Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of the effect of stretching exercises and a combination of massage - stretching exercises on primary dysmenorrheal of female students of RAZI University of Kermanshah

Protocol summary

Study aim
The comparison of the effect of stretching exercises and a combination of massage - stretching exercises on primary dysmenorrheal of female students of RAZI University of Kermanshah

Design
This study is a non-blinded clinical trial. The study population will be included all female students with painful menstruation of Razi university of Kermanshah.90 eligible students will be selected conveniently and randomly will be assigned to three groups (two intervention groups, one control group).

Settings and conduct
This study which will be conducted in Razi university of Kermanshah city is non-blinded .At the beginning and the end of the study, the pain questionnaire will be provided for eligible students and all three groups will be compared at the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having regular and painful menstruation; Lack of severe stress such as the death of a family member Exclusion criteria: Surgery in the last three months; Marriage record

Intervention groups
The first intervention group (stretching exercises), will receive abdominal, pelvic and groin stretching exercises, 4 days a week, 15 minutes each time for 8 weeks. The second intervention group (massage and stretching exercises) will receive massage and exercise, 4 days a week, 15 minutes each day for 8 weeks. The control group will not receive any intervention

Main outcome variables
dismenorrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N111**
Registration date: **2019-01-06, 1397/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-06, 1397/10/16**
Update count: **0**

Registration date
2019-01-06, 1397/10/16

Registrant information

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-06, 1397/09/15

Expected recruitment end date
2019-02-04, 1397/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The comparison of the effect of stretching exercises and a combination of massage - stretching exercises on primary dysmenorrheal of female students of RAZI University of Kermanshah

Public title
Comparison of the effect of stretching exercises and a combination of massage - stretching exercises on primary dysmenorrheal

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having regular and painful menstruation Lack of severe stress such as the death of a family member

Exclusion criteria:
Known physical or mental illness or treated Surgery in the last three months Non-use of pain relief medication during study Marriage record

Age
No age limit

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly Individually by random number table via code receipt. 90 similar cards will be provided which 45 of them are coded 1 which is indicative of the intervention group, and 45 of them are coded 2 which is indicative of the control group.Anyone who is eligible for inclusion in the study will selected one of these cards randomly (participants will not be aware of the type of intervention that they are assigned to).

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 Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2018-05-22, 1397/03/01

Ethics committee reference number
ir.kums.rec.1397.086

Health conditions studied

1

Description of health condition studied
Primary dismenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
dismenorrhea

Timepoint
Before and after the intervention

Method of measurement
Base on McGill Pain Questionnaire(MPQ)

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group (stretching exercises), will receive abdominal, pelvic and groin stretching exercises , 4 days a week ,15 minutes each time for 8 weeks .

Category
Treatment - Other

2

Description
The second intervention group (massage and stretching exercises) will receive massage and exercise, 4 days a week ,15 minutes each day for 8 weeks

Category
Treatment - Other

3

Description
The control group will not receive any intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi University
Full name of responsible person
Leila Farhadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
بلوار شهید بهشتی، ساختمان شماره 2، دانشگاه علوم پزشکی، معاونت تحقیقات و فناوری
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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
Kermanshah University of Medical Sciences
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
Kermanshah University of Medical Sciences
Full name of responsible person
Leila Farhadi
Position
Ph.D Student in Sport Pathology
Latest degree
Master
Other areas of specialty/work
sport pathology
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Latest degree
Master

Other areas of specialty/work
sport pathology

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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
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared.

When the data will become available and for how long
4 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
With the aim of using the results of studies to upgrade future studies

From where data/document is obtainable
To receive the documentation, email send for update manager

What processes are involved for a request to access data/document
In a 45-day period, the documents will be sent e-mail

Comments