Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparison of the Effectiveness of Emotion Efficacy Therapy and Mindfulness-Based Cognitive Therapy on Emotional Symptoms, Psychological Flexibility,Marital Satisfaction, and Sexual Function in Women with Vaginismus

Protocol summary

Study aim

To determine and compare the effectiveness of Emotion Efficacy Therapy and Mindfulness-Based Cognitive Therapy on emotional symptoms, psychological flexibility, marital satisfaction, and sexual function in women with vaginismus.

Design

A randomized controlled clinical trial with three parallel groups involving 60 women with vaginismus. Participants will be allocated to the Emotion Efficacy Therapy, Mindfulness-Based Cognitive Therapy, and control groups using simple randomization. As this is a non-pharmacological intervention, the study phase is not applicable

Settings and conduct

Randomized clinical trial at Kashan University of Medical Sciences in 60 women with vaginismus. Simple randomization to EET, MBCT, and control. Outcomes at pre-, post-test and follow-up. Single-blind

Participants/Inclusion and exclusion criteria

Women aged 18–45 years with vaginismus diagnosed by a gynecologist or obstetrician who meet the inclusion criteria and have no psychiatric disorders requiring immediate treatment or significant physical illnesses. Participants will be withdrawn in case of withdrawal of consent, absence from more than two therapy sessions, initiation of other psychological interventions, or incomplete questionnaire completion

Intervention groups

(EET):Participants will receive Emotion Efficacy Therapy in addition to usual treatment. The intervention consists of eight weekly 90-minute sessions.(MBCT):Participants will receive Mindfulness-Based Cognitive Therapy in addition to usual treatment. The intervention consists of eight weekly 90-minute sessions.Control Group:Participants will receive usual treatment only, according to the routine care provided by the treatment center, with no additional psychological intervention during the study period.

Main outcome variables

Emotional symptoms; Psychological flexibility; Marital satisfaction; Sexual function

General information

Reason for update

Acronym

EET-MBCT

IRCT registration information

IRCT registration number: **IRCT20260616069833N1**
Registration date: **2026-07-07, 1405/04/16**
Registration timing: **prospective**

Last update: **2026-07-07, 1405/04/16**
Update count: **0**

Registration date

2026-07-07, 1405/04/16

Registrant information

Name

Monire Artang

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

artang-m@kaums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2026-12-20, 1405/09/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison of the Effectiveness of Emotion Efficacy Therapy and Mindfulness-Based Cognitive Therapy on Emotional Symptoms, Psychological Flexibility,Marital Satisfaction, and Sexual Function in Women with Vaginismus

Public title
Comparison of the effectiveness of Emotion Efficacy Therapy and Mindfulness-Based Cognitive Therapy in improving symptoms and functioning in women with vaginismus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of vaginismus confirmed by a gynecologist or obstetrician. Age between 18 and 45 years. Absence of psychiatric disorders requiring immediate treatment. Absence of other significant physical illnesses. Not receiving any other psychological intervention or psychotherapy concurrently. Provision of written informed consent to participate in the study. Iranian nationality.
Exclusion criteria:
Receiving any other educational or therapeutic intervention concurrently. Development of psychiatric disorders during the study that require immediate treatment. Absence from more than two psychotherapy sessions. Incomplete completion of the study questionnaires. Withdrawal of consent to continue participation in the study at any stage of the trial. Use of medications that may affect sexual function.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After confirming eligibility and obtaining written informed consent, a unique identification code will be assigned to each participant. A random allocation sequence will then be generated using a random number table, and participants will be randomly assigned in a 1:1:1 allocation ratio to the Emotion Efficacy Therapy group, the Mindfulness-Based Cognitive Therapy group, or the control group. Allocation will be performed according to the pre-generated sequence obtained from the random number table.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features
The study will be conducted as an open-label trial. However, to minimize bias, the data analyst will be blinded to group allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences, Physician Blvd., Km 3, Ravand Road, Kashan, Isfahan, Iran
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2026-06-29, 1405/04/08
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1405.044

Health conditions studied

1

Description of health condition studied
Vaginismus
ICD-10 code
N94.2
ICD-10 code description
Vaginismus

Primary outcomes

1

Description
Emotional symptoms score measured by the DASS-21 questionnaire
Timepoint

At baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and 3 months after the completion of the intervention (follow-up).

Method of measurement

Depression, Anxiety and Stress Scale, 21-Item Version

2

Description

Psychological flexibility score measured by the AAQ-II questionnaire

Timepoint

At baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and 3 months after the completion of the intervention (follow-up).

Method of measurement

Acceptance and Action Questionnaire, Second Version

3

Description

Marital satisfaction score measured by the ENRICH Marital Satisfaction Questionnaire

Timepoint

At baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and 3 months after the completion of the intervention (follow-up).

Method of measurement

Enrich Marital Satisfaction Questionnaire

4

Description

Sexual function score measured by the Female Sexual Function Index (FSFI)

Timepoint

At baseline (pre-test), immediately after completion of the 8 intervention sessions (post-test), and 3 months after the completion of the intervention (follow-up).

Method of measurement

Female Sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will receive eight weekly 90-minute sessions of Emotion Efficacy Therapy, based on a standardized treatment protocol, in addition to usual treatment.

Category

Treatment - Other

2

Description

Intervention group: Participants will receive eight weekly 90-minute sessions of Mindfulness-Based Cognitive Therapy, based on a standardized treatment protocol, in addition to usual treatment.

Category

Treatment - Other

3

Description

Control group: Participants will receive usual treatment only, with no additional psychological intervention during the study period.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan University of Medical Sciences

Full name of responsible person

Monireh Artang

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Kashan University of Medical Sciences, Physician Blvd., Km 3, Ravand Road, Kashan, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Monire Artang
Position
Master's Student in Clinical Psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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No. 4, Fereshteh 3 Alley, Khwarizmi 1 St., Sepahan Shahr, Isfahan, Iran
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Person responsible for updating data

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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
Individual participant data will not be shared due to participant confidentiality.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
No Individual Participant Data Sharing Individual participant data will not be shared in order to protect participants' confidentiality and privacy. Only aggregated results and statistical analyses will be disseminated through the thesis and scientific publications.

When the data will become available and for how long

No access period is defined because there is no plan to share the study data.

To whom data/document is available

Individual participant data will not be available for access.

Under which criteria data/document could be used

The de-identified dataset may be used only for scientific research purposes. Access and use of the data will be granted upon approval by the study investigators and in accordance with ethical and confidentiality requirements. Re-identification of participants, sharing the data with unauthorized third parties, or commercial use of the data is not permitted.

From where data/document is obtainable

Requests for access to the de-identified study data should be submitted by email to the Principal Investigator. All requests will be reviewed by the research team and approved in accordance with research ethics and confidentiality requirements. Principal Investigator: Monire Artang Affiliation: Kashan University of Medical Sciences, School of Medicine Email:mnr.artang@gmail.com Address: No. 4, Fereshteh 3 Alley, Khwarizmi 1 St., Sepahan Shahr, Isfahan, Iran Phone: 09019805755

What processes are involved for a request to access data/document

Applicants should submit a written request by email to the Principal Investigator. The request will be reviewed by the research team with respect to the purpose of data use, ethical considerations, and confidentiality requirements. If approved, the de-identified dataset will be shared, subject to a data use/confidentiality agreement if required, within 2–4 weeks of receiving the request.

Comments