Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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Phone

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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 AABBCCDD 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
Street address
Moalem St., Shahid Anoushirvan Rezaei Square, University of Medical Sciences
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Khorram abad
Province
Lorestan
Postal code
6813833946
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

Street address

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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
Street address
Kilometer 5 of Tehran Road, Lorestan University
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6815144316
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nosratabadi.mo@fh.lu.ac.ir
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
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motahareh nosratabadi
Position
phd of student
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Latest degree
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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