

Immediate effect of thoracic mobilization on trunk motion, pain sensation and lumbar spine muscle activity in patients with chronic low back pain

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Registration date 22/10/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/11/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain in older people is a common degenerative disease that mainly involves the structures of the lumbar spine such as the intervertebral discs, facet joints, and ligaments leading to lumbar instability. Conservative management is recommended as first-line therapy for mild to moderate low back pain. A combination of clinical treatments shows beneficial effects to chronic low back pain (CLBP) patients. Thoracic mobilization is a common manual technique in clinical practice. However, the effects of thoracic mobilization on pain sensation and muscle function in individuals with CLBP have not been explored. The aim of this study is to investigate the immediate effects of thoracic mobilization and soft tissue release technique on trunk movement, pain sensation, and muscle activity in CLBP patients.

Who can participate?

Low back pain patients aged 40-70 years with mild degenerated lumbar spondylolisthesis

What does the study involve?

Participants are randomly allocated into two groups: the thoracic mobilization group and the soft tissue release group. The treatment is performed in a single session. Trunk motion, tissue hardness, pressure pain threshold, and trunk muscle activity during a lifting task are measured before and immediately after the treatment.

What are the possible benefits and risks of participating?

Both interventions would increase trunk range of motion and pressure pain threshold, as well as reduce tissue hardness and muscle activation. However, this study might have some minor risks such as feeling uncomfortable lying prone or muscle soreness after the interventions.

Where does the study run from?

National Cheng Kung University (Taiwan)

When is the study starting and how long is it expected to run for?
July 2015 to July 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Associate Professor Cheng-Feng Lin
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Contact information

Type(s)
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
Immediate effect of thoracic mobilization on trunk motion, pain sensation and lumbar spine muscle activity in patients with chronic low back pain

Study objectives

It is hypothesized that thoracic mobilization and soft tissue release intervention would improve the outcome variables and the mobilization technique might lead to superior effects than the soft tissue release.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/11/2015, Institutional Review Board of National Cheng Kung University Hospital (No.138, Sheng Li Road, Tainan, Taiwan 704, R.O.C.; +886 (0)6 2353535; hospital@mail.hosp.ncku.edu.tw), ref: A-ER-104-192

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Mild degenerated lumbar spondylolisthesis (chronic low back pain)

Interventions

Participants are randomly allocated into two groups: the thoracic mobilization group and the soft tissue release group. The randomization is performed by the primary investigator using the block randomization method. The first participant is randomly drawn using sealed envelopes and assigned to group A. Then, the other participants are assigned into groups B, A, B, A, B etc.

The mobilization technique is performed in the posteroanterior direction (PA technique) at the spinous process at least Grade III to grade IV described by Maitland concept. The experienced physiotherapist performs the mobilization along the middle (T5-9) and lower (T10-12) thoracic spine. The pressure is applied on the joint with hypomobility. The technique is carried out by oscillating pressure on the spinous process from posterior to anterior direction, produced by the movement of the trunk given by body weight and transmitted through the arms and to the thumb.

The soft tissue release technique is carried out by the same experienced physiotherapist. The thoracolumbar fascial release and Swedish massage technique were chosen in this study. The technique is bilaterally applied along the superficial backline from the sciatic notch to the

thoracolumbar junction. The Swedish application is also performed at the same location with the light effleurage technique.

The treatment is performed in a single session.

Intervention Type

Procedure/Surgery

Primary outcome measure

Measured before (pre-intervention) and immediately after the interventions (post-intervention):

1. Trunk range of motion measured in three movement planes using a goniometer and a measuring tape
2. Tissue hardness measured using the algometer combo equipment (OE-220) at the bilaterally lumbar muscle in a relaxed state
3. Pressure pain threshold measured using the algometer combo equipment (OE-220) at the bilaterally lumbar muscle in a relaxed state. A switch of the algometer is connected to the machine and the participants are requested to press the switch immediately if their feeling changes from pressure to pain sensation.
4. Lumbar muscle activity measured by surface electromyography to detect the signal of the thoracic erector spinae muscle and the lumbar erector spinae muscle. The muscle activity test is recorded during performing the ascending and descending phases of the lifting task.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/07/2015

Completion date

31/07/2016

Eligibility

Key inclusion criteria

1. Patients with mild degenerated lumbar spondylolisthesis aged 40-70 years old
2. Experiencing chronic low back pain for at least 6 months
3. Visual analog scale (VAS) ≥ 30 , ranging from 0 to 100
4. Spondylolisthesis clinically diagnosed by orthopedic surgeons confirmed with lateral view radiographic of the lumbar spine
5. Grade I spondylolisthesis was included based on the Meyerding grade classification from the lateral view radiographs

Participant type(s)

Patient

Age group

Mixed

Lower age limit

40 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

The sample size was calculated based on pilot data. The calculated effect size is 0.8, at least 24 participants were required

Total final enrolment

28

Key exclusion criteria

1. Patients with neurological signs, cardiovascular and respiratory diseases
2. Severe conditions that inhibit lifting a heavy object

Date of first enrolment

28/12/2015

Date of final enrolment

03/06/2016

Locations**Countries of recruitment**

Taiwan

Study participating centre

National Cheng Kung University
Department of Physical Therapy
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Sponsor information**Organisation**

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04zx3rq17>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in the Brazilian Journal of Physical Therapy. No additional documents or protocol will be available after the publication of the study.

Intention to publish date

25/10/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Associated Professor Cheng-Feng Lin (connie@mail.ncku.edu.tw). The datasets will be provided in an Excel format after the study is published. The datasets will be provided to someone who wants to use the data for further analysis such as a meta-analysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/09/2024	28/11/2024	Yes	No