

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Compare effectiveness of transcranial direct current stimulation (TDCS), schema therapy and combination therapy on anxiety, sexual pain and executive functions in women with vaginismus

Protocol summary

Study aim

Comparison of the effectiveness of transcranial direct current stimulation, schema therapy, and combination therapy on anxiety, sexual pain, and executive functions in women with vaginismus in Tehran

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 60 patients. Random allocation software will be used for randomization.

Settings and conduct

In 3 Nik Mehr Psychology Centers in Tehran, 60 women who will receive a diagnosis of vaginismus disorder by a psychiatrist and a psychologist were selected in the available manner and by the method of random blocks of 8 into three experimental groups and a control group with the number of people will be allocated equally. The interventions include 3 treatment protocols for 3 experimental groups: direct transcranial electrical stimulation, schema therapy and the combination of these two treatments, and the control group receives sham therapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of vaginismus disorder according to a structured clinical interview by a psychiatrist, non-diagnosis of women's diseases by a gynecologist. Exclusion criteria: women with psychotic symptoms and taking medication, outside the age range of 18-50 years and married for less than 1 year and more than 3 years.

Intervention groups

In three experimental groups (the first group (treatment with transcranial direct current stimulation), the second group (schema therapy) and the third group (combination of the treatment of the first and second groups) and a control group, equally (15 people in each group)

Main outcome variables

Treatment of sexual pain: McGill pain scale
Anxiety treatment: Cattle anxiety scale
Brain executive functions: Wisconsin test, Enbeck test, semantic Stroop test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220123053808N1**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **retrospective**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

Registration date

2022-09-11, 1401/06/20

Registrant information

Name

motahareh nosratabadi

Name of organization / entity

The university of lorestan

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-28, 1401/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare effectiveness of transcranial direct current stimulation (TDCS), schema therapy and combination therapy on anxiety, sexual pain and executive functions in women with vaginismus

Public title

The effect of extracranial direct current stimulation, schema therapy on vaginismus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All women diagnosed with vaginismus disorder who have at least a diploma. All women diagnosed with vaginismus disorder who do not have psychotic symptoms. All women diagnosed with vaginismus disorder who do not have substance abuse and psychological disorders (as diagnosed by a psychiatrist or psychologist). All women diagnosed with vaginismus disorder who do not have gynecological diseases (such as infection). All women diagnosed with vaginismus disorder who have been married for at least 1 to 3 years.

Exclusion criteria:

All women who have any disorder except vaginismus disorder. All women who have symptoms similar to vaginismus but do not have a Gynecologist diagnosis. All women who are not married or have been married for less than a year. All women who are under 18 years old and over 50 years old. All women who have symptoms of psychosis and take nerve medication. All women whose educational qualification is below diploma.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical sample will include 60 female patients suffering from vaginismus disorder who will be selected from the statistical population as available sampling. In order to randomly assign the subjects in experimental and control groups, as well as to avoid wasting time until the number of sample people is completely completed, the method of random blocks of 8 will be used. The size of all blocks is equal and in each block there are 2 people in the first intervention group (group A), 2 people in the second intervention group (group B), 2 people in the

third intervention group (group C) and 2 people in the control group (group D) will be placed randomly. The randomization tool will be the Random Allocation software. In this way, the output of the software includes different modes of AABCCDD random order, for each of the blocks, a different order is applied to assign the participants to the study groups. In this process, the order of participants based on blocks cannot be predicted.

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 Lorestan University of Medical Sciences

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Moalem St., Shahid Anoushirvan Rezaei Square, University of Medical Sciences

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Province

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Postal code

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Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.LUMS.REC.1401.112

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

Vaginismus

ICD-10 code

N94.2

ICD-10 code description

Vaginismus

Primary outcomes**1****Description**

Primary outcome: sexual pain score

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

McGill pain questionnaire

2

Description

Secondary outcome: anxiety score

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Kettle Anxiety Questionnaire

3

Description

Individual's executive performance scores

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Nback memory test, Wisconsin test, Semantic Stroop test

Secondary outcomes

1

Description

Sexual pain score

Timepoint

Before intervention and after intervention

Method of measurement

McGill Sexual Pain Questionnaire 22 questions

2

Description

anxiety

Timepoint

Before intervention and after intervention

Method of measurement

Kettle Anxiety Questionnaire 40 questions

3

Description

Executive functions

Timepoint

Before intervention and after intervention

Method of measurement

Semantic Strope, NB Memory Test, Wisconsin Test

Intervention groups

1

Description

The first intervention group: providing transcranial electrical stimulation of the brain using direct current (tDCS) in the form of ten 20-minute sessions with an

intensity of two milliamps and anodic electrical stimulation of the frontal cortex of the left hemisphere (f3) and the cathode in the right prefrontal cortex (fp2) will be placed with an intensity of 2 milliamps. In general, the treatment sessions will be held once a day for three weeks.

Category

Treatment - Devices

2

Description

The second intervention group: The treatment scheme is a treatment method based on Yang's scheme, which is implemented on clients with vaginismus disorder. This treatment process is carried out during eight treatment sessions in the form of two sessions of one and a half hours each week.

Category

Treatment - Other

3

Description

The third intervention group: combining two treatment protocols: protocol one: providing transcranial electrical stimulation of the brain using direct current (tDCS) in the form of ten 20-minute sessions with an intensity of two milliamps and anodic electrical stimulation of the frontal cortex area of the left hemisphere (f3) And the cathode will be placed in the right prefrontal cortex (fp2) with an intensity of 2 milliamps. In general, the treatment sessions will be held once a day for three weeks. Protocol two: The treatment scheme is a treatment method based on Yang's scheme, which will be used on clients with vaginismus disorder. This therapeutic process will be implemented during eight therapeutic sessions in the form of two sessions of one and a half hours each week.

Category

Treatment - Other

4

Description

The fourth intervention group: the control group that receives sham stimulation.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikmehr

Full name of responsible person

nima ganji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Lorestan
Full name of responsible person
Deputy of research and technology
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Kilometer 5 of Tehran Road, Lorestan University
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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
University of Lorestan
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
the university of lorestan
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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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Regression analysis is allowed on the delivered data

From where data/document is obtainable

Motahera Nosratabadi email nosratabadi.mo@fh.lu.ac.ir

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

By writing a formal request and the reason for needing access to the data and writing a little bit of your research resume

Comments