

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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, quadriceps, hip abductor, latissimus 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 psychotherapy

**Age**

From **20 years** old to **65 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Data analyst

**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 analyst 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

**Street address**

Shadman colony, Defense block, street 1, Gujrat

**City**

Gujrat

**Postal code**

50700

**Phone**

+92 331 6258175

**Email**

warriachmubashra@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

University of lahore

**Full name of responsible person**

Mubashra maqsood

**Street address**

street 1 defense block shadman colony gujrat

**City**

gujrat

**Postal code**

50700

**Phone**

+92 331 6258175

**Email**

warriachmubashra@gmail.com

**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

**Street address**

Shadman colony, defense block street 1, Gujrat

**City**

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**Province**

Punjab

**Postal code**

50700

**Phone**

+92 331 6258175

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

University of Lahore

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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 academic and working institutions

**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**