Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of sensorimotor training combined with transcranial electrical stimulation on cortical sensorimotor processing and clinical symptoms in patients with chronic low back pain

Protocol summary

Study aim
Investigation effect of sensorimotor training combined with transcranial electrical stimulation on cortical sensorimotor processing and clinical symptoms in patients with chronic low back pain

Design
Randomized clinical trial with control group, double-blind. Randomization with Randomization.com and balanced block randomization

Settings and conduct
Tehran School of Rehabilitation of Medical Sciences. Participants, evaluators and final analyzers (names will be given to this person via code) will be blind. Therapist blindness is not possible

Participants/Inclusion and exclusion criteria
20 to 55 years old, both men and women, duration of low back pain more than 6 months or 3 periods of more than one week during the last 12 months, unilateral radicular pain secondary to L4 / L5 and L5 / S1 disc herniation MRI diagnosed, positive for at least one of the tests Slump, Straight Leg Raise, Lasegues's sign, pain propagation path from anterior-posterior leg to dorsal area associated with L4 / L5 dermatome to posterior leg to heel and outer leg, moderate Pain numerical scale score 4 or higher, Oswestry Disability Index average score 4, Mini Mental Status Examination average score 24 or higher

Intervention groups
1) Sensory-motor training and real tDCS, 2) Sensory-motor training and sham tDCS

Main outcome variables
Mean sensory evoked potential amplitude, active motor threshold of multifidus and transverse abdominal / oblique transverse muscle, active motor evoked potential amplitude of these muscles, lumbar motor control, disability, pain

General information

Reason for update

Acronym
TDCS

IRCT registration information
IRCT registration number: **IRCT20211222053484N1**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

Registration date
2022-02-16, 1400/11/27

Registrant information

Name
Soheila Qanbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of sensorimotor training combined with transcranial electrical stimulation on cortical sensorimotor processing and clinical symptoms in patients with chronic low back pain

Public title
Effect of sensorimotor training and brain electrical stimulation on chronic low back pain treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from LBP for more than 6 (m) or experience LBP in 3 courses for more than 1 (w) in past 12 (w) Unilateral radicular pain secondary to disc herniation L4/L5 and L5/S1 diagnosed with MRI Being positive of slump test or straight leg raise test or Lasegues's test Pain from anterior lateral part of leg to back area of the leg associated with L4/L5 dermatome to the posterior part of the leg and heel and lateral part of the foot Average pain score ≥ 4 Oswestry disability index ≥ 4 Age range between 20 and 55 years Both genders

Exclusion criteria:
Having history of brain tumor, brain injury or brain stroke Having a history of cognitive disorders based on Mini-Mental Status Examination Scale (Mental Status Examination Scale < 24) Having history of spondylolysis and spondylolisthesis Having history of structural disorders or deformities such as scoliosis or kyphosis and hyper lordosis Having history of spinal cord fractures Having history of neurological disease such as Parkinson, Alzheimer or cerebellum disorders Having history of scratches or cut on the scalp Having sensory disorders or lack of sense Having history of seizure Being pregnant Having implantation or pulse maker Having history of dermal infection Having history of surgical procedure Having history of visual disorders Having history of vestibular disorders Having history of depression

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
After completion of the primary assessments, the participants randomly divided in to 2 groups using sequences of randomization via randomization.com and with balanced block randomization method. The size of the blocks is 4. Finally, each participants will placed in one of the two groups randomly and without knowing which group they are placed in. (Real or Sham)

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants, assessor and analyzer are blinded. The participants will placed in one of the two groups (real or sham) via randomization.com site and they will not know which group they are in.(the participants signed a consent sheet which mentioned that they may placed in one of the two groups without making them knowing). The assessor also doesn't know each participant's group side. The assessor provides all the final information to the third person who saves the participants names as codes. This third person provides all this codes to an analyzer (Therapist). Because of the type of study, blinding of the therapist (researcher) is not possible.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation-Tehran University of

Street address
Girl's Dormitory Complex of Tehran University of medical sciences, Next to the Masjedonnabi mosque, Above 16th street, North Amir Abaad, North Karegar street, Enghelab

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Province
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1439957181

Approval date
2021-12-20, 1400/09/29

Ethics committee reference number
IR.TUMS.FNM.REC.1400.170

Health conditions studied

1

Description of health condition studied
Chronic Low Back Pain

ICD-10 code
M51.17

ICD-10 code description
Intervertebral disc disorders with radiculopathy,

lumbosacral region

Primary outcomes

1

Description
Levels below N80 and N150 as the mean of sensory evoked potential amplitude
Timepoint
Before the first session and 48 hours after the 12th session
Method of measurement
By recording sensory evoked potential using EMG / NCV / EP5000 Q

2

Description
Active motor threshold of multifidus muscle and transverse abdominis / oblique internal
Timepoint
Before the first session and 48 hours after the 12th session
Method of measurement
TMS device model MagPro X100

3

Description
Active motor evoked potential amplitude of multifidus muscle and transverse abdominis / oblique internal
Timepoint
Before the first session and 48 hours after the 12th session
Method of measurement
TMS device model MagPro X100

4

Description
Lumbar movement control
Timepoint
Before the first session and 48 hours after the 12th session
Method of measurement
Clinical test (Luomajoki index)

Secondary outcomes

1

Description
Pain
Timepoint
Before the first session and 48 hours after the twelfth session
Method of measurement
By Visual Analogue scale

2

Description
Disability
Timepoint
Before the first session and 48 hours after the twelfth session
Method of measurement
Through the Oswestry Disability Index questionnaire

Intervention groups

1

Description
Intervention group: In this group, participants receive sensory-motor training and tDCS in real time for 4 weeks and 3 times a week (12 sessions). To apply electric current, tDCS device model neurostim2 of Medina Teb Gostar company will be used. Before the patient arrives, all instruments including electrodes, normal saline, stimulator, cable, elastic bands and measuring tape are checked to check for safety and the absence of possible damage. The patient sits in a chair. The scalp is then examined for any lesions or irritations, and the researcher asks the participant to report any skin irritations that occurred in the previous session or anything that is part of the exclusion criteria. First, the electrodes are placed in a sponge soaked in sterile salt (NaCl 0.9%) and the skin of the stimulation site is cleaned with alcohol. The size of the electrodes is 5 * 5. Stimulation through two active electrodes (anodal) on the skin The head is applied, an active electrode is placed on the M1 region, which according to the 10-20 International System corresponds to C3 or C4-10, the other active electrode is placed on the S1 region, which is 2 cm behind the C3 Or C4, the reference electrodes are also placed on the forehead and directly above the eyebrows. If the pain is in the center, the active electrode is placed on the dominant hemisphere of the person and the reference on the opposite side is placed in the supraorbital area. At the beginning of the current, we will have a ramping period of up to 10 seconds, at which the current is programmed to the maximum intensity, which is considered to be 2 mA. At the end, we will have a 10-second period of ramping down, which will gradually flow and the device will turn off. In general, according to the size of the active electrode, the average current density below these electrodes is 0.08 mA / cm2. The participant is also informed of the tingling or itching sensation associated with electrical stimulation and is constantly monitored during treatment. Sacroiliac and cervical vertebrae) to facilitate coordinated and automatic movement patterns. Therefore, in all stages of training, it is necessary to position the three areas correctly. To stimulate the soles of the feet (both feet), the exercises are performed barefoot and the soles of each foot are stimulated with a brush. The person is then asked to contract the soleus muscles; So that the inner arch of the foot is increased but the toes are not bent. Initially, for people who are unable to contract the soleus muscles, a strip of Thera-Band can be attached to the sole of the foot to help put the foot in position. During

exercise, the sacroiliac joints and cervical vertebrae should also be in a neutral position. The person is also asked to pull the umbilicus slightly inward to facilitate the function of the transverse abdominal muscles. In addition, a person with a chin tuck activates the deep flexor muscles of the neck. In general, the exercises are performed in 3 stages (static, dynamic and functional). Static stage: In this stage, the focus is on pelvic stability by contracting the muscles of the diaphragm, multifidus, pelvic floor and transverse abdominis to perform the movements of the limbs. Provide in the next steps. In other words, this stage is based on the principle of "proximal stability for distal movements". The way to advance in this stage is to stand on two legs, stand on one leg and then stand in a half-step. half-step is a position in which the person brings the trunk forward and keeps the cervical and lumbar vertebrae in a neutral position. Also, the support surface on which the person stands is first rigid and then unstable, such as foam, rocker board and wobble board. The center of gravity is also challenged by the application of perturbations or weight shifts by elastic bands, and the individual must maintain stability. These conditions trigger automatic postural and reflex reactions. Dynamic stage: When a person was able to maintain pelvic stability in the previous stage, he enters the dynamic stage in which the person performs upper and lower limb movements while maintaining pelvic stability. How to advance in this stage is like the static stage of standing on two legs, standing on one leg and then standing in half-step. Also, the support surface on which the person stands is first rigid and then unstable, such as foam, rocker board and wobble board. The center of gravity is challenged with the help of elastic bands and ball throwing. One of the best exercises at this stage is the T-Band Kick. These exercises re-train the feedforward mechanisms. Functional stage: After maintaining the stability of the pelvis while performing upper and lower limb movements, the person enters this stage. At this stage, the person does walking, squatting, lunge, jumping, running and any sport. These exercises will be performed on different levels and different positions. Intensity of exercises: 3 sets with 5 repetitions.

Category

Rehabilitation

2

Description

Control group: In this group, participants receive sensory-motor training and sham tDCS for 4 weeks and 3 times a week (12 sessions). tDCS is applied for 20 minutes. In this way, the electrodes are placed like the intervention group. The device is turned on and the intensity is increased until the patient feels a tingling sensation, but this feeling will be only for 15 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Soheila Qanbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Roya Khanmohammadi

Position
Professor Assistant

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Full name of responsible person
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Other areas of specialty/work
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Girl's dormitory complex of Tehran University of Medical Sciences, Next to Masjedonnabi Mosque, Above 16th street, North Amir Abaad, North Karegar street. Enghelab

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available