

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

#### Protocol summary

##### Study aim

To find the effects of Abdominal Strengthening exercises with and without Transcutaneous electrical nerve stimulation in patients with Primary Dysmenorrhea.

##### Design

Two groups, Single blinded, Randomized Controlled Trial.

##### Settings and conduct

The Perfect Physio And Spine Care Centre, Asjad Clinic, Minhaj Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Females aged 20 to 30 years; The characteristic of pain must be periodic (at least following 3 menstrual cycles) and gradually diminishes over 12 to 72 hours, ends after period. The pain must start generally in 2 to 3 years after start of menarche; regular menses (25-31 day). Exclusion Criteria: Chronic abdominal pain. Fibroids. Irritable bowel syndrome.

##### Intervention groups

Group A: Abdominal strengthening exercises with TENS.

Group B: Abdominal strengthening exercises without TENS.

##### Main outcome variables

Work, ability, Location, Intensity, Days of Pain, Dysmenorrhea (WaLIDD) Oswestry Disability Index (ODI) Numeric Pain Rating Scale (NPRS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191218045777N1**

Registration date: **2020-01-12, 1398/10/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

##### Registration date

2020-01-12, 1398/10/22

##### Registrant information

###### Name

sana qaisar

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 42 35126110

###### Email address

maazqaisar00786@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-01, 1398/09/10

##### Expected recruitment end date

2020-01-15, 1398/10/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

##### Public title

Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Females aged of 20 to 30 years. Nulliparous patients with symptoms of severe primary dysmenorrhea. The characteristic of pain must be periodic (at least following 3 menstrual cycles). Lower abdominal cramps or pelvic colic like pain that starts up to one day before menses lasts for the 3 days of bleeding. Gradually diminishes over 12 to 72 hours, ends after period. The pain must start generally in 2 to 3 years after menarche with regular menses (25-31 day).

#### **Exclusion criteria:**

Patients with history of pelvic inflammatory diseases (endometriosis, ovarian cysts). Chronic abdominal pain. Fibroids. Irritable bowel syndrome. Major abdominal or pelvic surgery. Intrauterine device and patients treated with oral contraceptive pills was contraindicated. Patients enrolled simultaneously into other studies that require drug intake or otherwise prevent compliance with protocol.

### **Age**

From **20 years** old to **30 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

- Outcome assessor

### **Sample size**

Target sample size: **22**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Written informed consent will be taken. After enrollment into study, patient will be allocated either to group A or Group B by lottery method. No. of Chits will be equal to total sample size, odd Numbers will be allocated to Group A and even number will be allocated to Group B. Each patient will be requested to draw a hit from the box and after that patient will be recruited into either Group A or Group B.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

Assessor blind: Data Being secretive will be ensured by assigning specific identity number and all documents and forms will be placed in locker to blind assessors.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Secretary ethical review committee, Riphah College of Rehabilitation and Allied Health Sciences

##### **Street address**

28-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore

##### **City**

Lahore

##### **Postal code**

54000

#### **Approval date**

2019-09-19, 1398/06/28

#### **Ethics committee reference number**

Ref. No, RCR & AHS/REC/MS-NMPT/S19/007

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Primary dysmenorrhea

#### **ICD-10 code**

N94.4

#### **ICD-10 code description**

Primary dysmenorrhea

## **Primary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

Before treatment and after completing the session

#### **Method of measurement**

Numeric pain rating scale (NPRS).

## **Secondary outcomes**

### 1

#### **Description**

Low back pain/symptoms severity

#### **Timepoint**

Before and after completing treatment session

#### **Method of measurement**

Owestry disability index (ODI).

### 2

#### **Description**

Severity of dysmmenorrhea

#### **Timepoint**

Before and after completing the session

#### **Method of measurement**

Working ability, Location, Intensity, Days of pain, Dysmmenorrhea (WaLIDD).

## Intervention groups

### 1

#### Description

Intervention group A Abdominal strengthening exercises with TENS

#### Category

Treatment - Other

### 2

#### Description

Intervention group B Abdominal strengthening exercises without TENS

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The Perfect Physio And Spine Care Centre

##### Full name of responsible person

Dr Saqib Fareed

##### Street address

The Perfect Physiotherapy and spine care Center,  
Opposite Faisal Stadium, D.G. Khan Road, Muzaffar  
Garh

##### City

Muzaffargarh

##### Postal code

34200

##### Phone

+92 66 2423000

##### Email

jugnomsf26@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Minhaj hospital

##### Full name of responsible person

Dr Aslam Minhaj

##### Street address

Ganishwa pool, near puranl Sabiz Mandi, Minhaj  
hospital.

##### City

Muzaffargarh

##### Postal code

34200

##### Phone

+92 66 2423000

##### Email

marifkhore@gmail.com

### 3

#### Recruitment center

##### Name of recruitment center

Asjad clinic

##### Full name of responsible person

Dr salma Ghouri

##### Street address

near city public school, karbala road, muzaffargarh

##### City

Muzaffargarh

##### Postal code

34200

##### Phone

+92 66 2423000

##### Email

kousarmehwish00786@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Riphah International University

##### Full name of responsible person

Muhammad Salman Bashir

##### Street address

28-M Quaid-e-Azam Industrial Estate, Kot Lakhpat,  
Lahore

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 35126110

##### Email

chistisalman@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Riphah International University

#### Proportion provided by this source

20

#### Public or private sector

Private

#### Domestic or foreign origin

Foreign

#### Category of foreign source of funding

Sponsor: country of origin

#### Country of origin

PK

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Riphah International University

##### Full name of responsible person

Muhammad Salman Bashir

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpat,  
Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

+92 42 35126110

**Email**

chistisalman@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Riphah International University

**Full name of responsible person**

Muhammad Salman Bashir

**Position**

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**Other areas of specialty/work**

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**Postal code**

54000

**Phone**

+92 42 35126110

**Email**

chistisalman@yahoo.com

**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