

# 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.

##### City

Lahore

##### Postal code

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.

##### City

Lahore

##### Postal code

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##### Phone

+92 336 4535979

##### Email

naddia.rasheed20@gmail.com

#### 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

35-KM, Ferozepur Road. Lahore.

##### City

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##### Province

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##### Phone

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**Email**

saheeqaqamar.77@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rashid Latif Medical College

**Full name of responsible person**

Hafiza Nida Rasheed

**Position**

Physical Therapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rashid Latif Medical College

**Full name of responsible person**

Hafiza Nida Rasheed

**Position**

Physical Therapist

**Latest degree**

Master

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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