

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2284 6510

###### Email address

fbaktriya@semnan.ac.ir

##### 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

##### Street address

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

##### City

Semnan

##### Province

Semnan

##### 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

##### Street address

No 3072,third floor,Valiasr street

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Tehran

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##### Postal code

28490358667

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

researchee

##### Full name of responsible person

Farzaneh Baktriya

##### Street address

Faculty ofPsychology & Education Mehdishahr  
Semnan University , Darband, Mehdishahr, Semnan,  
Iran

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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

##### Street address

Central Administration of Semnan University, Campus  
1, Semnan, I. R. of Iran

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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

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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