Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of stabilization exercises in addition to routine physical therapy in elderly patients with back pain; A randomized controlled trial

Protocol summary

Study aim
To compare the effects of stabilization exercises in addition to routine physical therapy in elderly patients with back pain

Design
Single Blinded randomized Controlled Trial (RCT)

Settings and conduct
Out patient department of Banu Bai Physiotherapy Centre, Zuleikhabai V.M. Gany Rangoonwala Trust, Karachi, Pakistan

Participants/Inclusion and exclusion criteria
participant of age 60 years of males and females with chronic back pain will be included. particpiants with vestibular,severe neurological dysfunction will be excluded

Intervention groups
The Patients will receive Routine Physical Therapy and Stabilization exercises in experimental group. These specific pattern of stabilization enhanced exercises will be performed by the experimental group. The exercises sessions are divided into four sections in accordance with week wise.

Main outcome variables
1. Visual analogue scale (VAS) 2. Endurance tests 3. Berg balance scale (BBS) 4. Oswestry low back pain disability questionnaire (ODI) 5. Range of motion (ROM), Goniometer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191218045786N1**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

Name
MUHAMMAD SHAHID

Name of organization / entity
University Institute of Physical Therapy, University of Lahore, Lahore Pakistan

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-29, 1399/11/10

Expected recruitment end date
2022-08-29, 1401/06/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of stabilization exercises in addition to routine physical therapy in elderly patients with back pain; A randomized controlled trial

Public title
Stabilization Exercises for elderly patients with back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 60 years and above Both male and female patients Elderly with chronic backache(more than 3 months) Independent gait ability with or without walking aid for a minimum of 15 m. Adequate vision and hearing for completion of the study protocol, as indicated by the ability to follow written and oral instructions during screening Capacity to understand and follow instructions Elderly with adequate stamina to perform stabilization

Exclusion criteria:

A history of stroke or other neurologic diseases or disorders Subjects with specific pathology, such as systemic inflammatory diseases (e.g. systemic lupus erythematous(SLE), rheumatoid arthritis(RA), nephritis etc.), prolapsed disc(PD), fractures and deformities (spine or extremities), bone tumors and bone infections Pain, limited motion, or weakness in the lower extremity that affects performance of daily activities (by self-report) Vestibular dysfunctions e.g. Benign Paroxysmal Positional Vertigo (BPPV) Acute cardiac surgeries e.g. Coronary artery bypass grafting (CABG`s) Unstable angina e.g. Myocardial infarction (MI) Persistent pulmonary pathology(e.g. exertional dyspnoea (ED)

Age

From **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

A single bind randomized controlled design will be used.Assessor will be blinded in the present study.Patients, once accepted into the study will be randomly assigned to a treatment group by Chit-box method, either experimental group (stabilization exercises and routine Physical therapy or control group (routine physical therapy and stretching exercises). There will be added co-intervention and home program for both groups. This will be parallel group randomized controlled trial with 1:1 allocation ratio into two groups. Each patient therefore will have an equal chance of being selected in either group. The patients will be allocated into two groups i.e. Experimental group and control group by randomization through Chit-box method. Experimental group patients will be treated with stabilization exercises and routine physical therapy while those of control group will be treated with routine physical therapy and stretching exercises. Chit-Box Method: For random allocation at least 60 cases into two groups equally, prepare 60 chits writing “C” (for Control group) on 30 chits and “E” (for Experimental group) on 30 chits. After folding the chits and putting in a box and well mixing, draw a chit, note the letter written on it, and then draw the second chit without replacing the first, note it and proceed similarly until the last i.e. 60th chit is drawn. According to the sequence the first case registered will go to the control group, second case to the experimental group and will continue the sequence till last participant selection.

Blinding (investigator's opinion)

Single blinded

Blinding description

This will be a single blinded randomized controlled trial .The assessor will only be kept blinded in this research study. The relevant details of the research study will be given to the participants at the time of taking consent; however they will remain unaware of their own group allocation. The assessor will remain unaware about who will be selected as research sample participants including unaware about experimental and control groups. The physical therapist will not be allowed to take the pre-post score outcome measurements. The assessors will not know the details of the treatment. The principal investigator alone will administer the treatment. Final session outcome measurements (post intervention) will be recorded by the above mentioned assessor.

Placebo

Not used

Assignment

Other

Other design features

Patients, once accepted into the study will be randomly assigned to a treatment group by Chit-box method, either experimental group (stabilization exercises and routine Physical therapy or control group (routine physical therapy and stretching exercises). There will be added co-intervention and home program for both groups. This will be parallel group randomized controlled trial with 1:1 allocation ratio into two groups. Each patient therefore will have an equal chance of being selected in either group. For random allocation of at least 60 cases into two groups equally, prepare 60 chits writing “C” (for Control group) on 30 chits and “E” (for Experimental group) on 30 chits. After folding the chits and putting in a box and well mixing, draw a chit, note the letter written on it, and then draw the second chit without replacing the first, note it and proceed similarly until the last i.e. 60th chit is drawn. . The first case registered will go to the control group, second group to the experimental group and the sequence will be continued till the selection of the last participant. The treatment procedures will be repeated for 5 sessions of 45 minutes each per week for 4 weeks (20 sessions).The Post-test scores of Visual analogue scale (VAS), berg balance scale (BBS), trunk muscles endurance tests, trunk range of motion (ROM) and functional disability will be collected after one month of treatment administration. The patients will have to read the letter of information and if they agree to participate then they will be asked to sign the letter of consent before they are allowed to participate in the study. All the patients can contact to the researcher in order to find out any further information regarding their participation in the study. The participants will be provided the facility as per required for the research. The health of the patients will be on priority and all the patients will be free to

withdrawn anytime.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Instituitional Review Board (IRB), University of Lahore, Lahore, Pakistan

Street address
1-KM Defence Road.off bhopatian Chowk, Lahore

City
Lahore

Postal code
54000

Approval date
2018-09-20, 1397/06/29

Ethics committee reference number
IRB-UOL-FAHS/373-1/2018

Health conditions studied

1

Description of health condition studied
Chronic Back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Back Pain

Timepoint
Before intervention and at 4 weeks after intervention

Method of measurement
Scoring by VAS (Visual Analigue Scale)

2

Description
ROM (Range of Motion)

Timepoint
Before intervention and at 4 weeks after intervention

Method of measurement
Scoring , Degree measurement by Goniometer

Secondary outcomes

1

Description
Endurance of Trunk Flexors and Extensors

Timepoint
Before intervention and at 4 weeks after intervention.

Method of measurement
Scoring by Endurance Tests

2

Description
Balance

Timepoint
Before intervention and at 4 weeks after intervention.

Method of measurement
Berg Balance Scale

3

Description
Functional Disability

Timepoint
Before intervention and at 4 weeks after intervention.

Method of measurement
Oswestry Disability Index

Intervention groups

1

Description
Experimental Group: The participants of the experimental group will perform routine Physiotherapy exercise plus specific Stabilization exercises of the back. The duration of the exercises will be 45 minutes.There will be total 20 sessions(4 weeks), including 5 sessions/ week.

Category
Rehabilitation

2

Description
Control group: The participants of the Control group will perform routine Physiotherapy exercise plus stretching exercises of the back. The duration of the exercises will be 45 minutes. There will be total 20 sessions(4 weeks), including 5 sessions/ week

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Banu Bai Physiotherapy Centre, Zuleikhabai V.M. Gany Rangoonwala Trust

Full name of responsible person
Dr.Muhammad Shahid

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ZVMG Rangonwala Trsut ,Dhoraji Colony, Karachi, Pakistan

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Dr. Muhammad Shahid
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Grant name
N/A
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Lahore , Main Campus
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
University of Lahore
Full name of responsible person
Dr. Muhammad Shahid
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
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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
Data will be available to the other people after the completion of the study and will remained available till 6 months

To whom data/document is available
Data will be available for the people working in academic institutions

Under which criteria data/document could be used
Data will be shared for the purpose of RCT and other interventional research studies. Data can be accessed by communicating with principle invigilator" Muhammad Shahid" through email address: Shahidmirkhan@yahoo.com

From where data/document is obtainable
Data is available by communicating with principle invigilator" Muhammad Shahid" through email address: Shahidmirkhan@yahoo.com

What processes are involved for a request to access data/document
Data/document can be accessed by communicating with principle invigilator" Muhammad Shahid" through email address: Shahidmirkhan@yahoo.com

Comments
N/A