Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Taping Therapy in Primary Dysmenorrhea (PD) and Premenstrual Syndrome (PMS) in female students of Sardasht universities in 2018-2019

Protocol summary

Study aim

The effect of taping therapy in primary Dysmenorrhea and Premenstrual syndrome in female students of Sardasht in 2019

Design

A randomized double-blind, before-after clinical trial

Settings and conduct

Participants will be followed for 3 cycles. In the first cycle, the sensitivity test was performed with a small piece of tape on hands, and in the next cycle, both groups had to inform the researcher about the menstrual cycle for 6 days. Installation of the tape in the Ava occupational therapy clinic by researcher who is also licensed to install the type In the Sardasht city of West Azerbaijan study area.

Participants/Inclusion and exclusion criteria

inclusion criteria:18-25 years, single, regular menstrual period (21-35 days), presence of primary menstrual pain in most menstrual cycles during the last 6 months, having a score of 4-10 Pain ruler, having at least one PMS diagnostic criteria, score below 92 based on MDQ questionnaire, no adverse events occurring in the last 6 months, no psychiatric medication, no type allergy, no history of any tendency to adhere to the tape, unwillingness to continue to cooperate, and significant change in one's lifestyle depending on his / her statement. exclusion criteria: Having any disease that affects the results of study, including mental illness and genital disease

Intervention groups

Intervention group: Kinesio tape adhesive strips have taped. After 5 days inform the researcher about the changeover to the clinic. It should be noted that the type stays on the skin does not interfere with their daily activities and since waterproof type will be used, there is no obstacle bathing with the type and this will be told to the students. This is done for 10 days. 5 days before and 5 days after menstruation. The control group will also receive a tape with a non-effect of Kinesio tape.

Main outcome variables

Primary Dysmenorrhea, Premenstrual Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045790N1**
Registration date: **2020-06-25, 1399/04/05**
Registration timing: **retrospective**

Last update: **2020-06-25, 1399/04/05**
Update count: **0**

Registration date

2020-06-25, 1399/04/05

Registrant information

Name

Seyran Khezri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4433 5574

Email address

seyran.khezri.m@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2019-09-22, 1398/06/31

Scientific title

The effect of Taping Therapy in Primary Dysmenorrhea (PD) and Premenstrual Syndrome (PMS) in female students of Sardasht universities in 2018-2019

Public title

The effect of Taping Therapy in Primary Dysmenorrhea and Premenstrual Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age range 18-25 single Regular menstrual cycle (35-21 days) The existence of Early dysmenorrhea cramps in most menstrual cycles over the past 6 months Having 4-10 score, based on visual analog pain Scale Having a below score 92, based on the Menstrual Distress Questionnaire Do not take psychiatric medications Lack of sensitivity to tape No history of alcohol use No smoking Having at least one of the diagnostic criteria for premenstrual syndrome

Exclusion criteria:

Having any disease that affects the results of study, including mental illness and genital disease

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **25**

Actual sample size reached: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, out of 393 female students of Sardasht universities, we will determine eligible people to participate in the study based on the entry and exit criteria. The goal of the study and the probability of being assigned to intervention or control group will be explained to eligible participants in the study. If someone wishes to participate in the study, a written consent will be obtained consciously and based on the output of the following software, from the first to fiftieth people who have tended to participate in the study will be assigned to intervention and control groups by method of random blocking of 4. Eligible individuals will be assigned to control and intervention groups in 13 blocks of 4 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants will be told that they have been chosen in order to examine the effect of taping therapy on the severity of primary dysmenorrhea and premestrual syndrome. they will be divided into two random groups but without them noticing it. the intervention group will be provided with the real tape, but the control group will be provided with the similar tape without having real impact.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Orumieh University of Medical Sciences

Street address

Jihad Square, next to the emergency

City

Urmia

Province

West Azarbaijan

Postal code

1107894302

Approval date

2019-06-10, 1398/03/20

Ethics committee reference number

IR.UMSU.REC.1398.044

Health conditions studied

1

Description of health condition studied

Dysmenorrhea, premenstrual syndrome

ICD-10 code

N94.6

ICD-10 code description

Dysmenorrhea, unspecified, premenstrual syndrome

Primary outcomes

1

Description

Pain score on Visual Analogue Scale questionnaire

Timepoint

Measurement of Visual Analogue Scale at the beginning and end of the study

Method of measurement

Visual Analogue Scale, menstrual distress questionaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Keynesian tape is a waterproof tape without chemical adhesive. The 3NS TEX brand, made in Korea, measures 5 cm by 5 m. It is installed by a researcher for two menstrual cycles from 5 days before menstruation, after 5 days it is removed by the person and after 24 hours of skin respiration, Re-installed by the researcher and left on the site for another 5 days. In total, the tape is installed on the pain area for 10 days.
Category
Treatment - Other

2

Description
Control group: The actions taken for the intervention group are done exactly for the comparison group without real tape
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Azad University of Sardasht, Payame Noor University of Sardasht
Full name of responsible person
Seyran Khezri
Street address
Mellat Street, Second Alley, Miss Puri's Home
City
Sardasht
Province
West Azarbaijan
Postal code
2035846441
Phone
+98 44 4433 5574
Email
seyran.khezri.m@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Doctor Mohebbi
Street address
Jihad Square, next to the emergency110
City
Orumieh
Province
West Azarbaijan
Postal code
1102598712
Phone
+98 44 3275 5001
Email
Soheila80@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Soheila Rabipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Nazlou, Urmia University of Medical Sciences, School of Nursing and Midwifery
City
Urmia
Province
West Azarbaijan
Postal code
8202254554
Phone
+98 44 3275 5001
Email
Soheila80@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Oroumia University of Medical Sciences
Full name of responsible person
Seyran Khezri
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Mellat
City
Sardasht
Province
West Azarbaijan
Postal code
2333565984
Phone
+98 44 4433 5574
Fax
Email
seyran.khezri.m@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Seyran Khezri
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Mellat
City
Sardasht
Province
West Azarbaijan
Postal code
2335659870
Phone
+98 44 4433 5574
Fax
Email
seyran.khezri.m@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available