

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**Street address**

Safoora Goth

**City**

Karachi

**Postal code**

75270

**Phone**

+92 21 99261810

**Fax**

+92 21 34691193

**Email**

ramal\_209@yahoo.com

**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**

Safoora Goth

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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

**Street address**

Safoora Goth

**City**

karachi

**Province**

Sindh

**Postal code**

75270

**Phone**

+92 21 99261810

**Fax**

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**Person responsible for scientific inquiries**

**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**

Physiotherapy

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

## 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**  
Physiotherapy

**Street address**  
Safoora

**City**  
Karachi

**Province**  
Sindh

**Postal code**  
75270

**Phone**  
+92 21 99261810

**Fax**  
+92 21 34861193

**Email**  
ramal\_209@yahoo.com

**Web page address**

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

## 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