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 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
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 dysmenorrheoa

**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
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
Street address
Parastar Blvd, Razi University
City
Kermanshah
Province
Kermanshah
Postal code
714241971
Phone
+98 83 3427 7605
Email
khalily1267@yahoo.com

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
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
fnajafi@kums.ac.ir
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

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
Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3826 1046
Email
khalily1267@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mozhgan Khalili
Position
Faculty Member of Kermanshah University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3826 1046
Email
khalily1267@yahoo.com
Person responsible for updating data

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
- Street address: Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery
- City: Kermanshah
- Province: Kermanshah
- Postal code: 6715847141
- Phone: +98 83 3826 6429
- Email: khalily1267@yahoo.com

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