

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

Hamadan

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

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

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

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Elahe Abdolmaleki

Position

Midwifery Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 38380572

Fax

Email

Elaheabdolmaleki.95@ gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Dr Seyyedh Zahra Masoomi

Position

Specialist in Fertility Hygiene

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0572

Fax

Email

zahramid2001@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

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