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How balance and hamstring exercises can help relieve lower back pain

Submission date
23/05/2024

Recruitment status
No longer recruiting

Registration date
28/05/2024

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain negatively affects people's lives. We don't yet know if balance and hamstring training can help.
We studied 26 adults with low back pain to see if balance combined with hamstring training can be an effective treatment.

Who can participate?
Patients with lower back pain, aged 18 - 65 years

What does the study involve?
We invited participants to do balance and hamstring exercises for 6 weeks. We tested them on pain intensity, balance ability, back and abdominal strength and endurance, and hamstring flexibility and strength. These tests showed if they felt better after 6 weeks of these exercises. We measured these tests at the beginning and end of the study.

What are the possible benefits and risks of participating?
Participants will receive guidance from a professional sport therapist during the 6-week study period. Exercise intervention is moderate physical activity and will be done under the supervision of the researcher, Thus the intervention is not expected to be associated with any risks.

Where is the study run from?
Shenzhen University (China)

When is the study starting and how long is it expected to run for?
October 2021 to September 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluating the therapeutic effect of combined balance and hamstring training (CBHT) in patients with nonspecific low back pain: a randomized controlled trial

Acronym
BALANCE-HAM

Study objectives
A 6-week of balance and hamstring training is effective in reducing pain intensity, improving back strength, abdominal and back endurance, and hamstring strength.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/06/2022, Medical Ethics Committee, Department of medicine, Shenzhen University (No. 3688, Nanhai Road, Nanshan District, Shenzhen, 518060, China; +86 755-86671906; spchen@szu.edu.cn), ref: PN-202200024

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Non-specific low back pain

Interventions
This study, conducted in the laboratory of the College of Physical Education, Shenzhen University, randomly allocated 26 patients with non-specific lower back pain into either an experimental group, receiving balance combined with hamstring training, or a control group with no intervention, using computer-generated randomization and employing assessor-blinded masking, with outcomes assessed over a 6-week period.

Participants in the experimental group (EG) were given balance combined with hamstring training, and control group (CG) received no intervention. EG completed the training program for a 45-min session, with 3 sessions per week for up to 6 weeks. Each training session consisted of 4 parts: warm-up (5min), balance training (20min), hamstring training (15min), and relaxation (5min). The goal of the warm-up was to activate the low back and abdominal muscles through some simple gymnastics. Balance training was the combination of static and dynamic balance, using the TOGU Balance training system During balance training, participants were constantly reminded to tighten the abdomen and exert strength with the buttocks and thighs to control

the core stability of the body. Hamstring training involved stretching and strength training. The goal was to release overstrained muscles and increase hamstring contraction. Relaxation included abdominal stretching, back stretching, and releasing muscle with a roller. In this part, participants used a roller to relax the muscles in the low back and legs. The goal was to relax the tired muscles after training and promote physical recovery.

Intervention Type
Behavioural

Primary outcome measure
Pain is measured using a visual analogue scale (VAS) at baseline and at the week 7, following completion of the 6 week exercise programme

Secondary outcome measures
1. Balance ability is measured using the TOGU Balance Test system at baseline and at the week 7, following completion of the 6 week exercise programme
2. Abdominal and back muscles strength is measured using isometric force testing device at baseline and at the week 7, following completion of the 6 week exercise programme
3. Abdominal and back muscles endurance is measured using holding time at baseline and at the week 7, following completion of the 6 week exercise programme
4. Hamstring extensibility is measured using sit-and-reach test at baseline and at the week 7, following completion of the 6 week exercise programme
5. Hamstrings strength is measured using isometric force testing device at baseline and at the week 7, following completion of the 6 week exercise programme

Overall study start date
01/10/2021

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Pain in the 12th costal to gluteal fold in the past year, with or without numbness and radiating pain in the lower extremities
2. Normal cognitive function, no craniocerebral injury, cerebrovascular disease, epilepsy, and other complications
3. No pacemaker and stent implantation in the body.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

65 Years

Sex
Both

Target number of participants
35

Total final enrolment
30

Key exclusion criteria
1. Tumor, tuberculosis, fracture, or specific low back pain caused by definite infection
2. Sciatica or radicular pain syndrome
3. A definite history of spinal trauma and surgery
4. Patients with severe heart disease and visceral disease
5. The lumbar injury is in the acute phase

Date of first enrolment
10/06/2022

Date of final enrolment
29/06/2022

Locations

Countries of recruitment
China

Study participating centre
Shenzhen University
Faculty of Physical Education
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Sponsor information

Organisation
Shenzhen University

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Sponsor type
University/education

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ROR
https://ror.org/01vy4gh70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of this study will be submitted for publication in a peer-reviewed journal and presented at conferences.

Intention to publish date
15/10/2024

Individual participant data (IPD) sharing plan
Data will be available upon reasonable request
1900371004@email.szu.edu.cn

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/05/2024	No	Yes
Statistical Analysis Plan			24/05/2024	No	No
Results article		28/02/2025	28/02/2025	Yes	No