ISRCTN91142724 https://doi.org/10.1186/ISRCTN91142724

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

Submission date
21/09/2025

Recruitment status
No longer recruiting

Registration date
25/09/2025

Overall study status
Completed

Last Edited
24/09/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] 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 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
Dr Vithika Singh

Contact details
Research Cell, Department of Brain and Mind Sciences
Swami Rama Himalayan University
Dehradun
India
248016
+91 (0)9540246442
ptvithikasingh@gmail.com

Additional identifiers

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