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Acute and chronic effects of a trunk decompression device on low back symptoms

Submission date
14/12/2023

Recruitment status
No longer recruiting

Registration date
19/01/2024

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Low back pain (LBP) is a major global musculoskeletal disability, causing work separation and significant healthcare expenses. Despite various diagnostic and treatment methods, there's only moderate improvement in successful LBP treatment. Neuromuscular adaptations, including changes in muscle activity, kinematics, and sensorimotor control, play a crucial role in musculoskeletal disorders. Chronic LBP often involves decreased stabilizing muscle coordination and function, contributing to long-term consequences.

This study aims to investigate the effects of a non-invasive, portable traction method on acute and chronic changes in forces, range of motion, ergonomic tasks, low back muscle activation, and sensory perception in individuals with LBP. Previous studies on traction have shown mixed results, and there's a need for an effective, consistent, and user-friendly solution for at-home use. Understanding the nature and mechanisms behind adaptations to LBP is essential for developing more effective treatments.

Who can participate?
Individuals aged between 18 and 70 years old who are suffering from non-specific chronic low back pain

What does the study involve?
Participants will be recruited to participate in an acute exercise session and, thereafter, a 4-week training program. They will be asked to do a sit-and-reach test to measure lower back range of motion. Participants will also be asked to hold a box with 20% of their body mass, bend at the hips to measure muscle activation and perform a back extension endurance test. Further, they will be asked to assess any discomfort with a visual analogue scale and assess pain or discomfort with a pain pressure device.

After the initial testing, there will be a training period involving a back traction/decompression device for 5 days per week (Monday to Friday) for 4 weeks. They will exert mild pressure with the traction device on their hips for 2 sets of 30 seconds each in the first week, 3 sets in the third week, and 4 sets in the fourth week. Similar testing measures will be implemented approximately 48 hours after the 4-week training program. Participation will be required to

come to our lab three times. Each visit will take one hour and be held at Dr Behm’s exercise-physiology laboratory in the Physical Education Building at the Memorial University of Newfoundland.

What are the possible benefits and risks of participating?
Participants will not receive any direct benefits from this research except a novel trunk decompression (traction) device will apply pressure with the device on the upper thighs while supine (lying on their back) and hips flexed, which has been reported anecdotally to reduce pain symptoms and associated movement dysfunctions. This novel device might help the participants reduce their lower back pain symptoms.

There will be a risk of fatigue for the participants during testing. Sufficient recovery time will be allocated between tests to minimize fatigue. Monitoring of EMG, force outputs, and visual analogue scales for discomfort will help to monitor the extent of fatigue and thus adjust rest periods to alleviate this possibility. All equipment will be cleaned with industrial-class cleaning agents before and after each data collection session.

Where is the study run from?
Memorial University of Newfoundland (Canada)

When is the study starting and how long is it expected to run for?
October 2023 to November 2024

Who is funding the study?
mitacs (Canada)

Who is the main contact?
Prof David Behm, dbehm@mun.ca (Canada)

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof David Behm

Contact details
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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
Acute and chronic effects of a trunk decompression device on low back symptoms

Acronym
ACE-TD-LB

Study objectives
A trunk decompression device can immediately reduce low back pain after just one acute session. This innovative device can significantly reduce low back pain after four weeks of training.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/12/2023, Interdisciplinary Committee on Ethics in Human Research (ICEHR) (Memorial University of Newfoundland, P.O. Box 4200, St. John's, A1C 5S7, Canada; +1 709-864-2561; icehr@mun.ca), ref: 20240943-HK

Study design
Acute chronic (4-week) intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Treatment of low back pain with the trunk decompression device.

Interventions
The effects of a single application (acute) and following 4 weeks of training with a trunk decompression device on low back pain will be examined. This will be compared to the 4 weeks without intervention. The trunk decompression device will be voluntarily self-applied to the pelvis with a mild force application (<50% of maximum force).

The same participants are recruited for the control and experimental programs in this repeated measures design. In the same session, an initial session will examine acute responses to the traction device with pre- and post-traction exercise testing. Participants will then undergo their normal daily activities for 4 weeks as their control program (no additional exercises). Post-control testing will determine if these subjects experience any losses or gains during this period. Following this testing session, participants will use the traction device daily for 4 weeks and then be tested soon (within a few days) thereafter. All testing will involve the same procedures as outlined in the initial proposal.

The study uses the https://www.random.org/lists/ website to randomize sessions and tests.

The study population will consist of 24 male and female participants. Most participants will be recruited from general populations. The recruitment process will consist of obtaining verbal and written consent from individuals willing to volunteer for the study. The study will be conducted using a snowball sampling technique. For this technique, participants will be recruited from friends, classmates, and colleagues of the researchers and participants who are willing to participate, as well as potential referrals from initial volunteers.

Mr. Zahiri and Mr. Goudini have extensive lab experience in data collection and analysis from their MSc (Kinesiology) programs and have published in peer-reviewed journals. Mr Zahiri and Mr Goudini have a Master of Science in Kinesiology. Dr Behm is the supervisor and will be available for direction and consultation. D. Behm has 384 research publications as of January 5, 2024.

The type of delivery will be face-to-face, and it will be provided individually. Participants will be individually instructed on the use of the traction device at the first testing session and again at the post-control testing session. Participants will then perform the exercises on their own for 4 weeks. The researchers will be available for help, instruction, and consultation if and when needed.

Testing will occur at Dr Behm's exercise-physiology lab, Physical Education Building, Memorial University of Newfoundland, St. John's campus. Participants will perform the training intervention (using the traction device daily) at their homes without direct supervision (following two instruction sessions). They will be provided with the device for this 4-week training intervention period.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Trunk decompression device

Primary outcome measure
1. Electromyography (EMG) data of the lumbosacral erector spinae muscles measured by holding a 20 percent load while standing at pre-test, acute post-test (single session), post-control testing (4 weeks later), post-training intervention (4 weeks after control period) testing
2. EMG data for back endurance test measured using the Biering-Sorenson back endurance test at acute post-test (single session), post-control testing (4 weeks later), post-training intervention (4 weeks after control period) testing
3. Lower back and hamstring range of motion measured using the sit and reach test at pre-test, acute post-test (single session), post-control testing (4 weeks later), post-training intervention (4 weeks after control period) testing
4. Subjective pain while performing physical tests measured using Visual analog pain scales at pre-test, acute post-test (single session), post-control testing (4 weeks later), post-training intervention (4 weeks after control period) testing

Secondary outcome measures
Electromyography (EMG) data of the upper and lower erector spinae muscles, and the mean amplitude of the root mean square (RMS) will be analyzed from the EMG data at pre-test, acute post-test (single session), post-control testing (4 weeks later), post-training intervention (4 weeks after control period) testing

Overall study start date
01/10/2023

Completion date
15/11/2024

Eligibility

Key inclusion criteria
Individuals suffering from idiopathic chronic low back pain

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
24

Total final enrolment
14

Key exclusion criteria
1. Low back surgery
2. Disc hernia

Date of first enrolment
08/01/2024

Date of final enrolment
10/09/2024

Locations

Countries of recruitment
Canada

Study participating centre
Dr. Behm’s exercise-physiology laboratory in the Physical Education Building
Memorial University of Newfoundland
230 Elizabeth Avenue
St. John's
Canada
A1C 5S7

Sponsor information

Organisation
Memorial University of Newfoundland

Sponsor details
St. John’s
Newfoundland
Canada
A1C 5S7
None provided
not@provided.com

Sponsor type
University/education

Website
https://www.mun.ca/

ROR
https://ror.org/04haebc03

Funder(s)

Funder type
Industry

Funder Name
mitacs

Results and Publications

Publication and dissemination plan
Data to be submitted for publication in a Q1 peer-reviewed international sports medicine-related journal.

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof David Behm, dbehm@mun.ca (Canada)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			12/09/2024	No	No