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Research Protocol

Physiotherapy Section

Efficacy of Low-level Laser Therapy on Motor Recovery, Functional Independence and Quality of Life among Individuals with Incomplete Spinal Cord Injury: A Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: A complete or incomplete Spinal Cord Injury (SCI) reduces a person's Quality of Life (QoL) by producing persistent neurological deficiencies from the disruption of nerve impulses that result in the loss of motor and sensory function. For these people, functional recovery and QoL enhancement are the main goals of rehabilitation. Even with advancement in the treatment of spinal cord injuries, many people still struggle with motor function deficits and functional independence, which significantly lowers their QoL and limits their capacity for independent living.

Need of the study: Low-Level Laser Therapy (LLLT) has numerous advantages, including preventing tissue and cell death, promoting injury healing and repair, reducing pain, oedema, and inflammation, promoting cell division and even apoptosis. LLLT has been shown to provide neuroprotection through a variety of outcomes, including cell regeneration, stimulation of Schwann cell growth, reduction of spasticity, improvement of function, reduction of nitric oxide levels and upregulation of the cytokine Interleukin 10 (IL-10) proving that LLLT provides neuroprotection. It is expected that LLLT will stimulate the cell growth while inhibiting the inflammation and other secondary changes after SCI.

Aim: To analyse the efficacy of LLLT for motor recovery, functional independence and QoL among incomplete SCI patients.

Materials and Methods: The present study will be a single blind, prospective, parallel group, randomised controlled trial recruiting 104 patients with incomplete SCI and will be allocated through block randomisation into two groups as per the inclusion and exclusion criteria. The duration of the study will be from 1st June 2023 to 28th February 2025. Control group will be treated with placebo LLLT and conventional therapy whereas experimental group will be treated with LLLT and conventional therapy for three times per week for four weeks. The performance of the participants will be assessed using amplitude-based lower extremity surface Electromyography (EMG) on lower extremity key muscles, Lower Extremity Motor Score (LEMS-ASIA), Spinal Cord Independence Measure (SCIM-III), Quality of Life (WHOQOL-BREF) at baseline and at the end of fourth week postintervention.

Keywords: Neurodegeneration, Photobiomodulation, Surface electromyography

INTRODUCTION

The LLLT is a harmless clinical treatment that utilises low-power lasers or light-discharging diodes to invigorate cell capability and promote tissue healing. SCI is a destroying condition that often leads to substantial physical and functional impairments. Currently, there are limited effective treatment options for SCI, which has led researchers to explore alternative therapies such as LLLT. LLLT has shown promise in the treatment of SCI [1]. According to several studies, LLLT has shown potential for the treatment of SCI [2-4].

A SCI refers to damage to the spinal cord that results in a change in its motor, sensory, or autonomic functions, which can be either temporary or permanent [5,6]. SCI can bring about a great many side-effects that change contingent upon the area and seriousness of the injury. The first set of symptoms experienced after a SCI are typically related to motor function loss and sensation below the level of the injury. This can include paralysis or weakness in limbs, loss of sensation or altered sensation, and trouble with coordination and equilibrium [7,8]. Likewise, due to motor and sensory changes, SCI can also lead to autonomic dysfunctions. These dysfunctions can include changes in blood pressure, heart rate and body temperature regulation [9]. Furthermore, individuals with SCI may experience bowel and bladder dysfunction, sexual dysfunction, respiratory complications and chronic pain. SCI can lead to sensory and motor impairments that may cause long-lasting and debilitating neurological deficits, significantly impacting an individual's QoL [10].

SCI can result in extensive cellular damage, including necrosis and apoptosis in both neuronal and glial cells. The primary drivers of progressive damage to the spinal cord are stress and inflammation [11]. Till date, little is known about how long the effect of LLLT lasts, which is a key to knowing how frequently LLLT would need to slow or prevent the progression of impairment caused by SCI. Moreover, it is not clear about ideal the site for non invasive irradiation, given the pattern of neurodegeneration in incomplete SCI. The photochemical effects of LLLT which is believed to be an immersive technology has not yet potentiated for proper dose for SCI patients. In LLLT studies [12-14], the site most frequently targeted was over the transverse processes and spinous processes of the vertebrae, the same stimulation site used for treatment of myelomeningocele [15]. This study will give a greater understanding of how LLLT should be irradiated over a SCI area as well as its effectiveness.

Thus, the present study aims to assess the effectiveness of LLLT on motor recovery, functional independence and QoL: among individuals with incomplete SCI. The objectives of the study will be to investigate the effect of LLLT on lower extremity motor recovery, functional independence and on QoL in individuals with incomplete SCI.

REVIEW OF LITERATURE

Hashmi JT et al., conducted a review to test the effects of LLLT delivered on neurological conditions such as stroke, traumatic brain injury, degenerative brain disease, SCI and peripheral nerve regeneration, will be covered. Their study also reported that LLLT had no adverse effects [16]. Da Silva FC et al., conducted a randomised clinical trial involving 25 SCI patients with incomplete SCI to evaluate the effects of LLLT. The results demonstrated that LLLT stimulated the injured tissue, achieving an improved motor response. EMG data demonstrate a difference in comparison to the preintervention evaluation, with higher Mean Difference Frequency (MDF) values at rest and during isotonic contraction 30 days after the end of treatment [17]. Da Silva FC et al., conducted another randomised sham-controlled clinical trial involving 30 participants with incomplete SCI have shown improvement in sensitivity and motor skills using American Spinal Injury Association Impairment Scale (ASIA) impairment scale and QoL assessed by using WHOQOL-BREF questionnaire before and after LLLT treatment in 12 sessions in which the irradiation was given in contact with the skin over spinous process of the vertebrae at 5 points marked above the injury in lateral decubitus of 808 nm for 12 sessions in four weeks and compared to Sham group, LLLT treatment improved the motor skills and QoL in the active group and was sustained at the one month follow-up [14]. Mohammadzadeh E et al., conducted a quasi-experimental matched-pair-design study to estimate the therapeutic effects of Photobiomodulation (PBM) on Bone-Mineral-Density (BMD), in Complete Spinal-Cord- Injury (C.SCI) patients with Osteoporosis (OP) by follow-up Dual-Energy X-Ray-Absorptiometry (DEXA). The results showed significant results in BMD in PBM group in both proximal-femur and forearm-mid-distallocations as compared to the control group [18].

MATERIALS AND METHODS

The present study will be a single-blind, prospective, parallel-group, randomised controlled trial examining the effects of LLLT in incomplete SCI patients. The duration of the study will be from 1st June 2023 to 28th February 2025. The study will be conducted at Indian Spinal Injury Centre, Vasant Kunj, New Delhi, India. The study protocol adheres to the principles mentioned in the Standard Protocol Items Recommendation for Interventional Trials (SPIRIT). The Indian Spinal Injuries Centre (Ref: ISIC/RP/2023/024) and Amity University's institutional review boards (AUUP/IEC/JULY/2022) have given their approval for the study protocol, and it has been registered with the Clinical Trials Registry-India (CTRI/2023/04/052093). This study will follow the 2017 National Code of Ethics for biomedical research involving human participants and the 2013 revised Declaration of Helsinki.

Inclusion criteria: The study will recruit participants who had suffered from SCI six months to one year before enrolment. To be eligible, the participants needed to be classified as Grade C or D and the level of injury should be between T2 to L5 according to the ASIA Scale [19-21]. They should be aged between 18 and 45 years, regardless of gender, with incomplete SCI. A score of 5/5 for the upper extremity muscles on physical assessment test through ASIA scale indicates adequate motor function in upper extremity.

Exclusion criteria: Patients will be excluded from the study if they have a history of any other underlying neurological or musculoskeletal condition that could complicate treatment. Subjects with any history of transient ischaemic attack, stroke, any other medical illness. Subjects with any skin problems like dark skin pigmentation, rashes or any skin allergy [22].

Sample size calculation: To evaluate the upgrades in the outcome measures in both the groups, sample size estimate was done. The sample size was calculated using the G*power version 3.1.2 software. The effect size d=0.805 (14) α=0.05, Power=0.95 level was established. Additionally, it was determined that the ultimate sample size would be N=104 after expecting for the 20% drop-out rate. Before recruiting anyone, patient information sheets will be hand over to every subject and collect their written informed consent. Following the neurological examination, demographic information will be gathered, and participants will be chosen based on eligibility requirements.

During a screening visit, various assessments will be conducted, including assessment through ASIA [21], Amplitude-based surface EMG [23], SCIM [24] and WHO QoL [25].

A written and verbal explanation of the trial's objectives, potential risks, costs, benefits and right to withdraw before screening will be provided to all prospective trial participants. Confidentiality shall be upheld when data is gathered, managed and kept. The complete trial data set will be available to all authors. The participants will not be permitted to take part in any other rehabilitation or research procedures during the study that might affect its results.

Randomisation

A computer-based randomisation succession developed by utilising the random allocation software by an individual other than the investigator will be used to conduct randomisation for individuals who have already been enrolled. To maintain secrecy, the participants will be allocated in two groups in 1:1 ratio using Sequentially, Numbered, Opaque, Sealed, and Stapled Envelopes (SNOSE). After each participant's assessment is complete, a person unrelated to the study will open the numbered envelopes in order to reveal the participant's group assignment. The consort flow chart shows information about the randomisation.

Blinding

The group allocation will be blinded by the assessor. However, given the nature of the treatments, the principal investigator will be made aware of the group assignment. The treatment group would not be known to the researchers performing the data analysis.

Intervention

Patients with incomplete SCI (n=104) will be randomised into two treatment groups; Group 1 will be treated with Placebo LLLT+ Conventional Therapy whereas, Group 2 with LLLT+Conventional Therapy as per the inclusion and exclusion criteria.

Before enrolling them in the study, the participants will receive informational materials, and their written informed permission will be collected. Following the neurological assessment, demographic information about the participant will be collected. Before any participant is enrolled in the intervention, a medical clearance from their treating physician will be obtained. The participant's requests or the investigator's notification of unfavourable events will be among the factors for discontinuation. Patients will be randomly allocated as per the allocation sequence by computer-based table in two groups till the completion of required sample size.

Patients having a spinal level injury at T2 and below will be given with placebo LLLT or LLLT followed by conventional therapy for three times per week for four weeks [17].

Group 1: Control group

Placebo LLLT+Conventional therapy

Placebo Low-Level Laser Therapy (LLLT) protocol

In the control group, participants are assigned to receive placebo LLLT in lateral decubitus posture. Nine locations around the vertebral damage will be indicated, starting from the midpoint of the fractured vertebrae (F), to the right facet of the fractured vertebrae, to the left facet of the fractured vertebrae, then to the 1st caudal vertebrae in relation to the fractured vertebrae, left facet of 1st caudal vertebrae, right facet of the 1st caudal vertebrae then to the 2nd caudal vertebrae

in relation to the fractured vertebrae, to the right facet of 2nd caudal vertebrae and to the left facet of 2nd caudal vertebrae.

Every 60 seconds over the course of nine minutes, the device will play a sound to indicate the beginning and end of radiation emission. The laser probe will be covered with a cap to avoid irradiation. All the participants will undergo 12 sessions over the course of four weeks, and the rest of the days will perform conventional physiotherapy exercises daily for four weeks.

Conventional Physiotherapy

Physiotherapists who are blinded to the outcomes of the assessments and the assignment of the patients to the placebo and LLLT groups will carry out the same physiotherapy exercises every week as mentioned in [Table/Fig-1].

Type of activity	Frequency	Intensity	Time duration (minutes)
Warm-up phase 1. Seated marching 2. Shoulder shrugs 3. Side bends 4. Biceps curl 5. Neck rotations	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises.	18 minutes
Rest for 3 minutes between the activity			
Lower extremity strength and core strength training 1. Motorised Cycling 2. Standing frame activities 3. Balance exercises in sitting and standing 4. Passive ROM for all joints for bilateral lower limb 5. Mat exercises for bed mobility	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises.	18 minutes
Rest for 3 minutes between the activity			
Cool-down phase 1. Seated marching 2. Shoulder shrugs 3. Side bends 4. Biceps curl 5. Neck rotations	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises.	18 minutes

[Table/Fig-1]: Conventional physiotherapy.

Exercises included: Chair-to-bench transfer training, sitting-to-standing training, stretching and strengthening exercises for all joints of bilateral lower limb, practice mat activities, cycling, standing in parallel bar, practicing all daily activities, core strengthening, standing balance exercises, posture care, gym activities and fall prevention for four weeks, there will be 60-minute sessions of traditional physiotherapy [26-28].

Group 2: Experimental Group

LLLT+Conventional therapy

Low-Level Laser Therapy (LLLT) protocol [Table/Fig-2]

Parameter	Infrared laser
Wavelength (nm)	810 nm
Operating mode	Continuous
Mean radiant energy (mW)	120
Polarisation	random
Exposure time (s)	60 (per point), 540 (total)
Number of points irradiated	9
Application method	Contact
Number and frequency of treatment sessions	3 per week for 4 weeks (total 12 sessions)

[Table/Fig-2]: Low-Level Laser Therapy (LLLT) Parameters [12].

In the experimental group, participants are assigned to receive LLLT in the lateral decubitus posture. Nine locations around the vertebral damage will be indicated, starting from the midpoint of the fractured vertebrae (F), to the right facet of the fractured vertebrae, to the left facet of the fractured vertebrae, then to the 1st caudal vertebrae in relation to the fractured vertebrae, left facet of 1st caudal vertebrae, right facet of the 1st caudal vertebrae then to the 2nd caudal vertebrae in relation to the fractured vertebrae, to the right facet of 2nd caudal vertebrae and to the left facet of 2nd caudal vertebrae.

Every 60 seconds over the course of nine minutes, the device will play a sound to indicate the beginning and end of radiation emission. All the participants will undergo 12 sessions over the course of four weeks, and the rest of the days will perform conventional physiotherapy exercises daily for four weeks [13,14,29].

Outcome Measures

Lower Extremity Motor Score (LEMS): LEMS, a component of the classification used by the ASIA measures the combined strength of the lower extremity muscles on both sides, from complete paralysis to some degree of function. Typically, the scores range from 0 to 5, with each number denoting a different degree of muscular function: 0) There is no apparent muscle contraction or movement; 1) Trace muscle contractions; but no movement; 2) Muscle can move the joint, but not defying gravity (that is, in a situation where gravity is abolished); 3) A muscle can only move a joint in the presence of gravity and not resistance; 4) The joint can be moved by the muscle despite some resistance, but not all of it; 5) The muscle is strong enough to move the joint despite full resistance. The five key muscles (hip flexors, knee extensors, ankle dorsiflexors, long toe extensors, and ankle plantar flexors) of each leg will be assessed [30,31].

Functional Independence (SCIM-III): The Functional Independence Measure (FIM), specifically the SCIM-III, is an assessment tool used to evaluate the functional independence and capabilities of individuals with SCI. The SCIM-III is a standardised questionnaire that assesses a person's ability to perform various Activities of Daily Living (ADLs) and mobility tasks, taking into account the unique challenges and limitations faced by individuals with SCI. The SCIM-III questionnaire includes a range of activities within these three domains: 1) Self-care; 2) Respiratory and Sphincter management; and 3) Mobility. Some examples of activities assessed include self-care tasks (e.g., feeding, grooming), respiratory management (e.g., use of mechanical ventilation), and mobility tasks (e.g., wheelchair mobility, transfers). Each activity is scored on a scale from 0 to a maximum value that reflects complete independence. The scores for all activities within each domain are added up to calculate the domain score, and the total SCIM-III score is the sum of these domain scores. The maximum total score is 100, indicating complete independence in all assessed activities [24,32,33].

The World Health Organisation QoL: Instrument is a widely used assessment tool designed to measure an individual's subjective QoL. It is a 26-item scale with two general health and overall QOL items and four domains (physical, psychological, social, and environmental) in total. On a 5-point Likert-response scale, respondents evaluated the severity, frequency, or evaluation of the chosen QOL traits before and after the intervention. By calculating the mean of transformed scores translated to a 0-100 scale for each domain, the mean score in each domain will be determined. Poor, moderate and good QOL were indicated by mean scores of 40, 41-60, and >60 in each domain, respectively. The WHOQOL-BREF has been shown to have strong internal consistency across all domains (Cronbach's alpha range, 0.74-0.78), except for the social interactions dimension (=0.54) among people with SCI. Participants who may find it challenging to complete the WHOQOL-BREF in English should use the Hindi version of the same [25,34,35].

Amplitude-based surface Electromyography (EMG) on lower extremity key muscles: The most common reporting methodology utilises the signal amplitude, typically representing the average or maximal value recorded at a given time or window after some

smoothing and normalisation steps. However, the raw sEMG signal has the potential to be analysed and expressed in many ways. Readings will be determined at isometric contraction and will be used to measure the EMG activity of the muscles. Reading will be recorded before intervention and postintervention (after four weeks) and will be compared [9,23].

STATISTICAL ANALYSIS

Data analysis will be conducted using using the G*power 3 software (v3.1.2-3.1.9; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/). The Kolmogorov-Smirnov test and Shapiro-Wilk will be used to determine normality. If the data are normally distributed, the within-group analysis will be conducted using paired t-test, and the between-group analysis will be conducted using an independent t-test. Mann-Whitney U test will be used for between-group analysis if the data are not normally distributed. Mean, Standard Deviation (SD), Median, and Interquartile Range (IQR) will be used to represent descriptive statistics. If the data are not normally distributed, the Wilcoxon test or paired t-test will be used to examine the intragroup comparison. At a p-value of 0.05, statistical significance is presumed to exist.

Authors' contribution: Conceptualisation: JS; Methodology: JS, DR, CK; Writing: DR, JS, Supervision: JS, CK.

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