

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Developing a schema therapy package for women with vaginismus and comparing its effectiveness with common schema therapy on sexual schemas, sexual equality, marital adjustment, sexual self-esteem and fear of intimacy in women with vaginismus disorder

Protocol summary

Study aim

The main purpose of this study is to develop a special schema therapy package for women with vaginismus and compare its effectiveness with conventional schema therapy methods on sexual schemas, sexual self-expression, marital adjustment, sexual self-esteem and fear of intimacy in women with vaginismus.

Design

This research is a three-group quasi-experimental method with a pre-test-post-test design and follow-up with a control group.

Settings and conduct

The statistical population of all women with vaginismus disorder referring to counseling centers and psychological services in Karaj in the winter of 1400 will be between the ages of 18 to 42 years, from which 45 will be purposefully selected. After the purposeful selection of the sample members, the randomly selected individuals will be divided into three groups of 15 people (in quasi-experimental research, at least 15 people are recommended for each group). Subjects will be divided into two experimental groups and one control group after sampling.

Participants/Inclusion and exclusion criteria

Inclusion conditions: Informed consent for treatment, being in the age group of 18 to 42 years according to the vaginismus diagnosis questionnaire, non-inclusion conditions: Having other sexual dysfunction.

Intervention groups

The first experimental group was the Special schema therapy Common schema therapy group, the second experimental group was the Special schema therapy Common schema therapy group and The third control group.

Main outcome variables

sexual schemas, sexual equality, marital adjustment,

sexual self-esteem and fear of intimacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211120053113N1**

Registration date: **2022-01-04, 1400/10/14**

Registration timing: **prospective**

Last update: **2022-01-04, 1400/10/14**

Update count: **0**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

Ronak Kakavand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing a schema therapy package for women with vaginismus and comparing its effectiveness with common schema therapy on sexual schemas, sexual equality, marital adjustment, sexual self-esteem and fear of intimacy in women with vaginismus disorder

Public title

Developing a schema therapy package for women with vaginismus and comparing its effectiveness with common schema therapy on sexual schemas, sexual equality, marital adjustment, sexual self-esteem and fear of intimacy in women with vaginismus disorder

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being in the age group of 18 to 42 years. According to the diagnosis of vaginismus questionnaire. At least 1 year of cohabitation. According to the diagnosis of vaginismus questionnaire. Being in a life together. Not undergoing psychiatric and psychological treatments. Conscious satisfaction and willingness to participate and continue treatment.

Exclusion criteria:

Dissatisfaction and unwillingness to participate. Other sexual dysfunction. Under the treatment of psychiatric and psychological therapies.

AgeFrom **18 years** old to **42 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

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

Sample sizeTarget sample size: **45****Randomization (investigator's opinion)**

Randomized

Randomization description

45 women with vaginismus from the community of women with vaginismus Women Clinic of Payambaran Hospital in a targeted manner based on sample adequacy (in experimental and quasi-experimental research recommend at least 15 to 20 people for each group) Will be selected. The assignment of both experimental groups, including the special schema therapy group and the conventional schema therapy group and the control group, will be randomly drawn by lot. In this way, each sample person is given a special

code and then the codes are poured into a bag or container and mixed. It then pulls out the codes one by one, writes down their number, and so on until the groups are completed. Then, for random and unpredictable allocation of 15 people in the first, second and third groups for two experimental groups and one control group, coin toss will be used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be a three-way blind. In this study, the three sample groups, the therapists, and the evaluation group, who analyze the data obtained, will be kept blind. In this study, the facilitator, participants, treatment executives, and the assessment team will not have any prior physical knowledge, contact, telephone, or online contact with each other. In this study, the three sample groups will be kept blind to each other and to the treatment. Also, the executors of the treatments and the information evaluation team will be outside the treatment plan team.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.IAU.KHUISF.REC.1400.288

Health conditions studied**1****Description of health condition studied**

vaginismus disorder

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

In the present study, the outcome variable is the score of sexual schemas in the female sexual schematic questionnaire above 100.

Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up)

Method of measurement

How to measure sexual schemas is the Women's Sexual Schematic Questionnaire.

2

Description

In the present study, the outcome variable, the score of sexual self-expression in the sexual self-expression questionnaire is less than 70.

Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up).

Method of measurement

How to measure sexual self-expression is a sexual self-expression questionnaire.

3

Description

In the present study, the outcome variable, the score of marital adjustment in the marital adjustment questionnaire is lower than 101.

Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up).

Method of measurement

How to measure marital adjustment is the marital adjustment questionnaire.

4

Description

In the present study, the outcome variable, the score of sexual self-esteem in the sexual self-esteem questionnaire is less than 100.

Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up).

Method of measurement

How to measure sexual self-esteem is the sexual self-esteem questionnaire.

5

Description

In the present study, the outcome variable is the fear of intimacy score in the Intimacy Fear Questionnaire above 65.

Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up).

Method of measurement

How to measure the fear of intimacy is the fear of intimacy questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Schema therapy group is special. The experimental group or the first intervention will receive a special schema therapy for 10 sessions one day a week for 90 minutes. The intervention of the first group is based on the protocol developed by Kakavand, Khayatan and Golparvar (1400) based on the need-based inductive thematic analysis (theme) based on the needs of women with vaginismus and interviews with them, then matching the needs with therapeutic texts. Special and common schema therapy and finally obtaining specialized agreement and approval of initial executive validity. The content of special schema therapy includes: 1. Treatment of traumatic thoughts and emotions related to vaginismus 2. Exposure to physical symptoms and 3. Treatment of functional problems related to it is vaginismus.

Category

Behavior

2

Description

Intervention group2: Schema therapy group is common. The second experimental or intervention group will receive sessions for 10 sessions one day a week for 90 minutes. Conventional schema therapy sessions were prepared according to the validated and tested protocol of Yang (1999). The content of common schematic therapy sessions includes: 1. Identifying early maladaptive schemas, coping styles, schematic mindsets, and self-injurious patterns of life and case-by-case conceptualization of problems; Healthy behaviors replace previous behaviors.

Category

Behavior

3

Description

Control group: without receiving any treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Clinic of Payambaran Hospital

Full name of responsible person

Felor Khayatan

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Islamic Azad University

Full name of responsible person

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Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Felor Khayatan

Position

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Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access to the data will start 4 months after the results

are published and in 1401

To whom data/document is available

Anyone interested in psychological studies in the field of vaginismus and its effects can benefit from the information published in this study. Researchers and students with studies related to the present study, if they need more information about the research process and more information about the results can be informed through the email address and phone number of the responsible author.

Under which criteria data/document could be used

1. Researchers and researchers can refer to the present study by citing the source 2. Researchers and researchers can compare the treatments used in the present study with other studies by mentioning the reference or by referring to the reference as a new protocol

From where data/document is obtainable

Applicants can refer to the following e-mail address and contact numbers to receive the required documents or data. F.khayatan@yahoo.com; kakavandronak3@gmail.com- 09131289531 : 031 - 35002612 2 -09127853144

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

1. Sending an official e-mail or telephone call requesting a respectful and formal request on the subject of the research requesting the documents and the reason for the need for the documents 2. Receive valid details from the applicant for documents, including complete and valid personal details, valid email address, valid contact number to verify the validity of the request of the document applicant 3. Check emails and calls within 48 hours and if the request of the applicant is confirmed, send the documents while maintaining the privacy and confidentiality in the form of email, fax and post for the applicant

Comments