

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	stress urinary incontinence
ICD-10 code	N39.3
ICD-10 code description	Stress incontinence (female) (male)

Primary outcomes	
<u>1</u>	
Description	Urinary tract symptoms
Timepoint	Before intervention and 4 weeks after intervention
Method of measurement	Urinary distress incontinence-6
<u>2</u>	
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	
<u>1</u>	
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 be 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 be 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 be asked 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.

City

Lahore

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54900

Phone

+92 313 9465214

Email

saheeqaqamar.77@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rashid Latif Medical college

Full name of responsible person

Hafiza Nida Rasheed

Street address

35-KM, Ferozepur Road. Lahore.

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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

Physiotherapy

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Hafiza Nida Rasheed

Position

Physical Therapist

Latest degree

Master

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Person responsible for updating data

Contact

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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