

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effectiveness of hypnotherapy and behavioural therapy on sexual function, catastrophizing pain and fear of sexual intercourse in women diagnosed with Genito-Pelvic Pain/Penetration Disorder

Protocol summary

Study aim

The purpose of this study is to compare the effectiveness of behavioral therapy and hypnotherapy on sexual function, catastrophizing pain and fear of sexual intercourse in women with Genito-Pelvic Pain/Penetration Disorder

Design

Clinical trial with follow-up and control group, with parallel groups, not blind, randomized.including 45 women with GPPPD divided into three groups of 15 people

Settings and conduct

This study take place in Dr.Mokhtary' office.Treatment is performed individually.There are three questionnaires that they have to fill out in the begining,the end and a two-month follow up.

Participants/Inclusion and exclusion criteria

Diagnosis of GPPPD, married, age between 15 to 35 years; ability to read and write, not having physical abnormality related to diagnosis, not having severe marital problem; absent for more than two sessions, not fill out the forms; and hypnotic susceptibility less than two for hypnotherapy group.

Intervention groups

hypnotherapy and behavioral therapy

Main outcome variables

sexual function catastrophizing pain fear of sexual intercourse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042619N1**

Registration date: **2019-07-19, 1398/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-19, 1398/04/28**

Update count: **0**

Registration date

2019-07-19, 1398/04/28

Registrant information

Name

Farzaneh Baktriya

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-08, 1398/03/18

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of hypnotherapy and behavioural therapy on sexual function, catastrophizing pain and fear of sexual intercourse in women diagnosed with Genito-Pelvic Pain/Penetration Disorder

Public title

Behavioral therapy versus Hypnotherapy in women diagnosed with Vaginismus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of GPPPD by a gynecologist. Ability to write and read. Not having related physical diseases Not having severe marital problem Not having severe psychological disorders The Stanford hypnotic susceptibility should be at least in the medium range.

Exclusion criteria:

Hypnotic susceptibility less than two Not fill out the questionnaires Be absent more than two sessions

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the purposeful sampling, forty-five people are randomly assigned to three 15-member groups by minimization method. For this purpose the order of the groups is randomly determined and the first participant is allocated to a treatment group considering the produced order and the next participants enter the next groups respectively.

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 committees of Semnan University of Medical Sciences

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Semnan University of Medical Sciences.Basij Blvd.Semnan.Iran

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Postal code

3519899951

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.SEMUMS.REC.1398.053

Health conditions studied

1

Description of health condition studied

Genito-Pelvic Pain/Penetration Disorder

ICD-10 code

N94.2

ICD-10 code description

Vaginismus

Primary outcomes

1

Description

sexual function

Timepoint

Before intervention, after intercourse , and a two- month follow-up

Method of measurement

sexual function questionnaire

2

Description

catastrophizing pain

Timepoint

Before intervention, after intercourse , and a two-month follow-up

Method of measurement

catastrophizing pain questionnaire (Salivan & AL,1995)

3

Description

fear of sexual intercourse

Timepoint

Before intervention, after intercourse , and a two-month follow-up

Method of measurement

fear of sexual intercoures questionnaire (Jaber & AI,1378)

Secondary outcomes

empty

Intervention groups

1

Description

The behavior group receive eight individual sessions of 45-60 minutes each week (Al-Sughayir protocol 2005).

Category

Behavior

2

Description

hypnotherapy group receives maximum six individual sessions,90 minutes hypnosis with systematic desensitization (Fuchs.Karl,1980).

Category

Treatment - Other

3

Description

Control group after the end of study can choose one type of treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Mokhtari's office

Full name of responsible person

Farzaneh Baktriya

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No 3072,third floor,Valiasr street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

researchee

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

researchee

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

2

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Semnan University

Full name of responsible person

Dr.Ali Haghighi Asl

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Grant code / Reference number

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Title of funding source

Vice Chancellor for Research and Technology of Semnan
University

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

Faculty of Psychology & Education Mehdishahr

Full name of responsible person

Farzaneh Baktriya

Position

PhD student of psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable