Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
anxiety; pain intensity; Symptoms of dysmenorrhea

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

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

Public title
The effect of Mandala staining in girls with dysmenorrhea

Purpose
Treatment

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

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

Blinding description
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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij Square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3813944438

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: n 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
Name of organization / entity
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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

Full name of responsible person

Mahsa Hosseini

Position

Nursing student of Arak University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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