Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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

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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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Person responsible for updating data

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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