Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of active segmental stretching and 30-minute walking on fibromyalgia symptoms reduction in female

Protocol summary

Study aim

1. To check efficacy of active segmental stretching and 30-minute walking on pain reduction. 2. To check life's quality in fibromyalgia patients.

Design

A parallel group, single blinded, randomized controlled trial conducted on 62 females diagnosed with fibromyalgia between August to November 2022 with a 6 week follow up.

Settings and conduct

This study was conducted in orthopedic department of Aziz Bhatti THQ hospital, Gujrat Data analyser is only blinded in our study because he does not know which and how interventional exercises were performed by patients.

Participants/Inclusion and exclusion criteria

Inclusion: Female from 20 to 65 year old diagnosed with fibromyalgia in outpatient/inpatient clinics or by America College of Rheumatology Criteria in general population. Exclusion: Joint disorders (Grade 4 arthritis, hip or knee arthroplasty, rheumatoid arthritis) that can cause hindrance in the exercise program. Respiratory diseases or cardiovascular diseases (heart failure, cardiac pacemaker, uncontrolled arterial hypertension) that would prevent physical exercise. Pregnant and post-partum women.

Intervention groups

Active segmental stretching group: Participants undergone through a 6-week supervised exercise program involving active segmental stretching of muscles mostly involving large muscles (paravertebral, gluteus, quadricep, hip abductor, latissmus dorsi, pectoral, trapezius and calf stretches). Each exercise was held for 30 seconDS 30- minute walking group: participants only undergo 30 min of brisk walk in bouts of 15 minute with no other specific exercises or Each intervention was done thrice a week for first three weeks and four time per week for the next three weeks

Main outcome variables

Fibromyalgia impact questionnaire-revised (FIQR) for symptoms and impact of Fibromyalgia Numeric pain rating scale for pain SF-12 for quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221205056715N1**
Registration date: **2022-12-21, 1401/09/30**
Registration timing: **retrospective**

Last update: **2022-12-21, 1401/09/30**
Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Mubashra Warriach

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 331 6258175

Email address

warriachmubashra@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-05, 1401/05/14

Expected recruitment end date

2022-11-30, 1401/09/09

Actual recruitment start date

2022-08-15, 1401/05/24

Actual recruitment end date
2022-11-15, 1401/08/24
Trial completion date
2022-11-20, 1401/08/29

Scientific title
Effectiveness of active segmental stretching and 30-minute walking on fibromyalgia symptoms reduction in female

Public title
Effectiveness of active segmental stretching and 30-minute walking on fibromyalgia symptoms reduction in female
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
20 to 65 years females Participants diagnosed with fibromyalgia in outpatient/inpatient clinics or diagnosed by American College of Rheumatology Criteria in general population. Written informed consent was considered necessary from study participants to enable them to take part.
Exclusion criteria:
joint disorders (Grade 4 arthritis, hip or knee arthroplasty, rheumatoid arthritis) that can cause hindrance in the exercise program respiratory diseases or cardiovascular diseases that would prevent physical exercise pregnant and post-partum women recent modifications to FM therapy such as pyschotherapy
Age
From **20 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **62**
Actual sample size reached: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random sampling method was used with individual randomization unit. Randomization is done by computer software. Patients were haphazardly placed in either of 2 interventional group with 31 fibromyalgia patient in each. no allocation concealment was done
Blinding (investigator's opinion)
Single blinded
Blinding description
data analyser is blinded in my study because he does not know anything about patients being randomized into any group and he also does not know which exercises are performed.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Lahore
Street address
Shadman colony, Defense block, street 1, Gujrat
City
Gujrat
Postal code
50700
Approval date
2022-08-15, 1401/05/24
Ethics committee reference number
REG/GRT/22/AHS-81

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Fibromyalgia symptom reduction
Timepoint
Baseline, 3rd week and 6th week
Method of measurement
Fibromyalgia impact questionnaire-revised (FIQR)

Secondary outcomes

1

Description
Pain
Timepoint
baseline, 3rd week and 6th week
Method of measurement
Numeric pain rating scale(NPRS)

2

Description
Quality of life
Timepoint

baseline, 3rd week and 6th week

Method of measurement

SF-12 Health survey questionnaire

Intervention groups

1

Description

Intervention group: Active segmental stretching exercises should be performed to patients thrice a week for 1st 3 weeks and 4 times a week for the last 3 weeks. Exercises include trapezius, pectoral, calfs, gluteal and many other stretches of large muscles.

Category

Rehabilitation

2

Description

Intervention group: 30 minute walking thrice a week from baseline to 3rd week, further frequency increases from 4 times a week for last 3 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Lahore

Full name of responsible person
Mubashra Maqsood

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Shadman colony, Defense block, street 1, Gujrat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

University of lahore

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
University of Lahore

Full name of responsible person
Mubashra Maqsood

Position
Consultant

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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
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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Effectiveness of active segmental stretching and 30 minute walking on fibromyalgia symptom reduction
When the data will become available and for how long
after publication
To whom data/document is available
to all acadamic and working insititutions
Under which criteria data/document could be used
for rehabilitation purposes
From where data/document is obtainable
from researcher
What processes are involved for a request to access data/document
will let you know later
Comments