Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of computer-based Stress Inoculation Training (SIT) approach on the pelvic pain, depression, and anxiety in students with primary dysmenorrhea

Protocol summary

Study aim
Determining the effectiveness of computer-based stress Inoculation approach on pelvic pain, depression, and anxiety symptoms of students with primary dysmenorrhea

Design
Clinical trial study before and after the intervention

Settings and conduct
The present study is a clinical trial study before and after the intervention, which was conducted on 100 students with primary dysmenorrhea at Babol University of Medical Sciences. Eligible students for the study were randomly selected and received individual counseling with the SIT approach for 8 sessions (once a week and each session lasts 50 minutes). All study questionnaires were completed in four stages (the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention).

Participants/Inclusion and exclusion criteria
Being Iranian Declaration of consent to participate in the study Age range from 18 to 38 years Having any degree (one, two, or three) of primary dysmenorrhoea having regular menstrual cycles with intervals of 21 to 35 days and a duration of 3 to 10 days at least during the last six months Obtaining a score of 8 or higher on the HADS questionnaire Access to smartphones

Intervention groups
Intervention group with sIT approach

Main outcome variables
Pelvic pains, symptoms of depression and anxiety, menstrual distress, pain self-efficacy and perceived stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230130057274N5**
Registration date: **2024-04-29, 1403/02/10**
Registration timing: **retrospective**

Last update: **2024-04-29, 1403/02/10**
Update count: **0**

Registration date
2024-04-29, 1403/02/10

Registrant information

Name
Hajar Adib-Rad
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-01, 1400/09/10

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
2021-12-01, 1400/09/10

Actual recruitment end date
2023-04-21, 1402/02/01

Trial completion date
2023-04-21, 1402/02/01

Scientific title
The effect of computer-based Stress Inoculation Training (SIT) approach on the pelvic pain, depression, and

anxiety in students with primary dysmenorrhea

Public title
The effect of computer-based Stress Inoculation Training (SIT) approach on the pelvic pain, depression, and anxiety in students with primary dysmenorrhea
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being Iranian Declaration of consent to participate in the study Age range from 18 to 38 years Having any degree (one, two, or three) of primary dysmenorrhoea having regular menstrual cycles with intervals of 21 to 35 days and a duration of 3 to 10 days at least during the last six months Obtaining a score of 8 or higher on the HADS questionnaire Access to smartphones
Exclusion criteria:
History of genital diseases, surgery, and known and chronic underlying diseases Taking birth control pills Having hormonal disorders, irregular menstruation Pelvic infection, burning and itching, and abnormal vaginal discharge Professional sports activities Complaining about another pain in the hip area according to the student Current or history of severe mental illness such as severe depression, bipolar, suicidal thoughts Consumption of psychoactive substances or alcohol and drugs Having symptoms of depression or anxiety Taking anti-depressants and anxiety medications during the study Participation in other psychological interventions such as psychotherapy, meditation, yoga The occurrence of stressful events at least six months before the start of the study
Age
From **18 years** old to **38 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Health Research Institute - Babol University of Medical Sciences (Research Ethics
Street address
Ganj Afrooz St., Babol University of Medical Sciences
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2021-08-07, 1400/05/16
Ethics committee reference number
IR.MUBABOL.REC.1400.184

Health conditions studied

1

Description of health condition studied
Pelvic pains
ICD-10 code
N00-N99
ICD-10 code description
Diseases of the genitourinary system

2

Description of health condition studied
Anxiety and depression
ICD-10 code
F41.2
ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Pelvic pains
Timepoint
on the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Short-Form McGill Pain Questionnaire

2

Description
Depression
Timepoint
on the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Hospital anxiety and depression questionnaire

3

Description
Anxiety
Timepoint
on the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Hospital anxiety and depression questionnaire

Secondary outcomes

1

Description
Menstrual distress
Timepoint
On the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Moos Menstrual Distress Questionnaire

2

Description
pain self-efficacy
Timepoint
On the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Pain Self-efficacy Questionnaire

3

Description
perceived stress
Timepoint
On the second day of the first menstrual cycle before the study and three consecutive cycles after the intervention
Method of measurement
Perceived Stress Scale Questionnaire

Intervention groups

1

Description
Intervention group: Sit treatment method
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol University of Medical Sciences
Full name of responsible person
محبوبه فرامرزی
Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mehdi Rajab Nia
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Vice-Chancellor's Office for Research, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Iran
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ramazan69@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Hajar Adib-Rad
Position

Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Faculty member - Assistant professor

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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