Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: A randomized trial.

Protocol summary

Study aim
The aim of this study is to compare the effect of spinal manipulation therapy, general exercise therapy and motor control exercises in chronic low back pain patients.

Design
Randomize control clinical trial, three parallel groups with single blinded study

Settings and conduct
Sample size is 36. Randomized clinical trial will be conducted and the data will be collected from Kannan physiotherapy and spinal clinic,Lahore.

Participants/Inclusion and exclusion criteria
INCLUSION CRITERIA:Non-specific low back pain for at least 3 months,Age between 18 and 35 years EXCLUSION CRITERIA:Neurological signs, Specific spinal pathology ,Back surgery. Serious low back pathology

Intervention groups
Three interventional groups named as general exercises, motor control exercises and spinal manipulation therapy are formed. First two groups participants will attend eight sessions of one hour, twice a week, for four weeks.The first group class will be modeled on the 'Back to Fitness' program described by(Klaber Moffett and Frost, 2000). The classes will start with Warm-up and Stretching. After about seven to ten minutes, stretching exercises are started then Warm-down and Relaxation. Secong group will be teached how to contract the transversus abdominis and multifidus muscles in isolation from the more superficial trunk muscles, but in conjunction with the pelvic floor muscles. Spinal manipulative group participants will be given joint mobilization or manipulation techniques applying to the lumber spine (Maitland et al.,2001). Participants in this group will not get exercises or a home exercise program, and they will get advice to avoid pain-aggravating activities. Manipulative therapy will discontinue if the participant completely recover before the 8 sessions are complete.

Main outcome variables
Two primary outcomes. • Function •Pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200511047391N1**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **retrospective**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**

Registration date
2020-06-27, 1399/04/07

Registrant information

Name
Ammara Khalid

Name of organization / entity
Riphah International University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-26, 1398/09/05

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: A randomized trial.

Public title

Effect of general exercise, motor control exercise and spinal manipulative therapy in treatment of low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

o Non-specific low back pain for at least 3 months o Age between 18 and 80 years o Written informed voluntary consent

Exclusion criteria:

o Neurological signs o Specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease) o Back surgery. o Serious low back pathology

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomisation is done through simple random sampling. Concealment of allocation through sealed envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

An accessor will be hired who will access the initials and outcome of the patients at the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah College of Rehabilitation and Allied health science

Street address

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

City

Lahore

Postal code

54770

Approval date

2019-10-08, 1398/07/16

Ethics committee reference number

REC/RCRS/20/1014

Health conditions studied

1

Description of health condition studied

Chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Function

Timepoint

Once before intervention and one after the discharge that is 4 weeks.

Method of measurement

Patient-Specific Functional Scale

2

Description

Pain

Timepoint

Once before intervention and one after the discharge that is 4 weeks.

Method of measurement

Numerical pain rating scale

Secondary outcomes

1

Description

Secondary outcome is Disability measured by:• Oswestry Disability Index.

Timepoint

Once at the start of the study and once at the end of the study that is after 4 weeks.

Method of measurement

Disability measured by Oswestry Disability Index.

Intervention groups

1

Description

General exercise group determine:• How physically active the participant is• How troublesome the back problem is• The ability of the participant to perform the exercises. Participant will attend eight sessions of one hour, twice a week, for four weeks. The exercises will be performed under the supervision of a physical therapist in classes of up to 12 people. The intensity of the exercises will be progressing over the 8 treatments with participants being encouraged to improve their own performance rather than competing with other members of the class. The main aims of the program will be to improve physical function and confidence in using the spine, and to teach participants how to cope with their back problems.The exercises aim to:• Strengthen the main muscle groups of the body, including the abdominal and trunk muscles,• Stretch the main muscle groups • Increase cardiovascular fitness with low-impact aerobic exercises. The classes will start with Warm-up and Stretching: After about seven to ten minutes, stretching exercises are started. Warm-down and Relaxation:These are similar to the warm-up exercises, but should allow the body gradually to slow down and cool down.After a warm-down session, there will be a short relaxation session and then, at the end of the class, a brief educational message will be provided as a ‘‘tip of the day’’.

Category

Rehabilitation

2

Description

Participants allocating to the motor control exercise group will be prescribing exercises aiming to:• Improve function of specific trunk muscles thought to control inter-segmental movement of the spine, including transversus abdominis, multifidus, the diaphragm and pelvic floor muscles.Initially participants are going to teach how to contract the transversus abdominis and multifidus muscles in isolation from the more superficial trunk muscles, but in conjunction with the pelvic floor muscles. • Proper engagement of your TVA and Pelvic Floor feels like a gentle upward and inward pulling. Inhale to prepare. Exhale as you gently pull upward on pelvic floor and inward with tummy to spine. Inhale to release the muscles. Multifidus Activation: The difficulty of the tasks will be progressing by incorporating more functional positions and training the coordination of all trunk muscles during functional.When treating participants in both exercise groups, physical therapists will apply principles of cognitive-behavioural therapy.Participants in both exercise groups will be encouraged to exercise at home at least once a day and to finish all 8 training sessions regardless of the extent of recovery.

Category

Rehabilitation

3

Description

Participants allocating to the spinal manipulative therapy group will get treated with:• Joint mobilization or manipulation techniques applying to the lumber spine. •Grade I-IV joint mobilization may be useful as a pre-test for the appropriateness of manipulation, as a pre-treatment for manipulation, or as a substitute for manipulation in patients where manipulation might be contraindicated. Grade V mobilization should be construed as joint manipulation or adjusting. The particular dose and techniques will be at the discretion of the treating physical therapist, based on:• Each participant’s physical examination findings. Participants in this group will not get exercises or a home exercise program, and they will get advice to avoid pain-aggravating activities. Manipulative therapy will discontinue if the participant completely recover before the 8 sessions are complete, as is standard clinical practice.The physical therapist will qualify to apply all three interventions. Participants in all groups are going to ask not to seek other treatments and where possible not to change current medications for the 4 week trial period.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Kannan physiotherapy and spinal clinic

Full name of responsible person
Dr. Naveed Anwar

Street address
Shahrah Aiwan-e-Sanat-o-Tijarat Opposite Governor House Main Gate, , Lahore, Pakistan-00054

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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?
No
Title of funding source
self funded
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general 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
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

all collected deidentified IPD

When the data will become available and for how long

most probably starting 6 months after publication

To whom data/document is available

For researchers

Under which criteria data/document could be used

for research purposes

From where data/document is obtainable

Through email

What processes are involved for a request to access data/document

Data will be available through email.

Comments