Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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.

City

Lahore

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54900

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+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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Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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