Trials

STUDY PROTOCOL

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Effect of aerobic exercise program on neuropathic pain and quality of life in person with paraplegia: study protocol for a randomized controlled trial

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Abstract

Background Individuals with spinal cord injury (SCI) often suffer from neuropathic pain which is often disabling and negatively affects function, participation, and quality of life (QoL). Pharmacological treatments lack efficacy in neuropathic pain reduction hence studying alternatives to drug treatment is necessary. Preclinical evidence of various aerobic exercises has shown positive effects on neuropathic pain but scientific studies investigating its effect in the SCI human population are limited.

Methodology This study is a double-blind, parallel, two-group, randomized controlled trial with an interventional study design that aims to evaluate the effectiveness of aerobic exercise program on neuropathic pain and quality of life (QoL) in individuals with chronic paraplegia. Thirty individuals with chronic paraplegia with the neurological level of injury from T2 to L2 will be recruited from the rehabilitation department at a super specialty hospital based on the inclusion criteria. Using a 1:1 allocation ratio, the participants will be randomly assigned to one of the two groups. The intervention group will perform high-intensity interval training (HIIT) aerobic exercise using an arm ergometer based on their peak heart rate, and the control group will perform free-hand arm aerobic exercise. In both groups, the intervention will be delivered as 30-min sessions, four times a week for 6 weeks.

Outcome measures International Spinal Cord Injury Pain Basic Data Set Version 3.0 will be used for diagnosing and assessing neuropathic pain and its interference with day-to-day activities, mood, and sleep. The International Spinal Cord Society (ISCoS) QoL basic data set will be used to assess QoL, and 6-min push test distance will be used to assess peak heart rate and aerobic capacity.

Discussion The effectiveness of the aerobic exercise program will be assessed based on the changes in neuropathic pain score and its interference with day-to-day activities, mood, sleep, QoL, and aerobic capacity after 3 weeks mid-intervention and after 6 weeks post-intervention. The trial will provide new knowledge about the effectiveness of the aerobic exercise program in improving neuropathic pain and QoL in individuals with chronic paraplegia.

Trial registration Clinical Trials Registry-India CTRI/2023/08/056257. Registered on 8 August 2023.

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Keywords Paraplegia, Neuropathic pain, Aerobic exercise, High-intensity interval training, Randomized controlled trial

Background

Pain is one of the most common medical consequences following spinal cord injury (SCI). It has high prevalence rates estimated to be approximately 60% [1]. Neuropathic pain following SCI is typically characterized by spontaneous numbness, tingling/shooting, or burning pain which presents significant challenges, with detrimental effects on function, participation, and quality of life (QoL) [2]. The overall prevalence rate for neuropathic pain was established at 53% following SCI [3]. Neuropathic pain is often difficult to treat, and only a few patients experience full relief. The burden of symptoms and complicated treatment of neuropathic pain often comes with high economic costs [2]. Pharmacological treatments are recommended as the first line of treatment for neuropathic pain. It has limited efficacy and various associated events, which limit compliance [4]. Therefore, patient preference is for non-pharmacological treatment. Hence studying alternatives to drug treatment is necessary. Prior studies have examined the effect of several non-pharmacological treatments for the management of neuropathic pain in people with SCI such as transcranial direct current stimulation (tDCS) [5], combined visual illusion and transcranial direct current stimulation [6], TENS [7], neurofeedback training [8], breathing-controlled electrical stimulation (BreEStim) [7], and transcranial magnetic stimulation [9]. Exercise has also been proven to be effective in the management of neuropathic pain in various conditions such as chemotherapy-induced peripheral neuropathy [10], and diabetic peripheral neuropathy [2]. The effects of exercise on pain and QoL in the human SCI population have been assessed in very few studies reporting its positive effects on both pain as well as QoL [11, 12]. The immediate analgesic effect of a single session of 15 min of aerobic exercise training using wheelchair propulsion was observed in the SCI population that only persisted transiently [13]. However, the persistent effect of aerobic exercise training alone using different dosages of exercise has never been explored in the human SCI population.

There are various pre-clinical evidence examining the effect of aerobic exercises such as treadmill running, wheel running, body weight supported treadmill training, and swimming on neuropathic pain in different conditions like sciatic nerve injury [14], diabetic peripheral neuropathy [15], complex regional pain syndrome [16], and spinal cord injury [2] which has proven to be effective. According to Canadian Clinical Practice Guidelines 2021, there are a very small number of low-quality studies examining the effect of exercise as an effective treatment for neuropathic pain reduction [7].

Therefore, this study aims to investigate the effect of aerobic exercise program on neuropathic pain, and its interference with day-to-day activities, overall mood, night's sleep, and QoL in persons with paraplegia. Also, to investigate if the intensity of aerobic exercise matters for its above-mentioned potential benefits. This would help the professionals and persons with SCI to provide evidence for the potential analgesic effect of aerobic exercise training which can be incorporated into the multidisciplinary rehabilitation program. It is hypothesized that a significant reduction in neuropathic pain and its interference with day-to-day activities, mood, and sleep along with improvement in aerobic capacity and QoL of persons with paraplegia will be noticeable after 3 weeks and 6 weeks of HIIT when compared with the active control group performing low-intensity free hand arm aerobic exercise.

Materials and methods

A clinical trial is designed to see the effect of the aerobic exercise protocol on neuropathic pain and QoL in persons with paraplegia.

Patient and study design

A double-blind, parallel, two-group, and randomized controlled trial with equal subject allocation (1:1) will be undertaken. A convenient sample of 30 participants with paraplegia will be recruited from the inpatient and outpatient rehabilitation departments of the Indian Spinal Injuries Centre Hospital, New Delhi, India. All participants will be provided with information sheets, and written consent will be obtained by the principal investigator before recruitment. The demographic details will be obtained, and the participants will be selected based on the eligibility criteria after the neurological examination (Table 1).

DRRC and RRC of the research department of the Indian Spinal Injuries Centre hold the legal liability and keep the check and record of all potential recruits and monitor the data collection throughout the intervention. The members of DRRC along with the consultants and physiotherapists in the hospital provide day-to-day support to all aspects of the local organization of the trial. The trial is supervised by the guides and co-guides twice a week. This research protocol is consistent with

Table 1 Eligibility criteria

	Criteria
Inclusion criteria	Willing to participate and sign informed consent
	Traumatic SCI (> 1 year)
	Paraplegics with neurological level of injury T2 to L2
	ASIA- AIS Category A, B, C, and D
	Age: 18–65 (male and female)
	Diagnosis of Neuropathic Pain Using International SCI Pain Basic Data Set
	Without diagnosed cardiopulmonary, neurological, and cognitive deficits
	Self-reported ability to independently self-propel a manual wheelchair
	Ability to complete a 6-min push test (6MPT)
Exclusion criteria	Self-reported or history of unstable angina or MI within the past 1 month
	Resting Heart rate > 120
	Systolic BP > 180 mm Hg and diastolic BP > 100 mm Hg
	Self-reported active medical issues, such as pressure sores, UTI, and cardiovascular disorders contraindicated for exercise testing
	Musculoskeletal complaints of upper extremity
	Person with neurological deficits (other than SCI) and uncontrolled psychiatric illness
	Individual who self-report the use of type 2 diabetes mellitus medication or on insulin that affects glucose metabolism

the current Consolidated Standards of Reporting Trials (CONSORT) guidelines (Fig. 1) and follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT schedule) (Table 2) [17] and is developed based on the SPIRIT checklist (Additional file 1). A visual description of the study regarding enrolment, assessments, and interventions is shown in Table 2. Baseline assessments (T_0) will be done before group allocation. Mid-intervention assessments of both groups (T_1) will be taken after the third week which will serve to compare the short-term effects of respective interventions delivered to the subjects. Post-intervention assessments of both groups (T_2) will be done after 6 weeks of intervention to detect potential long-term effects.

Ethical considerations

The enrolled participants will be informed orally and in writing about the purpose of this trial, its potential risks, benefits of participation, and the right to withdraw from the trial at any point during the study. A written informed consent signed by the participants will be taken from those who are willing to participate in the study.

The data of the participants will be collected, documented, and managed confidentially using the paper-based entry data sets. Only all the authors related to the trial will have access to the final trial dataset. The masked datasets analyzed during the current study and statistical code will be available from the corresponding author upon reasonable request. The study protocol has been approved by the Institutional Ethical Committee and the trial is registered with Clinical Trials Registry.

Randomization

Eligible individuals will be assigned randomly to either the Intervention or Control group. Randomization will be performed using a computer-generated randomization sequence generated by the Random Allocation Software, using a 1:1 allocation ratio.

To ensure concealment, the allocation sequence will be marked sequentially and sealed in opaque envelopes. An individual not associated with the study will sequentially open the numbered envelopes to reveal the participant's group allocation. Based upon this, participants will be allocated to group A; intervention, or group B; the control group.

Blinding

The trial is a double-blinded study where the outcome assessor who will be a physiotherapist and participants will be blinded to group allocation. The principal investigator will be informed of the group allocation given the nature of the interventions. Also, the statistician who will perform data analysis would be unaware of the existence of treatment groups.

Exercise intervention

The planned protocol is reported in accordance with the Consensus on Exercise Reporting Template (CERT) checklist. In both groups, the intervention will be carried

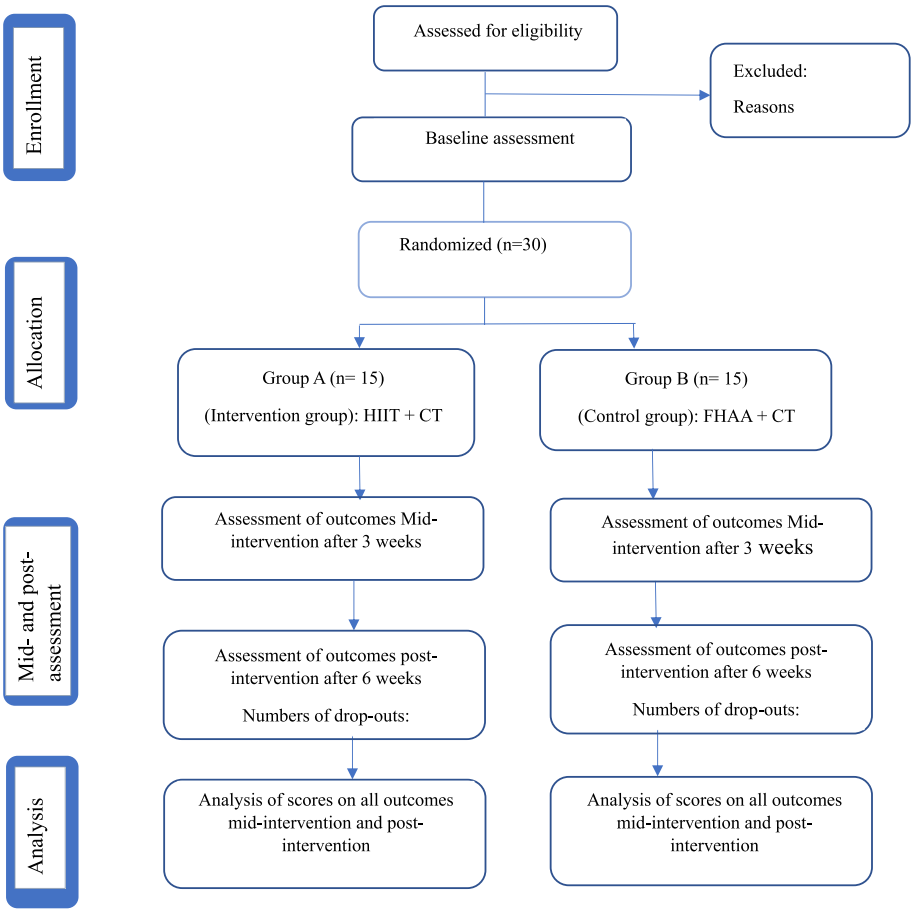

Fig. 1 CONSORT (Consolidated Standards of Reporting Trials). HIIT + CT, high-intensity interval training along with conventional training; FHAA + CT, free hand arm aerobics along with conventional training

Table 2 Schedule of enrollment, interventions, and assessments according to the Standard Protocol Items: Recommendations for Interventional Trials guideline

Variables	Enrollment	Allocation	Baseline (T_0)	Post-allocation	
				Mid-intervention (T_1) (3 weeks)	Post-intervention (T_2) (6 weeks)
Enrollment					
· Eligibility screen	×				
· Informed consent	×				
· Allocation		×			
Intervention					
· HIIT + CT				×	
· Free hand aerobics + CT				×	
Assessments					
· ISCIPBDS	×		×	×	×
· ISCoS QoL DATA SET	×		×	×	×
· 6- Minute push test distance	×		×	×	×

Abbreviations: HIIT high-intensity interval training, *CT* conventional therapy, *ISCIPBDS* International Spinal Cord Injury Pain Basic Data Set, *ISCoS QoL* International Spinal Cord Society Quality of Life

out individually along with conventional physiotherapy treatment, under the supervision and guidance of the physiotherapist for 30 min each day, 4 days a week for a total of 6 weeks. Special considerations of the American College of Sports Medicine (ACSM) for exercise prescription in spinal cord injury will be followed such as; participants will be asked to empty their urinary bladder before beginning of the exercise session [18]. To compensate for blood pooling, the participants will be required to wear stockings on the legs and abdominal binder during the intervention. Considering the enhanced thermoregulatory drive and lower sweat rates in persons with SCI the use of light clothing and maintaining proper hydration during the intervention will be ensured [19, 20].

The intervention will be divided into three phases for both groups (Table 3). Phase 1 will consist of a warm-up period. Participants will be asked to perform gentle upper extremity stretching exercises and low-intensity arm ergometer exercises at a rate of perceived exertion (RPE) between 2 (light) and 3 (moderate) for 5 to 10 min [11]. This will be followed by phase 2 of the aerobic training, i.e., in the intervention group HIIT will be performed which consists of 20 min of cycling with the arms using an arm ergometer (Thera Trainer) at high and low intensities during 60- and 60-s intervals, respectively, and to repeat this sequence 10 times over a period of 20 min. During the 60-s high-intensity interval, participants will be required to reach their 80- 90% HR_{peak} which will be achieved during aerobic exercise testing [21, 22]. Each high-intensity interval will be followed by a 60-s active recovery period at low intensity at an RPE between 1 (very light) and 2 (light) on the Borg CR10 scale.

The active control group was designed to perform free hand-arm aerobic exercise consisting of five dynamic arm movements such as marching with arms, arm-swing side-to-side and front-to-back, and figure-of-eights mimicking kayak paddling [23]. Each movement will be performed for 1 min in a sequence and the whole sequence of these five movements will be repeated 4 times over a period of 20 min. These movements will be performed at low intensity guided by the metronome at 60 beats per minute [24].

In phase 3 of the training, there will be a 5–10-min cool-down period in the form of low-intensity arm ergometry at an RPE between 2 and 3 and gentle UE stretching resulting in a total exercise time of 30 min [11]. No rest will be provided during the session. Participants will be asked to wear an HR monitoring device (Samsung Galaxy Watch 4 Classic) on their wrist during the training to monitor their HR response in real-time. Adverse events will be monitored throughout.

Progression and feedback

To account for changes in fitness and ensure progression, in the intervention group the intensity will be increased by 5% every 2 weeks (i.e., 80% HR_{peak} for weeks 1 and 2, 85% HR_{peak} for weeks 3 and 4, and 90% HR_{peak} for weeks 5 and 6) [22]. In the control group, the intensity will remain the same throughout without any progression. In the intervention group feedback on the heart rate and the time to change the intensity during the intervention will be given by the stopwatch placed in front of the patient and HR monitoring device. Whereas, in the control group the intensity will remain the same throughout the 6 weeks of the program. The participants will receive concomitant auditory feedback of intensity via metronome beats. Motivation will be provided by the therapist to achieve and maintain the targeted intensity.

Termination criteria

The exercise will be terminated if any signs or symptoms of autonomic dysreflexia appear or if any kind of unusual

Table 3 Description of exercise protocol with intervention

Intervention phase	Details of intervention
Phase 1 (5–10 min)	low-intensity arm ergometry at RPE between 2 and 3 on the Borg CR10 scale and gentle UE stretching for 5–10 min
Phase 2 (20 min)	
Intervention group	• **Frequency**: 4 times per week, for 6 weeks • **Intensity**: 10 × 60 s intervals at 80–90% HR peak with 60 s. active recovery at RPE between 1 and 2 on the Borg CR10 scale in between the intervals • **Progression**: intensity will be increased by 5% after every 2 weeks • **Time**: 20 min a day • **Type**: Arm ergometry
Control group	• **Frequency**: 4 times per week, for 6 weeks • **Intensity:** Low intensity using a metronome at 60 bpm • **Time**: 20 min a day • **Type**: Free hand arm aerobic exercise
Phase 3 (5–10 min)	Low-intensity arm ergometry at RPE between 2 and 3 on the Borg CR10 scale and gentle UE stretching for 5–10 min

Abbreviations: RPEs rating of perceived exertion, *UE* upper extremity, *HR* heart rate

uneasiness is reported by the participants. Protocol modification, if required will be done only after proposing the changes to the Research Review Committee and Internal Ethical Committee and after approval, the same will be notified to CTRI and the Journal. Any deviations from the protocol will be fully documented using a breach report form.

Adherence

The adherence of the participants recruited in the study will be monitored by documenting the details of sessions attended, and the targeted intensity of the training protocol in different phases of intervention. As interval training elicits higher enjoyment, it keeps the person more engaged in the active intervention. Whereas, in the control group, matching the pace of the metronome to achieve the intensity and random order of the dynamic movements may positively influence the adherence and reduce attrition rates.

The participants will be permitted to increase the training duration by 1 week keeping in mind the "intention-to-treat" analysis principle if the participants are unable to complete the total number of sessions within the stipulated 6 weeks. Also, the type, extent, and pattern of missing data throughout the study will be fully reported by the authors.

Outcome variables

1. International Spinal Cord Injury Pain Basic Data Set Version 3.0: The International SCI Pain Basic Data Set (ISCIPBDS) standardizes the characterization and reporting of pain (primary outcome measure) and pain interference with day-to-day activities, overall mood, and sleep in persons with SCI by interviewing the participants [25]. It is based on the International SCI Pain Classification (ISCIP) which classifies pain based on its type (nociceptive, neuropathic, other, or unknown), subtype (nociceptive: musculoskeletal, visceral, or other), pain locations, intensity of pain on a numerical pain rating scale, frequency, and duration [26]. The ISCIPBDS has good validity and reliability as a self-reported measure of pain in individuals with SCI [27].
2. International SCI Quality of Life Data Set-Version 2.0: It is a tool to measure QoL in persons with SCI. It reflects subjective QoL based on each person utilizing his or her own personal perspective, internal standards, and assessment to assess his or her own QoL. It considers all factors that they feel contribute to or detract from their QoL, whether these are related to health, pain, family, finances, or any other domains of life. It has four questions in which participants provide a subjective rating of the past 4 weeks in four different domains related to QoL, i.e., general QoL (overall well-being), satisfaction with physical health, psychological health, and social life [21]. Each domain is ranked on a 0–10 scale, where 0 indicates complete dissatisfaction and 10 indicates complete satisfaction. Data will be collected by interviewing the participants. It has good internal construct validity [28].
3. 6- Minute Push Test: Aerobic capacity will be evaluated using a 6-min push test (6-MPT). It is a reliable and valid measure for cardiorespiratory fitness testing in the SCI population (ICC > 0.90) [29]. The guidelines for conducting 6-MPT will follow the standardized American Thoracic Society guidelines and instructions for the administration of 6-MPT [30]. The test will be conducted along a flat corridor with clear space using a personal wheelchair at a 30-m loop course, marked 15 m apart by two cones with 2.8 m on either end to allow space for turning. The distance traveled in 6 min will be used to estimate the aerobic capacity of the individual. This is a valid and reliable measure of aerobic capacity in persons with SCI [29].

Sample size

A priori sample size estimation was done using the statistical formula by considering pain intensity as the primary outcome measure. It is based on an expected drop-out of ~15%. The total sample size was calculated at 28 by using an α level of 0.05, a power of 80%, and a calculated medium effect size of 0.67 at 95% CI. It was increased to 30 on a suggestion from the ethical committee.

Statistical analysis

To check for selection bias, we will apply Pearson's chi-square test for categorical variables and Student's *t*-test for numerical variables. This will be performed to know if the randomization process generated between each group of participants has homogenous clinical and demographic characteristics before the intervention.

Continuous variables will be summarized as mean ± standard deviation for normal distribution and median ± interquartile range for non-normal distribution. The Shapiro–Wilk test will be used to know the normality of data. In the case of normal distribution of data, we will analyze the intergroup comparison by applying a two-sample *t*-test. In case of skewed data, we will use the Mann–Whitney *U* test for the intergroup comparison. The intragroup comparison will be analyzed by Repeated measure ANOVA or Friedman's test (if data is not normally distributed). The final statistical analysis

will be performed using IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA). This will be done based on the modified intention-to-treat principle, whereby each participant must complete > 75% (18 of 24 sessions) of planned exercise sessions. The principle of the "last observation carried forward" shall be applied in case of missing data of dropped-out individuals. This means that the missing final values of the outcome variable will be replaced by the last known value. The level of statistical significance is assumed at p-value < 0.05.

Discussion

Neuropathic pain is one of the most disabling consequences following SCI with several detrimental effects on functions and QoL having limited effective treatment options. There are various potential benefits of exercise training in the SCI population which include improving physical health, mental health, and QoL. To the best of our knowledge, no study till now has examined the long-term effect of aerobic exercise training alone for neuropathic pain reduction in the human SCI population. The results of this trial will provide information about the effectiveness of the aerobic exercise program in decreasing neuropathic pain and improving QoL in persons with SCI. This will provide an alternative to the pharmacological treatment which would decrease the global economic burden of neuropathic pain. HIIT in the study keeps the person more engaged and involves a rapid gain in exercise tolerance and cardiorespiratory fitness with minimum time commitment. Also, this trial meets the methodological demand for adequate randomization, allocation concealment, and blinding of outcome assessor and statistician. Future studies can be conducted to identify the impact of intervention with follow-up and to explore the physiological mechanisms for the analgesic effect of aerobic exercise training in the SCI population. The limitation of this trial is that the therapist administering the treatment will not be blinded and the recruitment of participants will be done through a convenience sample which may result in a possible selection bias.

Trial status

The fifth version of the original protocol after amendments was finalized on 07 July 2024. The first participant in the trial was recruited in December 2023 and the expected duration of the participant's recruitment to complete the study is approximately in August 2024.

Abbreviations

SCI	Spinal cord injury
QoL	Quality of life
HIIT	High-intensity interval training
HR	Heart rate
6 MPT	6 Minute push test
RPE	Rating of perceived exertion
CT	Conventional treatment
AIS	ASIA Impairment Scale
BP	Blood pressure
UTI	Urinary tract infection

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08430-0.

Additional file 1. SPIRIT checklist.

Acknowledgements

Not applicable.

Dissemination policy—trial results

The results of the study will be shared through scientific research publications, databases, the trial register, data-sharing arrangements, social media, and conferences. There are no publication restrictions. Also, a layman's summary of the results of this study can be provided to all the participants.

Authors' contributions

All authors were involved in the conception and design of this study. The leading author prepared the protocol manuscript and all authors contributed to the review and approval of the final manuscript.

Funding

There is no funding involved with this trial. This is an investigator-initiated RCT.

Availability of data and materials

Any data required to support the protocol can be provided on request by keeping the participant's details confidential.

Declarations

Ethics approval and consent to participate

The trial is approved by the Institutional Ethical Committee of Indian Spinal Injuries Centre REGD NO: ECR/96/Inst/DL/2013/RR-19 with reference number ISIC/RP/2023/028. Written, informed consent to participants will be obtained from all participants.

Consent for publication

Not applicable—no identifying images or other personal or clinical details of participants are presented here or will be presented in reports of the trial results. The participant information materials and informed consent form are attached.

Competing interests

No potential conflict of interest relevant to this study protocol is reported among the authors.

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