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
Country
Iran (Islamic Republic of)
Phone
+98 26 3334 2256
Email address
kakavandronak3@gmail.com

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.
Age
From **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 size
Target 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
کمیته اخلاق دانشگاه آزاد اصفهان
Street address
EasternJey Ave,University Blvd, Isfahan Azad University
City
Isfahan
Province
Isfehan
Postal code
۳۹۹۹۸-۸۱۵۵۱
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

Street address
Eastern Jey Ave, University Blvd, Isfahan Azad University

City
Isfahan

Province
Isfehan

Postal code
۳۹۹۹۸-۸۱۵۵۱

Phone
+98 31 3500 2612

Email
kakavandronak3@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr.Hadi Farhadi

Street address
Eastern Jey Ave, University Blvd, Isfahan Azad University

City
Isfahan

Province
Isfehan

Postal code
۳۹۹۹۸-۸۱۵۵۱

Phone
+98 31 3500 2612

Email
FarhadiHadi@yahoo.com

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
Islamic Azad University

Full name of responsible person
Dr.Felor Khayatan

Position
Assistant Professor, Faculty

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Eastern Jey Ave, University Blvd, Isfahan Azad University

City
Isfahan

Province
Isfehan

Postal code
۳۹۹۹۸-۸۱۵۵۱

Phone
+98 913 128 9531

Email
F.khayatan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr.Felor Khayatan

Position
Assistant، Professor Faculty

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Eastern Jey Ave, University Blvd, Isfahan Azad University

City
Isfahan

Province
Isfehan

Postal code
۳۹۹۹۸-۸۱۵۵۱

Phone
+98 913 128 9531

Email
F.Khayatan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Felor Khayatan

Position
Assistant Professor, Faculty

Latest degree
Ph.D.

Other areas of specialty/work
Psychology
Street address
Eastern Jey Ave, University Blvd, Isfahan Azad University
City
Isfahan
Province
Isfehan
Postal code
۳۹۹۹۸-۸۱۵۵۱
Phone
+98 31 3500 1226
Email
F.Khayatan@yahoo.com

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