

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of pelvic floor muscle training with or without biofeedback therapy for urinary incontinence

Protocol summary

Study aim

The purpose of the study is to evaluate the effects pelvic floor muscle training with biofeedback therapy for urinary incontinence. The purpose of the study is to evaluate the effects pelvic floor muscle training without biofeedback therapy for urinary incontinence.

Design

A prospective comparative randomized controlled trial (RCT)

Settings and conduct

To study the difference between improvement in symptoms and quality of life of patient receiving pelvic floor muscle training with and without biofeedback therapy for urinary incontinence, a randomized controlled trial will conduct in Memon Medical Institute Hospital Karachi Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Patient who are willing to participate in the study. Menopausal women. Pre and post-menopause. Urinary incontinence with the effort. Age limit is 19-50 years Exclusion Criteria Experiencing psychotic symptoms at baseline Females with neurological conditions that affect sphincteric function or colorectal, pelvic, gynecological or genitourinary. Surgery or malignancy where the exciting pathology interferes with the prescribed pelvic floor muscle training program will exclude. Biofeedback-assisted pelvic floor muscle training were not suitable will also exclude

Intervention groups

We will use biofeedback therapy machine for pelvic floor muscles training

Main outcome variables

The kings health questionnaire, Pelvic floor Impact questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220804055615N2**

Registration date: **2022-12-08, 1401/09/17**

Registration timing: **retrospective**

Last update: **2022-12-08, 1401/09/17**

Update count: **0**

Registration date

2022-12-08, 1401/09/17

Registrant information

Name

Mohabbat Ali

Name of organization / entity

Memon Medical Intitute Hospital

Country

Pakistan

Phone

+92 21 99261810

Email address

ramal_209@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-01, 1401/07/09

Expected recruitment end date

2022-10-30, 1401/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of pelvic floor muscle training with or without biofeedback therapy for urinary incontinence

Public title

Effectiveness of pelvic floor muscle training with or without biofeedback therapy for urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient who are willing to participate in the study. Menopausal women Pre and post-menopause Urinary incontinence with the effort Age limit is 19-50 years

Exclusion criteria:

Experiencing psychotic symptoms at baseline Females with neurological conditions that affect sphincteric function or colorectal, pelvic, gynecological or genitourinary Surgery or malignancy where the exciting pathology interferes with the prescribed pelvic floor muscle training program will exclude Biofeedback-assisted pelvic floor muscle training were not suitable will also exclude

Age

From **19 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients refereed from Gynecology out patient department. We will maintain a excel sheet on computer every odd number will consider in controlled group and even number in conventional group. We will use biofeedback therapy machine for controlled group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients with the complain of urinary incontinence filled the concern form for study but not inform regarding two different groups, distributed the patients with odd and even numbers in two groups.

Placebo

Not used

Assignment

Parallel

Other design features

4

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Intitutional Review Board Memon Medical Institute Hospital

Street address

Safoora Goth Scheme 33

City

Karachi

Postal code

75270

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

IRB/MMIH/2022/12

Health conditions studied

1

Description of health condition studied

pelvic floor muscles weakness

ICD-10 code

N39.46

ICD-10 code description

Mixed incontinence

Primary outcomes

1

Description

Pelvic floor muscles weakness

Timepoint

3 month

Method of measurement

Muscle will measure by biofeedback therapy

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group participants will be treated with bio feed back therapy followed by pelvic floor exercises. bio feed back therapy(exercises) 30 minutes session done with a machine of enraf nonius with brand name of myomed. In inventional group there will be no intervention of any chemical. Total sessions of exercises will be 12 and 3 session in a week. duration of study is 3 month

Category

Rehabilitation

2

Description

Controlled group will treated with conventional pelvic floor exercises only

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Memon Medical Institute Hospital

Full name of responsible person

Dr. Mohabbat Ali

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Web page address

<https://mmi.edu.pk/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Memon Medical Intitute Hospital

Full name of responsible person

Dr. Mohabbat Ali

Street address

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Grant name

Institute budget

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Memon Medical Intitute Hospital

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Memon Medical Instute Hospital

Full name of responsible person

Dr. Mohabbat Ali

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Effectiveness of Pelvic floor muscles training with or without biofeedback therapy for urinary incontinence

When the data will become available and for how long

With in 3 three month

To whom data/document is available

Data will be available only who are working in the out patient department

Under which criteria data/document could be used

Data not allowed to others

From where data/document is obtainable

Out patients department

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

Not allowed to any other researchers

Comments

This is gynecology and physiotherapy department research

Person responsible for updating data

Contact

Name of organization / entity
Memon Medical Institute Hospital
Full name of responsible person
Dr. Mohabbat Ali
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
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