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	Ľ

Prospectively registered

[] Protocol

[X] Statistical analysis plan

[X] Results

📋 Individual participant data

Plain English Summary

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? 1900371004@email.szu.edu.cn

Contact information

Type(s) Principal Investigator

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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 hypothesis

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

Condition

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

 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
 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

Overall study end date

30/09/2022

Eligibility

Participant 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

Participant 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

Recruitment start date

10/06/2022

Recruitment end date 29/06/2022

Locations

Countries of recruitment China

Study participating centre Shenzhen University Faculty of Physical Education Shenzhen China 518060

Sponsor information

Organisation Shenzhen University

Sponsor details Faculty of Physical Education Shenzhen China 518060 +86 755-26534772 szuyz@szu.edu.cn

Sponsor type University/education

Website http://www.szu.edu.cn/2014/en/

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
<u>Statistical Analysis Plan</u>			24/05/2024	No	No
<u>Results article</u>		28/02/2025	28/02/2025	Yes	No