

Utility of neuromodulation, mindfulness and person-centered therapy in chronic low back pain

Submission date 21/09/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/09/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Low back pain (LBP) is a widespread public health issue with significant socioeconomic implications globally, affecting individuals across all age groups. Non-specific chronic low back pain (NSCLBP) is diagnosed after ruling out serious spinal pathology or nerve root involvement using clinical red flags and imaging such as X-rays or MRI scans. NSCLBP is among the leading causes of physician visits and disability, often resulting in missed work and reduced physical function, particularly in individuals under 45 years of age. This study aims to compare the effects of transcranial direct current stimulation (tDCS), mindfulness-based stress reduction therapy (MBSR), and cognitive functional therapy (CFT) as adjuvant therapy with standard medical treatment in patients with NSCLBP.

Who can participate?

Patients aged 20 to 55 years with NSCLBP

What does the study involve?

Participants were randomly allocated to one of four groups:

Group 1: standard medical treatment (pharmacological) (pain modification treatment)

Group 2: standard medical treatment and tDCS for 20min 5 days per week for 2 consecutive weeks

Group 3: standard medical treatment and group therapy was given to the participants in two groups (15 participants in each group). Duration of each session was between 90-120 minutes. Sessions were given weekly. A total of 8-10 sessions was given.

Group 4: standard medical treatment and individually tailored CFT sessions were given to the patients. Sessions ranged from 8-12 sessions over a period of 12 weeks.

What are the possible benefits and risks of participating?

The potential benefits include reduction in pain and disability and improved overall wellbeing of the participants. Risks associated with the study are potential adverse effects of medication and tDCS.

Where is the study run from?
Swami Rama Himalayan University (India)

When is the study starting and how long is it expected to run for?
February 2022 to March 2025

Who is funding the study?
Swami Rama Himalayan University (India)

Who is the main contact?
Vithika Singh, ptvithikasingh@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

SRHU/Ph.D.Cell/Sup/2023-14

Study information

Scientific Title

Effects of transcranial direct current stimulation, mindfulness based stress reduction therapy, and cognitive functional therapy on pain intensity and disability in patients with non-specific chronic low back pain

Study objectives

Hypotheses:

1. Transcranial direct current stimulation (tDCS) will be useful as an adjunctive treatment for non-specific chronic low back pain (NSCLBP).
2. Mindfulness-based stress reduction therapy (MBSR) will be useful as an adjunctive treatment for NSCLBP.

3. Cognitive functional therapy (CFT) will be useful as an adjunctive treatment for NSCLBP.
4. There is no difference in efficacy of tDCS, MBSR and CFT in treatment of NSCLBP.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/01/2023, Ethics Committee (Swami Rama Nagar, P.O. Jolly Grant, Dehra Dun, 248016, India; +91 (0)135 2471111; research@srhu.edu.in), ref: SRHU/HIMS/ETHICS/2023/30

Study design

Single-centre interventional open-label randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Non-specific chronic low back pain

Interventions

Participants were randomly allocated to either of the four groups using a computer generated random number sequence:

Group 1: standard medical treatment (pharmacological) (pain modification treatment)

Group 2: standard medical treatment and received 2 mA of direct current was delivered for 20 min via sponge electrodes 5 days per week for 2 consecutive weeks. The active electrode (anode) was placed over the primary motor cortex using the International 10–20 system contralateral to the side of the worst low back pain (LBP). The reference electrode (cathode) was positioned over the contralateral supraorbital region ipsilateral to the side of pain.

Group 3: standard medical treatment and group therapy was given to the participants in two groups (15 participants in each group). Duration of each session was between 90-120 minutes. Sessions were given weekly. A total of 8-10 sessions was given.

Group 4: standard medical treatment and individually tailored CFT sessions were given to the patients. Sessions ranged from 8-12 sessions over a period of 12 weeks.

Intervention Type

Mixed

Primary outcome(s)

1. Pain intensity measured using numeric rating scale at baseline (day 0), 3 months and 6 months
2. Disability measured using the Oswestry Disability Index at baseline (day 0), 3 months and 6 months

Key secondary outcome(s)

1. Quality of life measured using RAND Sf36 questionnaire at baseline (day 0), 3 months and 6 months
2. Mindfulness assessed using Chronic Pain Acceptance Questionnaire, Mindfulness Awareness and Acceptance Questionnaire and Difficulty in Emotion Regulation scale within group 3 at baseline (day 0) and at 3 and 6 months from baseline

Completion date

30/03/2025

Eligibility

Key inclusion criteria

1. Patients with NSCLBP
2. Aged between 20 and 55 years
3. Normal or minimal or non-specific changes on x-ray/MRI of lumbosacral spine
4. In case of multiple site pain, patient having low back pain as the most prominent presenting symptom
5. Patient who gives written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

55 years

Sex

All

Total final enrolment

134

Key exclusion criteria

1. Altered sensory or motor functions
2. Subjects with major painful comorbid medical conditions e.g., diabetic neuropathy, cancer, disc degeneration or prolapse, chronic kidney disease, chronic liver disease and other orthopaedic, rheumatological and painful neurological conditions
3. Any spine surgery in the preceding 6 months
4. Increased erythrocyte sedimentation rate (>30 mm/h)
5. Bone mineral density having t-score <-2.5
6. Specific psychiatric condition
7. Significant structural abnormality on imaging

Date of first enrolment

31/01/2023

Date of final enrolment

30/09/2024

Locations

Countries of recruitment

India

Study participating centre

Himalayan Institute of Medical Sciences

SRHU, Swami Rama Nagar, Jolly Grant

Dehardun

India

248016

Sponsor information

Organisation

Swami Rama Himalayan University

ROR

<https://ror.org/02nw97x94>

Funder(s)

Funder type

University/education

Funder Name

Swami Rama Himalayan University

Alternative Name(s)

SRHU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

India

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Vithika Singh (ptvithikasingh@gmail.com)

IPD sharing plan summary

Available on request