Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of myofascial release technique on pain and quality of life in patient of fibromyalgia: a randomised controlled trial

Protocol summary

Study aim
To compare the effects of myofascial release technique on pain and quality of life in patients with fibromyalgia.

Design
Randomized Controlled Trial; single-blinded; on 110 samples; parallel groups; randomized by computer-generated method and further concealed envelop method used for allocation in the group. In the envelope, 1 will be code for the control group and 2 will be code for the experimental group.

Settings and conduct
The study will be conducted at the department of Physiotherapy, Nishtar Hospital, Multan. The study will be single-blinded. The assessor will unaware of the treatment given to either group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Both gender. Age between 20-40 years. Diagnosis of fibromyalgia according to the criteria of the American College of Rheumatology. History of wide spread chronic pain for more than 3 months. Patient must exhibit more than 11 of 18 tender point. Exclusion Criteria: The cognitive deficit that does not allow the understanding of the evaluation instruments. The physical activity started or changed in the last three months.

Intervention groups
Intervention group: Myofascial mobilization with routine physical therapy in the intervention group. The participants executed a 12-week supervised strengthening exercise program of 40-minute sessions performed twice a week, with progressive overload. In the first two sessions, no load was used. Subsequently, 0.5kg was added each week if the patient identified the effort as slightly intense on the Borg scale (score = 13)22. Control group: Routine physical therapy.

Main outcome variables
Pain; Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210321050752N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date
2023-02-20, 1401/12/01

Registrant information

Name
Muhammad Waqas

Name of organization / entity
The University of Lahore

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-02, 1401/10/12

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of myofascial release technique on pain and quality of life in patient of fibromyalgia: a randomised controlled trial

Public title
Myofascial release technique on pain and quality of life in patient of fibromyalgia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Both gender Age between 20-40 years Diagnosis of fibromyalgia according to the criteria of the American College of Rheumatology History of widespread chronic pain for more than 3 months The patient must exhibit more than 11 of 18 tender point

Exclusion criteria:
Cognitive deficit that does not allow the understanding of the evaluation instruments Physical activity started or changed in the last three months

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized by using the computer-generated method and further concealed envelop method is used for allocation in the group. In the envelop, 1 will be code for the control group and 2 will be code for the experimental group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Assessor will only assess the patient at baseline and after follow-up for treatment outcomes. Assessor safe the data for follow-up and will not share it with any therapist or patient. At any stage, the assessor is unaware of the treatment and control group. The study was single-blinded. The assessor was unaware of the treatment given to either groups 1 or 2.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The rules and regulations set by the ethical committee of The University of Lahore wIll be followed

Street address
RAIWIND ROAD CAMPUS: 1-Km, Raiwind Road, Near Thokar Niaz Big, Lahore

City
Lahore

Postal code
54000

Approval date
2023-02-01, 1401/11/12

Ethics committee reference number
REC-UOL-289-01-2023

Health conditions studied

1

Description of health condition studied
Fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Pain

Timepoint
Data will be calculated at baseline, 1st follow up at 8th week and 2nd follow up at 16th week.

Method of measurement
● Numeric pain rating scale to measure pain

2

Description
Quality of life

Timepoint
Data will be calculated at baseline, 1st follow up at 8th week and 2nd follow up at 16th week

Method of measurement
WHO Quality of life questionnaire used to assess quality of life.

Secondary outcomes

empty

Intervention groups

1

Description
Group B: Myofascial mobilization with routine physical therapy: The participants executed a 12-week supervised myofascial mobilization program of 40-minute sessions performed twice a week.

Category
Rehabilitation

2

Description
Group A: Routine physical therapy: The routine physical therapy group underwent a 12-week supervised exercise program of 40- minute sessions performed thrice a week. Stretching and strengthening exercises. TENS units, ultrasound are applied on participant. The targeted muscles for stretching were: gluteus, iliopsoas, ischiotibials, paravertebralis, latissimus dorsi, hip adductor muscles, trapezium and pectoralis. At early stages of the program, participants performed three repetitions; from the fifth week, four repetitions; and from the ninth week, five. The stretch intensity were increased gradually to the point of moderate discomfort and the position was held for 30 seconds. Myofascial mobilization release will be given before every session of stretching exercise. Readings will be taken at baseline, 6th or 12th week of interventionThe participants executed a 12-week supervised strengthening exercise program of 40-minute sessions performed twice a week, with progressive overload. In the first two sessions, no load was used. Subsequently, 0.5kg was added each week if the patient identified the effort as slightly intense on the Borg scale (score = 13)22.The patients were instructed to do a series of eight repetitions of strengthening exercises for the following muscles23: triceps surae, hip adductors and abductors, hip flexor, shoulder flexor and extensor, anterior and posterior deltoids, pectoralis major and rhomboids

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Physiotherapy, Nishtar Hospital, Multan

Full name of responsible person
Dr Talha Qazi

Street address
Nishter hospital Multan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Self Supported

Full name of responsible person
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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
Self Supported

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
The University of Lahore

Full name of responsible person
Muhammad Waqas

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Numeric pain rating scale will be used for the assessment of pain. WHO Quality of life questionnaire will be used to assess the quality of life.
When the data will become available and for how long
6 months after publication.
To whom data/document is available
academic and clinical research writers.
Under which criteria data/document could be used
Never without permission.
From where data/document is obtainable
From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account. https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf
What processes are involved for a request to access data/document
From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account. https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf
Comments