

Effects of sling exercises on pain, function, and brain-muscle coordination in individuals with chronic low back pain

Submission date 17/05/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/05/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/05/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic low back pain (CLBP) is a disabling condition that affects all populations. Exercise training has been proven to achieve promising outcomes for pain and function among patients with CLBP. Nevertheless, the mechanism that mediates pain reduction after exercise training is not well understood. Some studies have found deficits in neural connection and decreased trunk control in people with CLBP. Whether training-related symptom reduction is attributed to enhanced brain-trunk muscle control has not yet been explored. Therefore, this study aims to investigate whether improvement of back pain and function is attributed to a change in the link between brain and trunk muscle activities.

Who can participate?

Healthy volunteer control people and patients with chronic low back pain aged between 20-50 years old

What does the study involve?

All participants receive 40 minutes of sling exercises twice a week for 6 weeks. Selected exercises include chess press, hamstring curl, hip abduction in plank, and single-leg squat. All training is supervised by a licensed physical therapist. Exercise intensity and rest are adjusted according to each participant's performance.

What are the possible benefits and risks of participating?

Participants with back pain may benefit from some extent of symptom relief. For healthy volunteers, they may experience the benefits of engaging in physical activities, and contribute to scientific understanding of the mechanism of exercise therapy on back pain. The risks involved in the intervention are similar to participating in daily exercises, where participants may experience soreness during or after exercises.

Where is the study run from?

Department of Physical Therapy and Assistive Technology, National Yang-Ming Chao Tung University (Taiwan), and Department of Rehabilitation Medicine, Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (Taiwan)

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

July 2014 to October 2016

Who is funding the study?

Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (Taiwan)

Who is the main contact?

Prof Li-Wei Chou, lwchou@nycu.edu.tw

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

Effects of sling exercises on pain, function, and corticomuscular functional connectivity in individuals with chronic low back pain - A preliminary study

Study objectives

Patients suffering from chronic low back pain can greatly benefit from performing sling exercises. The reason behind this improvement can be attributed to the enhancement of corticomuscular coherence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 10/11/2014, Institutional Review Board of National Yang-Ming University (now National Yang Ming Chao Tung University) (No. 155, Sec. 2, Linong Street, Beitou Dist., Taipei City, 112, Taiwan; +886228239753; rec@nycu.edu.tw), ref: YM103090E
2. Approved 20/10/2014, Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (No. 289, Jianguo Rd., Xindian Dist., New Taipei City, 231405, Taiwan; +886266289779 ext. 1136; hrpc@tzuchi.com.tw), ref: 03-XD14-039

Study design

Quasi-experimental design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Nonspecific chronic low back pain

Interventions

There are two study groups, namely a patient group with chronic low back pain and a healthy control group. Patients diagnosed with nonspecific chronic low back pain are screened by a physiatrist at the Department of Rehabilitation Medicine of Taipei Tzu Chi Hospital. The eligible patients are interviewed by a licensed physical therapist (Bo-Jhen Chen, one of the principal investigators). For healthy controls, asymptomatic adults (aged 20-50) are recruited at National Yang-Ming Chao Tung University (formerly called National Yang-Ming University). The principal investigator Professor Li-Wei Chou will explain the purpose and method of the study for candidates. Written informed consent is obtained from each participant before the commencement of assessment and training, which is conducted at the laboratory of the Department of Physical Therapy and Assistive Technology, National Yang-Ming Chao Tung University.

Both the healthy control and patients receive 40 minutes of sling exercises twice a week for 6 weeks. Selected exercises include chess press, hamstring curl, hip abduction in plank, and single-leg squat. All training is supervised by a licensed physical therapist, who receives formal training in TRX (a sling exercise toolkit). Exercise intensity and rest are adjusted according to each participant's performance.

Intervention Type

Behavioural

Primary outcome measure

The following primary outcome measures are assessed at baseline and 6 weeks:

1. Pain measured using the Numeric Pain Rating Scale
2. Disability measured using the Oswestry Disability Index
3. Neuromuscular activity measured by calculating corticomuscular (electroencephalogram [EEG] –electromyography [EMG]) coherence

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/07/2014

Completion date

29/10/2016

Eligibility

Key inclusion criteria

1. Chronic low back pain for more than 3 months
2. Aged 20-50 years old

Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

20 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

30

Total final enrolment

23

Key exclusion criteria

Patient:

Spinal stenosis/fracture, radiculopathy, or history of surgery

Healthy adults:

1. Aged outside of 20–50 years
2. Neurological diseases

Date of first enrolment

23/11/2014

Date of final enrolment

19/10/2016

Locations**Countries of recruitment**

Taiwan

Study participating centre**Taipei Tzu Chi Hospital**

Buddhist Tzu Chi Medical Foundation

No. 289, Jianguo Rd.

Xindian Dist.

New Taipei City

Taiwan

231405

Sponsor information

Organisation

Taipei Tzu Chi Hospital

Sponsor details

Buddhist Tzu Chi Medical Foundation

No. 289, Jianguo Rd

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+886 2 6628 9779 - 1136

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Sponsor type

Hospital/treatment centre

Website

https://taipei.tzuchi.com.tw/file_tp/IRB/index.htm

ROR

<https://ror.org/00q017g63>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Taipei Tzu Chi Hospital

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Taiwan

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed international journal

Intention to publish date

01/07/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author Prof Li-Wei Chou, lwchou@nycu.edu.tw. The patient group is recruited from the Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Taiwan (R.O.C.), and their associated medical records are governed by the Personal Data Protection Act in Taiwan (R.O.C.). Prior to requesting access to these data from the corresponding author, please inform the Human Research Protection Center of Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Taiwan (R.O.C.) (hrpc@tzuchi.com.tw) in advance.

Standardized written informed consent was obtained from each participant. All personal information will be de-identified. The demographic data (number of included subjects, age, body mass index, and symptom duration and severity) and the brain-muscle activities of the participants will be shared upon request.

IPD sharing plan summary

Available on request