

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of knack maneuver with or without diaphragmatic breathing on urinary tract symptoms and quality of life among patients of stress urinary incontinence

Protocol summary

Study aim

To compare the effects of knack maneuver with or without diaphragmatic breathing on urinary tract symptoms and quality of life among patients of stress urinary incontinence.

Design

It will be single blinded, parallel study groups and randomized clinical trial

Settings and conduct

The study will be held at Arif memorial teaching hospital Lahore

Participants/Inclusion and exclusion criteria

Participants which will have age 18-50 years and diagnosed with stress urinary incontinence symptoms will be added to this study while Women who are pregnant or already having previous pelvic floor training or patients taking blood pressure medications, sedatives, muscle relaxants, and diuretics and diagnosed with mental illness will excluded from this study.

Intervention groups

Group A: Group A will given knack maneuver along diaphragmatic breathing. In group A, We will take diagnosed patients of stress urinary incontinence and will perform knack maneuver along diaphragmatic breathing. Group B: In group B, We will take diagnosed patients of stress urinary incontinence and will perform knack maneuver. The training program will be 2 days per week for 4 weeks.

Main outcome variables

Urinary distress incontinence-6: The UDI 6 is a valid and reliable six points survey, use particularly to investigate symptoms associated with lower urinary tract dysfunction; Incontinence Impact Questionnaire (IIQ-7): The IIQ 7 is a seven point's questionnaire specific to UI to impact the quality of life and

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221205056713N4**

Registration date: **2024-08-02, 1403/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-02, 1403/05/12**

Update count: **0**

Registration date

2024-08-02, 1403/05/12

Registrant information

Name

hafiza Nida Rasheed

Name of organization / entity

Rashid Latif Medical college, Lahore

Country

Pakistan

Phone

+92 336 4535979

Email address

naddia.rasheed20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2024-12-10, 1403/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of knack maneuver with or without diaphragmatic breathing on urinary tract symptoms and quality of life among patients of stress urinary incontinence

Public title

Pelvic floor strengthening exercises in stress urinary incontinence patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 50 years Patients diagnosed with stress urinary incontinence

Exclusion criteria:

Women who are having previous pelvic floor training. Pregnant women are excluded Patients taking blood pressure medications, sedatives, muscle relaxants, and diuretics are excluded. Patients with diagnosed mental illness are excluded

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly divided in two groups (group A group B) by using lottery method. Both groups will given conventional physical therapy treatment. Group A patients will be treated with the knack maneuver along diaphragmatic breathing and Group B patients will treated with the Knack maneuver. Both group will be assessed before and after the treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Subjects in two groups will blinded from other treatment options. However they will be instructed to report any adverse effects during trial. Data will assessed by a third person which will not known about the study so trial will be single blinded study. (as outcome assessor will be blinded)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of Rashid Latif Medical College, Lahore

Street address

Rashid Latif Medical Complex 35-KM, Ferozepur Road. Lahore.

City

Lahore

Postal code

54000

Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IRB/2023/135

Health conditions studied

1

Description of health condition studied

stress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

Urinary tract symptoms

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Urinary distress incontinence-6

2

Description

Quality of life

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Incontinence Impact Questionnaire (IIQ-7)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: will given knack maneuver along diaphragmatic breathing. In group A, We will take

diagnosed patients of stress urinary incontinence and we will perform Knack maneuver along diaphragmatic breathing. Firstly patient will perform diaphragmatic breathing, we will command patient to slowly and deeply take breaths through the nose using the diaphragmatic with a minimum movement of the chest in a supine position with one hand placed on the chest and the other on the belly. During breathing, we should be careful that chest remains as still as possible and stomach moves against the hand focusing on contracting the diaphragm. Generally, inhale and exhale for approximately six seconds. Now the patient will perform Knack maneuver. During Knack training, patients is warned not to hold their breath, pull their stomach inward, strain, or contract their legs or hip muscles. The relationship between IAP increase and PFM contraction and the situations causing IAP increase (coughing, sneezing, laughing, lifting a heavy object, pushing, and bending down, etc.).The women will asked to perform the Knack maneuver before and during situations that increase intraabdominal pressure. The training program will include 2 days per week for 4 weeks

Category

Treatment - Other

2

Description

Intervention group 2 will given Knack maneuver. In group B, We will also take diagnosed patients of stress urinary incontinence and we will perform Knack maneuver. During Knack training, patients is warned not to hold their breath, pull their stomach inward, strain, or contract their legs or hip muscles. The relationship between IAP increase and PFM contraction and the situations causing IAP increase (coughing, sneezing, laughing, lifting a heavy object, pushing, and bending down, etc.).The women will ask to perform the Knack maneuver before and during situations that increase intra-abdominal pressure. The training program will include 2 days per week for 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Arif memorial teaching hospital, Lahore
Full name of responsible person
Saheeqa Qamar
Street address
35-KM, Ferozepur Road. Lahore.
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Lahore
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54900
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rashid Latif Medical college
Full name of responsible person
Hafiza Nida Rasheed
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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
Rashid Latif Medical college
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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rashid Latif Medical College
Full name of responsible person
Saheeqa Qamar
Position
Physical Therapist
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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