

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Mandala staining on anxiety, Intensity of pain and dysmenorrhea symptoms in girls with dysmenorrhea

Protocol summary

anxiety; pain intensity; Symptoms of dysmenorrhea

Study aim

The effect of mandala staining on anxiety, Intensity of pain and dysmenorrhea symptoms in girls with dysmenorrhea

Design

Clinical trial with control and intervention groups, randomized, with a sample size of 80 people. The rand function of Excel software was used for randomization.

Settings and conduct

This study will be conducted on female students at Arak University, in the form of pre-test and post-test in two control and intervention groups, for two consecutive cycles. In the intervention group, during two days before menstruation and 3 days at the beginning of menstruation 5 days) they will color a mandala design that will be given to them by the researcher at the beginning of the month along with a pack of 6 colored pencils. It is better to color in the early morning and after waking up. Due to the higher concentration, no intervention is performed in the control group during one cycle.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Arak university students; having at least 18 years of age; Absence of known physical and mental illness Exclusion criteria: irregular menstrual cycle, chronic pelvic disease, surgery in the last three months, Continuous use of painkillers

Intervention groups

In the intervention group, during two days before menstruation and 3 days at the beginning of menstruation (5 days in total), they will color a mandala design, which will be provided to them by the researcher at the beginning of the month along with a pack of 6 colored pencils. and this work will continue for two menstrual periods. It is better to paint in the beginning of the morning and after waking up due to higher concentration. In the control group, no intervention is done during one cycle.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055351N1**

Registration date: **2022-09-02, 1401/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-02, 1401/06/11**

Update count: **0**

Registration date

2022-09-02, 1401/06/11

Registrant information

Name

Mahsa Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-05, 1401/04/14

Expected recruitment end date

2022-10-06, 1401/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	sequence, the person who examined the participants in terms of entry and exit criteria and enrolled them in the study, and the person who divided the participants into groups is the data allocation, the person who performs the data analysis and the researcher will not know about the group allocation.
Scientific title The effect of Mandala staining on anxiety, Intensity of pain and dysmenorrhea symptoms in girls with dysmenorrhea	Placebo Not used
Public title The effect of Mandala staining in girls with dysmenorrhea	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Female students of Arak universities Having at least 18 years of age Exclusion criteria: Presence of known physical and mental illness Presence of known chronic pelvic disease Surgery in the past three months Use of contraceptive pills The onset of menstrual pain after the age of 20 Irregular menstrual cycles	Secondary Ids empty
Age From 18 years old	Ethics committees
Gender Female	1
Phase N/A	Ethics committee
Groups that have been masked • Care provider • Investigator • Outcome assessor • Data analyser • Data and Safety Monitoring Board	Name of ethics committee Ethics committee of Arak University of Medical Sciences
Sample size Target sample size: 80	Street address Arak University of Medical Sciences, Basij Square, Sardasht, Arak
Randomization (investigator's opinion) Randomized	City Arak
Randomization description In the first step, to create a random sequence or random sequence generation, first, each of the 80 volunteers who meet the criteria for entering the study by randomization using the random block method by statistical software and individually and assigning students in two groups of 40 Intervention and control will be based on even and odd numbers. The second stage of concealment of randomization or Allocation concealment, in this research, according to the allocation of the drawing of the Mandela plan for one group and not doing this for the second group of participants will be studied. In the third stage of randomization or implementation of the process, the person who created the random sequence, the person who examined the participants in terms of entry and exit criteria and enrolled them in the study, and the person who divided the participants into groups is the data allocation, the person who performs the data analysis and the researcher will not know about the group allocation.	Province Markazi
Blinding (investigator's opinion) Double blinded	Postal code 3813944438
Blinding description In the third stage of randomization or implementation of the process, the person who created the random	Approval date 2022-03-06, 1400/12/15
	Ethics committee reference number IR.ARAKMU.REC.1400.344
	Health conditions studied
	1
	Description of health condition studied Primary dysmenorrhea
	ICD-10 code N94.4
	ICD-10 code description Primary dysmenorrhoea
	Primary outcomes
	1
	Description Anxiety
	Timepoint once before the intervention from the time people entered the study and once after the intervention by the relevant questionnaire in the control and intervention groups.
	Method of measurement Spellberger's questionnaire

2

Description

intensity of pain

Timepoint

once before the intervention from the time people entered the study and once after the intervention by the relevant questionnaire in the control and intervention groups.

Method of measurement

Numerical Pain Scale Questionnaire

3

Description

Symptoms of dysmenorrhea: In this research, symptoms of dysmenorrhea will be measured using the standard mouse menstrual questionnaire.

Timepoint

once before the intervention from the time people entered the study and once after the intervention by the relevant questionnaire in the control and intervention groups.

Method of measurement

Mouse menstrual standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, during two days before menstruation and 3 days at the beginning of menstruation (5 days in total), they will color a mandala design, which will be provided to them by the researcher at the beginning of the month along with a pack of 6 colored pencils. and this work will continue for two menstrual periods. It is better to paint in the beginning of the morning and after waking up due to higher concentration. In the control group, no intervention is done during one cycle. And in order to achieve the most accurate date of the intervention, the intervention group is asked to write down the exact date of their menstruation one cycle before the start of the intervention and fill the relevant questionnaires immediately after the end of this cycle. Mandala coloring includes circular designs that are used as a tool for meditation and psychological improvement, 10 designs are provided to each participant in the intervention group.

Category

N/A

2

Description

Control group: In the control group, no intervention is performed during one cycle.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medical Sciences

Full name of responsible person

mahsa hosseini

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Sponsors / Funding sources

1

Sponsor

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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

Arak 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
Arak University of Medical Sciences
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Mahsa Hosseini
Position
Nursing student of Arak University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available