

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 premenstrual 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 questionnaire

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