entity

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Recruitment status

Not enough for processing

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of exercises program versus no exercise on duration and severity of dysmenorrhea among students with primary dysmenorrhea: a randomized clinical trial

Public title

Effects of exercises program versus no exercise on duration and severity of dysmenorrhea among students with primary dysmenorrhea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 25 years; single; mild or moderate dysmenorrhea; regular cycles with 21 to 35 days interval. Exclusion criteria: chronic diseases; genital organ diseases; physical disability; educated in midwifery; regular physical activity in control group; resident of dormitory.

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Postal code

6517838695

Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

IR.UMSHA.REC.1396.312

Health conditions studied

1

Description of health condition studied

Dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Assessing the severity of dysmenorrhea

Timepoint

Before intervention and 12 weeks after that

Method of measurement

Using McGill pain ruler

2

Description

Assessing duration of dysmenorrhea

Timepoint

Before intervention and 12 weeks after that

Method of measurement

By history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care plus physical activity one hour per day 3 times a week for 12 weeks.

Category

Other

2

Description

Control group: Just routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nursing and Midwifery

Full name of responsible person

Elahe Abdolmaleki

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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research and Technology, Hamadan 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

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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