Effect of Lumbodorsal Skin Displacement on Lumbopelvic Range of Motion, Flexion-Relaxation Ratio, and Skin-Fascial Shear-Strain Ratio in nonspecific Low Back Pain patients.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56867

Source
ToetsingOnline

Brief title
Skin- and fascia displacement in nonspecific low back pain

Condition

- Other condition
- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
Low back pain without any pathoanatomical cause, Nonspecific low back pain

Health condition

Myofascia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Vrije Universiteit Amsterdam en Fysio Physics

Intervention

Keyword: Back muscles: Musculature of the BACK (mesh), EMG: (mesh)., Fascia (mesh), ROM: Range of motion (mesh), Ultrasonography (mesh), &bullet

Outcome measures

Primary outcome

Arm 1

• Lumbopelvic flexion range of motion (Inertial Measure Units) [Primary]

• Flexion relaxation ratio (ElectroMyography)

Arm 2

• Shear strain ratio*s (sliding mobility, Ultrasonography)

- Skin relative to underlying fasciae

- Skin relative to the underlying back muscles

Secondary outcome

Arm 1

• Pain level quantification during flexion

Arm 2

• Lumbodorsal fasciae stiffness

Study description

Background summary

Manual therapy is frequently utilized by physiotherapists to alleviate stiff back muscles and reduce pain while simultaneously promoting flexibility. It is presumed that the skin can influence the back muscles through the connective tissue. Imagine applying a specific force, such as pushing or pulling. This force passes through your skin and then through various layers of connective tissue and muscles in your body, altering the way muscles and other parts of your body function. This can result in the activation or deactivation of specific muscles.

This phenomenon seems to occur because there are small sensors in your body, akin to antennae. It appears that activating or deactivating these sensors may influence the way we move. Consequently, the way you lift, bend, or move in general may appear to change.

This study, titled 'Skin- and fascial displacement in nonspecific low back pain,' investigates how the skin can influence the muscles in the back and hamstrings. We employ advanced measurement techniques, including ultrasound, electromyography, and motion tracking, to analyze the effects of these techniques on connective tissues, muscles, muscle activity, and trunk flexibility. This research contributes to a better understanding of skin displacement on muscle activity and trunk flexibility in individuals with chronic low back pain. We aim for more effective approaches to treating low back pain.

Study objective

With this research, we are examining the impact of skin displacement in individuals with chronic low back pain. We are investigating its effects on the mobility of the back and hip, as well as its influence on muscle activity in the back and hamstrings, along with the deformation of back muscles due to skin displacement. The study is divided into two parts and will be conducted in a single day.

In the first part, we are exploring whether the movement of the skin affects the mobility of the back and muscle activity in individuals with chronic low back pain. We are utilizing specialized sensors attached to the skin to measure the movements of the back and muscle activity. A total of 38 individuals with low back pain will participate in this part of the research.

The second part of the study investigates whether the movement of the skin impacts the shape of connective tissue and muscles beneath the skin. We are comparing individuals with low back pain to healthy individuals. For this purpose, we are using specialized equipment employing sound waves (ultrasound) displayed in imaging (echography).

Through this research, we aim to gain a better understanding of the influence of the skin on muscle activity and the flexibility of the back.

Study design

The study consists of two arms conducted on one day. Arm 1 is a randomized controlled trial examining the effects of SKD on the flexion relaxation ratio. This trial focuses on individuals with nonspecific chronic LBP (NSCLBP). Arm 1 comprises an experimental group (n=19) and a sham control group (n=19). Notably, subjects allocated to the experimental group in arm 1 will also participate in arm 2 (Figure 1). Arm 2 is an observational case-control study aiming to compare the effects of SKD on skin-fascia-muscle shear strain ratios, between individuals with NSCLBP (n=19) and 19 healthy controls.

Intervention

In this study, two skin tests are being compared. The individual conducting the skin test is aware of the form being applied. However, the participants are not informed about the specific skin test they will receive. The allocation is done randomly, akin to drawing lots.

Group 1: Participants in this group will undergo a specific skin displacement test.
Group 2: Participants in this group will undergo a different skin displacement test.

Study burden and risks

Non

Contacts

Public
Vrije Universiteit

Boelelaan 7
Amsterdam 1081 BT
NL

Scientific
Vrije Universiteit

Boelelaan 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, the NSCLBP subject must meet all of the following criteria, all in line with patient profile 2, Royal Dutch Guidelines for LBP [5]: Low back pain >=12 weeks, without dominant presence of central sensitization measured with the Central Sensitization Inventory (CSI >=39) [48], at least moderated pain during lumbopelvic flexion measured with the Numeric Rating Scale (NRS >=4) in the lumbosacral region with or without radiating pain in the gluteal region and the upper leg classified with the Quebec Task Force (QTF 1-3) [49], unable in touching the floor (FFD >=4.5cm) [50], age between 25 and 65 years, Body Mass Index (BMI) range (18,5 <= 30). Before taking part in this study, a red flag screening for NSCLBP of the individuals was carried out by a physiotherapist with a master in manual therapy (Robbert van Amstel). Additionally for arm 2: Healthy individuals with no current low back pain or a history of LBP in the past 6 months, age between 25 and 65 years, and BMI range (18,5 <= 30). We have chosen this age category because disability due to low back pain is highest or most severe at the age of 25-65 years [51].

Exclusion criteria

Excluded are those who do not meet the abovementioned criteria and have or had a specific spinal disease, infection, presence of a tumor, osteoporosis, bone

fracture, inflammatory disorder, or cauda equina syndrome, or a hip arthroplasty in the last 6 months [6]. Despite our stations for measuring muscle activity and trunk mobility not having a specific limit, participants weighing more than 150 kg will be excluded from participation due to the exclusion criteria related to the use of a physio plinth capable of supporting a maximum weight of 150 kg. Individuals who previously took part in our SKD-study [52] and/or are familiar with the DAMT-Test procedure as described in the 4xT for LBP shall be excluded from participation [53].

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-06-2024
Enrollment:	57
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-07-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85530.018.23