

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparing of the Effectiveness of Systemic Sex Therapy and Single Session Therapy on the Treatment of Vaginismus Patients

Protocol summary

Study aim

Comparing the Effectiveness of Systemic Sex Therapy and single-session therapy on successful penetration, marital satisfaction, sexual distress, experience of pain intensity, and the multidimensional perspective of the patient and spouse in vaginismus patients.

Design

Two arm parallel groups non-randomised trial, without control group, without blinding, on 30 patients.

Settings and conduct

Place of study: Systemic Sex Therapy at the Kayhan Psychology Clinic in Tehran and Single-session Treatment at the Sexual Health Clinic of Imam Khomeini Hospital in Tehran; Study population: 30 women with vaginismus. No blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: married women over 18 years old; Active avoidance of penetration during the last 6 months and no experience of penetration; presence of fear, severe anxiety or significant pain when trying to penetrate; Spouse's presence in treatment. Exclusion criteria: Visiting a doctor or a psychiatrist due to the presence of a known medical or acute mental illness; the presence of women's diseases, including acute infections of the genital tract; pregnancy; Consumption of drugs and alcohol through the patient's statement

Intervention groups

There are two intervention groups: Systemic Sex Therapy intervention group: sex education and relaxation, gradual exposure and couple therapy in 12 one-hour sessions. Single-Session Treatment intervention group: introducing the automatic brain system and teaching independent control of vaginal muscles and practicing with the therapist's finger during the treatment session during one session.

Main outcome variables

Vaginal Penetration, Marital Satisfaction, Sexual Distress, The Intensity of pain experience and Multidimensional Perspective of Vaginal Penetration of the patient and

spouse.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220307054215N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **prospective**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

Fatemeh Tehranchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8878 1851

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the Effectiveness of Systemic Sex Therapy and Single Session Therapy on the Treatment of Vaginismus Patients

Public title

The Effectiveness of Systemic sex therapy and Single Session therapy on Vaginismus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women over 18 years old Trying to penetrate during the last 6 months and not experiencing penetration Existence of active avoidance of penetration Diploma and higher education Presence of significant fear or extreme anxiety when trying to penetrate Presence of significant pain when trying to penetrate The presence of the wife in the treatment

Exclusion criteria:

Visiting a doctor or a psychiatrist due to the presence of a known medical or acute mental illness based on the patient's statement The presence of women's diseases, including acute infections of the genital tract Pregnancy Consumption of drugs and alcohol through the patient's statement

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Roudhen Branch, Islamic Azad University

Street address

Ayatollah Khamenei Blvd; Rodhan

City

Tehran

Province

Tehran

Postal code

3973188981

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.IAU.R.REC.1402.015

Health conditions studied

1

Description of health condition studied

Vginismus

ICD-10 code

F52.5

ICD-10 code description

Vaginismus not due to a substance or known physiological condition

Primary outcomes

1

Description

Successful vaginal penetration

Timepoint

In the systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In the single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Patient self-report

Secondary outcomes

1

Description

Female Sexual Distress

Timepoint

In systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Female Sexual Distress Scale (FSDS)

2

Description

Marital Satisfaction

Timepoint

In systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Enrich Marital Satisfaction (EMS)

3

Description

Multidimensional Vaginal Penetration Disorder perspective

Timepoint

In systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Multidimensional Vaginal Penetration Disorder Questionnaire (MVPDQ)

4

Description

Partner Version of the Multidimensional Vaginal Penetration Disorder perspective

Timepoint

In systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Partner Version of the Multidimensional Vaginal Penetration Disorder Questionnaire (PV-MVPDQ)

5

Description

intensity of pain

Timepoint

In systemic sex therapy: before the intervention, at the end of the fourth week, at the end of the eighth week, and at the end of the twelfth week. In single session therapy: before the intervention, at the end of the second week, at the end of the fourth week, at the end of the sixth week.

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

The first intervention group is Systemic sex therapy that is specifically a combination of sex therapy and couple therapy. It deals with the cognitive reconstruction of the

individual from a cognitive-behavioral perspective, and in the behavioral part, in addition to the correction of couple relationships and sex education, it deals with gradual exposure to the process of penetration. In twelve one-hour sessions, to assess and correct and reconstruct dysfunctional sexual cognitions, sexual organ anatomy training, sexual communication training, mindfulness and expansion of the sexual repertoire, relaxation training, familiarization with the pain cycle, gradual exposure through graduated therapeutic dilators and regular desensitization. And couple skills training including listening and understanding, empathic message and problem solving and Consistent daily homework are discussed.

Category

Treatment - Other

2

Description

The second intervention is a single-session therapy that working on dimming the brain's autonomous control on genitalia and pelvic muscles by handing over the power of decision, getting control over her body, and attempting to insert the therapist's or husband's finger in her vagina at the clinic and voluntarily penetrate with penis at home. This treatment uses muscle exercises to retrain and improve brain power for vaginal penetration. During a session of one hour and forty-five minutes, with the presence of the wife, he explained about the automatic system of the brain, the method of independent control over the sexual organ, finger insertion training and the technique of contracting and relaxing the muscles in the deep part of the pelvis and the movement of the zipper/muscle lift. Levatorani + contraction of the pelvic floor muscles while the doctor's finger is inside, wrist twisting and simultaneous two-person zip/lift exercise, wrist twisting and zip/lift in a three-person workout with a spouse, and providing home exercises in two parts of testing and treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kayhan Counseling and Psychotherapy Center

Full name of responsible person

Fatemeh Tehranchi

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Fifth floor, No. 152, West Mirzaei Zainali St.,
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2

Recruitment center

Name of recruitment center

Sexual health clinic of Imam Khomeini Hospital

Full name of responsible person

Dr Effat Alsadat Merghati Khoei

Street address

Reyhaneh building; Imam Khomeini hospital; Doctor Gharib St. Keshavarz Blvd

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Email

effat_mer@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neuroscience Research Institute, Tehran University of Medical Sciences

Full name of responsible person

Seyed Amirhossein Javadi

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Reyhaneh Building, Imam Khomeini Hospital, Doctor Gharib St. Keshavarz Blvd.,

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Email

tini@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Neuroscience Research Institute, Tehran University of Medical Sciences

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

Fatemeh Tehranchi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Effat Alsadat Merghati Khoei

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Sex & Drug Tx & Prevention Clinical Trail Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Tehranchi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Tehran

Postal code

1968956381

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+98 21 8878 1851

Email

Mahnaz_tehranchi@yahoo.com

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

Due to sensitive and confidential nature

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

Undecided - It is not yet known if there will be 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

A part of the data related to the results of the study is shared after coding the people

When the data will become available and for how long

6 months after the publication of study results

To whom data/document is available

Researchers of national and international scientific centers

Under which criteria data/document could be used

In order to use the findings in treatment and scientific research, with the permission of the ethics committee of the Islamic Azad University of Roudhen

From where data/document is obtainable

Submit the request by email to the main researcher at Mahnaz_tehranchi@yahoo.com

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

Send the request to the main researcher's email and if approved by the ethics committee of the Islamic Azad University of Roudhen, it is possible to provide the required information via email within a period of two weeks to one month.

Comments