

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of pelvic floor physical therapy on sexual function and pelvic floor muscle strength and endurance in women complaining dyspareunia

#### Protocol summary

##### Study aim

The effects of Pelvic floor rehabilitation in treatment of women with dyspareunia

##### Design

Two arm parallel group randomized controlled trial with blinded outcome assessment, sample size 64

##### Settings and conduct

Dyspareunia patients from Alzahra hospital and physiotherapy center who met the criteria were included in the study. Treatment was done by one of the researchers and assessment was done by another one who was blinded to group allocation.

##### Participants/Inclusion and exclusion criteria

Women with pain in the genital area before, during, or after vaginal intercourse, and pain was greater than 8 on a 10-cm visual analogue scale (VAS). If the women had any history of other pathophysiological conditions, such as infections, tumors, major psychiatric illnesses, vaginismus, vestibulodynia, vulvar dermatological conditions, painful bladder syndrome or interstitial cystitis, endometriosis, pregnancy, surgery on pelvic organs, or any ongoing treatment for dyspareunia, they were excluded from the study.

##### Intervention groups

Intervention Group: Pelvic floor physiotherapy (n=32)  
Control group: No treatment(n=32)

##### Main outcome variables

pain; pelvic floor muscles and deep abdominals strength and endurance; female sexual functional index (FSFI).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014070118311N1**

Registration date: **2014-08-09, 1393/05/18**

Registration timing: **prospective**

Last update: **2019-04-25, 1398/02/05**

Update count: **1**

##### Registration date

2014-08-09, 1393/05/18

##### Registrant information

###### Name

Parvin Bastani

###### Name of organization / entity

Tabriz University of medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1443 5590

###### Email address

bastanip@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

##### Expected recruitment start date

2014-07-11, 1393/04/20

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

2014-09-21, 1393/06/30

##### Actual recruitment end date

2016-09-20, 1395/06/30

##### Trial completion date

2016-09-20, 1395/06/30

##### Scientific title

The effect of pelvic floor physical therapy on sexual function and pelvic floor muscle strength and endurance in women complaining dyspareunia

##### Public title

The effect of pelvic floor physical therapy on dyspareunia

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Women with pain in the genital area before, during, or after vaginal intercourse, and pain was greater than 8 on a 10-cm visual analogue scale (VAS).

**Exclusion criteria:**  
If the women had any history of other pathophysiological conditions, such as infections, tumors, major psychiatric illnesses, vaginismus, vestibulodynia, vulvar dermatological conditions, painful bladder syndrome or interstitial cystitis, endometriosis, pregnancy, surgery on pelvic organs, or any ongoing treatment for dyspareunia, they were excluded from the study.

**Age**  
From **20 years** old to **50 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **64**  
Actual sample size reached: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
participants were randomly assigned to one of two groups using a block randomization procedure . The allocation sequence was generated by random allocation software.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Blinding only occurred for assessor and statistician. Because of the nature of the intervention and control, participants and physiotherapist couldn't be blinded. blinded assessor did the assessment procedure including questionnaires and examination.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Faculty of rehabilitation, Tavanir Ave, Tabriz, Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5167631444

#### Approval date

2014-06-26, 1393/04/05

#### Ethics committee reference number

5/4/2979

## Health conditions studied

### 1

#### Description of health condition studied

Dyspareunia

#### ICD-10 code

N94.1

#### ICD-10 code description

Dyspareunia

## Primary outcomes

### 1

#### Description

dyspareunia

#### Timepoint

Before and after intervention

#### Method of measurement

VAS

### 2

#### Description

Female sexual function index (FSFI)

#### Timepoint

before and after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

PFM strength

#### Timepoint

before after intervention

#### Method of measurement

oxford scale- vaginal examination

### 2

#### Description

PFM endurance

#### Timepoint

before after intervention

#### Method of measurement

oxford scale- vaginal examination

## Intervention groups

1

### Description

Patients had 10 physiotherapy sessions for three months

### Category

Rehabilitation

2

### Description

Control group: no treatment ( waiting list)

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Fariba Ghaderi

#### Full name of responsible person

Fariba Ghaderi

#### Street address

Faculty of rehabilitation, Tavanir Ave, Tabriz, Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5167631444

#### Phone

+98 41 3337 5359

#### Email

ghaderimailbox@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tabriz University Of Medical Sciences

#### Full name of responsible person

Fariba Ghaderi

#### Street address

Faculty of rehabilitation, Tavanir Ave, Tabriz, Iran

#### City

Tabriz

#### Province

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#### Postal code

5167631444

#### Phone

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#### Email

ghaderimailbox@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Tabriz University Of Medical Sciences

### 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Fariba Ghaderi

#### Position

Associate Professor of Obstetrics and Gynecology

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Faculty of rehabilitation, Tavanir Ave, Tabriz, Iran

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#### Postal code

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#### Phone

+98 41 3337 5359

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#### Email

ghaderimailbox@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Parvin Bastani Alamdari

#### Position

Associate Professor of Obstetrics and Gynecology

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Golgasht Street ,Tabriz University Of Medical Sciences

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**Province**

East Azarbaijan

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5138665793

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**Fax****Email**

ghaderimailbox@gmail.com

**Web page address****Web page address****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**

There is no further information

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be 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**

study protocol- data set

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

data analysis with referencing this study

**From where data/document is obtainable**

researcher email ghaderimailbox@gmail.com

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

sending an email

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fariba Ghaderi

**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

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