Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ecexercises without TENS.

Main outcome variables
Work, ability, Location, Intensity, Days of Pain, Dysmenorrhea (WaLIDD) Owestry 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
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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 chit 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
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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
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54000
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+92 42 35126110
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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
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28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore
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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