

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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

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Faculty of rehabilitation, Tavanir Ave, Tabriz, Iran

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ghaderimailbox@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Sciences

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

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

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Name of organization / entity

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Full name of responsible person

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Fax**Email**

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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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